Report Details - EON-376360		
ICSR:	2061170	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-14 16:46:57 EST	
Reported Problem:	**Problem Description:**	2 other dogs in household affected previously Eating various BEG diets Early DCM with infrequent ventricular ectopy Have been following - owner agreed to change diet at December 2018 appointment so will follow Taurine normal
	Date Problem Started:	12/21/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating
Product Information:	**Product Name:**	Annamaet chicken and rice dry + Honest kitchen beef, chicken, or turkey
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	**Description:** See diet history
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Doberman Pinscher
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	34.6 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	3
	Number of Animals Reacted:	3
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone: B6
		Email: B6
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman
		Phone: (508) 887-4523
		Email: lisa.freeman@tufts.edu

		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	**B6** rpt_medical_record_preview.pdf	
	Description:	Records	
	Type:	Medical Records	

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/1/2019 9:24:38 PM

Subject: Orijen Adult Original dry (until Aug 2018): Lisa Freeman - EON-375110

Attachments: 2060739-report.pdf; 2060739-attachments.zip

A PFR Report has been received and PFR Event [EON-375110] has been created in the EON System.

A "PDF" report by name "2060739-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060739-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375110
ICSR #: 2060739
EON Title: PFR Event created for Orijen Adult Original dry (until Aug 2018); 2060739

AE Date	12/19/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Terrier - Border		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2060739
Product Group: Pet Food
Product Name: Orijen Adult Original dry (until Aug 2018)
Description: Diagnosed with degenerative mitral valve disease in Aug 2017. Progressed to CHF. On pimobendan, furosemide, enalapril. At regular re-evaluation on 12/19/18, reduced contractile function was noted on echo. Dog was noted to be eating BEG diet. Taurine pending Will recheck in 3 months Will evaluate other dog in household also eating same diet (asymptomatic). Owner is ok to provide further info.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Orijen Adult Original dry (until Aug 2018)		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
B6

To view the PFR Event Report, please click the link below:
B6

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Report Details - EON-375110

ICSR:	2060739	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-01 16:15:01 EST	
Reported Problem:	**Problem Description:**	Diagnosed with degenerative mitral valve disease in Aug 2017. Progressed to CHF. On pimobendan, furosemide, enalapril. At regular re-evaluation on 12/19 /18, reduced contractile function was noted on echo. Dog was noted to be eating BEG diet. Taurine pending Will recheck in 3 months Will evaluate other dog in household also eating same diet (asymptomatic). Owner is ok to provide further info.
	Date Problem Started:	12/19/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Degenerative mitral valve disease
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Orijen Adult Original dry (until Aug 2018)
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	**Description:** See diet history for additional details/diets
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Terrier - Border
	Gender:	Male
	Reproductive Status:	Intact
	Weight:	20.6 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone: B6
		Email: B6
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine

		Contact:	**Name:**	Lisa Freeman
			Phone:	(508) 887-4523
			Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	

Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

Additional Documents:		
	Attachment:	B6 medical record.pdf
	Description:	B6 records
	Type:	Medical Records

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/1/2019 9:48:33 PM

Subject: Orijen grain free original dry: Lisa Freeman - EON-375114

Attachments: 2060741-report.pdf; 2060741-attachments.zip

A PFR Report has been received and PFR Event [EON-375114] has been created in the EON System.

A "PDF" report by name "2060741-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060741-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375114
ICSR #: 2060741
EON Title: PFR Event created for Orijen grain free original dry; 2060741

AE Date	B6	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Doberman Pinscher		
Age	9 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2060741
Product Group: Pet Food
Product Name: Orijen grain free original dry
Description: DCM and CHF diagnosed B6 at emergency clinic. Started on furosemide, diltiazem, digoxin, pimobendan Seen by Tufts cardiology B6. Eating Orijen grain free original dry so unclear if just genetically associated DCM or if diet associated.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable

Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Orijen grain free original dry		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6 USA

To view this PFR Event, please click the link below:
B6

To view the PFR Event Report, please click the link below:
B6

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Report Details - EON-375114

ICSR:	2060741	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-01 16:41:40 EST	
Reported Problem:	**Problem Description:**	DCM and CHF diagnosed B6 at emergency clinic. Started on furosemide, diltiazem, digoxin, pimobendan Seen by Tufts cardiology B6 Eating Orijen grain free original dry so unclear if just genetically associated DCM or if diet associated.
	Date Problem Started:	B6
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Orijen grain free original dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Doberman Pinscher
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	32.6 Kilogram
	Age:	9 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone: B6
		Email: B6
		Address: B6 United States
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman
		Phone: (508) 887-4523
		Email: lisa.freeman@tufts.edu

		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	rpt_medical_record_preview_ B6 .pdf	
	Description:	B6 ecords	
	Type:	Medical Records	

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 12/27/2018 3:00:35 PM

Subject: Orijen Original dry: Lisa Freeman - EON-374783

Attachments: 2060598-report.pdf; 2060598-attachments.zip

A PFR Report has been received and PFR Event [EON-374783] has been created in the EON System.

A "PDF" report by name "2060598-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060598-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374783
ICSR #: 2060598
EON Title: PFR Event created for Orijen Original dry; 2060598

AE Date	10/05/2017	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Mixed (Dog)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2060598
Product Group: Pet Food
Product Name: Orijen Original dry
Description: DCM diagnosed 10/2017. We saw July 2018 Originally feeding Orijen original dry since he was a puppy. Started taurine at time of diagnosis (10/2017). Heart improved significantly between echoes. Changed to Purina Proplan Adult 7+ July 2018. Will be rechecking soon.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Orijen Original dry		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6 USA

To view this PFR Event, please click the link below:
B6

To view the PFR Event Report, please click the link below:
B6

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Report Details - EON-374783

ICSR:	2060598			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)			
Reporting Type:	Voluntary			
Report Submission Date:	2018-12-27 09:51:12 EST			
Reported Problem:	**Problem Description:**	DCM diagnosed 10/2017. We saw July 2018 Originally feeding Orijen original dry since he was a puppy. Started taurine at time of diagnosis (10/2017). Heart improved significantly between echoes. Changed to Purina Proplan Adult 7+ July 2018. Will be rechecking soon.		
	Date Problem Started:	10/05/2017		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Better/Improved/Recovering		
Product Information:	**Product Name:**	Orijen Original dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	**Description:**	Fed Orijen puppy then Orijen Original (chicken) adult. Then changed to Orijen Senior in Oct 2017 after diagnosis	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	**Name:**	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Mixed (Dog)		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	30.1 Kilogram		
	Age:	8.4 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:	**Owner Information provided:**	Yes	
		Contact:	**Name:**	B6
			Phone:	B6
			Email:	B6
		Address:	B6 United States	
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine	
		Contact:	**Name:**	Lisa Freeman
			Phone:	(508) 887-4523

		Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States

Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

Additional Documents:		
	Attachment:	**B6** medical records.pdf
	Description:	Medical records
	Type:	Medical Records

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/14/2019 10:08:36 PM

Subject: Taste of the Wild Sierra Mountain dry: Lisa Freeman - EON-376361

Attachments: 2061171-report.pdf; 2061171-attachments.zip

A PFR Report has been received and PFR Event [EON-376361] has been created in the EON System.

A "PDF" report by name "2061171-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061171-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376361
ICSR #: 2061171
EON Title: PFR Event created for Taste of the Wild Sierra Mountain dry; 2061171

AE Date	01/02/2019	**Number Fed/Exposed**	7
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2061171
Product Group: Pet Food
Product Name: Taste of the Wild Sierra Mountain dry
Description: Eating Taste of the Wild Sierra Mountain since June 2018 (Acana Heritage Poultry before that). This diet was fed to multiple dogs - have not screened other dogs yet so unknown whether they are also affected. Echo showed reduced contractility and mild left atrial enlargement. BNP and troponin mildly elevated, troponin =0.547. Taurine WNL (88 and 250) Changing to Pro Plan Sensitive Skin/Stomach dry and will recheck in 3 months
Submission Type: Initial

Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 7
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Sierra Mountain dry		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
B6

To view the PFR Event Report, please click the link below:
B6

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Report Details - EON-376361

ICSR:	2061171	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	B6 16:58:04 EST	
Reported Problem:	**Problem Description:**	Eating Taste of the Wild Sierra Mountain since June 2018 (Acana Heritage Poultry before that). This diet was fed to multiple dogs - have not screened other dogs yet so unknown whether they are also affected. Echo showed reduced contractility and mild left atrial enlargement. BNP and troponin mildly elevated, troponin =0.547. Taurine WNL (88 and 250) Changing to Pro Plan Sensitive Skin /Stomach dry and will recheck in 3 months
	Date Problem Started:	01/02/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Taste of the Wild Sierra Mountain dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	**Description:** See diet history for more details. TOTW fed June, 2018 to present; Acana Heritage Free Run Poultry before that
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Female
	Reproductive Status:	Intact
	Pregnancy Status:	Not Pregnant
	Lactation Status:	Not lactating
	Weight:	30.4 Kilogram
	Age:	3 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	7
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone: B6
		Email: B6
		Address: B6 United States

	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine
		Contact:	**Name:** Lisa Freeman
			Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	rpt_medical_record_preview_**B6**.pdf	
	Description:	records	
	Type:	Medical Records	

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/15/2019 8:56:35 PM

Subject: Zignature - various flavors (venison: Lisa Freeman - EON-376446

Attachments: 2061214-report.pdf; 2061214-attachments.zip

A PFR Report has been received and PFR Event [EON-376446] has been created in the EON System.

A "PDF" report by name "2061214-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061214-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376446
ICSR #: 2061214
EON Title: PFR Event created for Zignature - various flavors (venison goat kangaroo lamb turkey pork); 2061214

AE Date	01/09/2019	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Boxer (German Boxer)		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2061214
Product Group: Pet Food
Product Name: Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)
Description: 2 syncopal episodes in summer got echo in October 2018 and arrhythmia identified Feeding BEG diets all of her life (Zignature) DCM and VPCs identified 1/9/19 Owner changing to Purina EN Fiber and we will recheck in 3 months BNP elevated, troponin and taurine pending
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
USA

To view this PFR Event, please click the link below:
B6

To view the PFR Event Report, please click the link below:
B6

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Report Details - EON-376446

ICSR:	2061214	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-15 15:49:52 EST	
Reported Problem:	**Problem Description:**	2 syncopal episodes in summer got echo in October 2018 and arrhythmia identified Feeding BEG diets all of her life (Zignature) DCM and VPCs identified 1 /9/19 Owner changing to Purina EN Fiber and we will recheck in 3 months BNP elevated, troponin and taurine pending
	Date Problem Started:	01/09/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Boxer colitis as young dog. Successfully treated
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	**Description:** Rotated proteins/flavors of Zignature for past 8-9 years
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Boxer (German Boxer)
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	21 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner Information provided:** Yes
		Contact: **Name:** B6
		Phone: B6
		Email: B6
		Address: B6
	Healthcare Professional Information:	**Practice Name:** Tufts Cummings School of Veterinary Medicine
		Contact: **Name:** Lisa Freeman
		Phone: (508) 887-4523

		Email:	lisa.freeman@tufts.edu
		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States

Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

Additional Documents:		
	Attachment:	rpt_medical_record_preview **B6** .pdf
	Description:	Records
	Type:	Medical Records

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/14/2019 10:24:45 PM

Subject: Zignature kangaroo dry: Lisa Freeman - EON-376363

Attachments: 2061172-report.pdf; 2061172-attachments.zip

A PFR Report has been received and PFR Event [EON-376363] has been created in the EON System.

A "PDF" report by name "2061172-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061172-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376363
ICSR #: 2061172
EON Title: PFR Event created for Zignature kangaroo dry; 2061172

AE Date	04/11/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2061172
Product Group: Pet Food
Product Name: Zignature kangaroo dry
Description: Eating BEG diet; developed DCM and CHF 4/11/18 Owner changed diet to Royal Canin Early Cardiac and dog has improved significantly. Will recheck again in 3 months. Have not gotten approval for you to contact owner but sent an email today
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Zignature kangaroo dry		

Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6 USA

To view this PFR Event, please click the link below:
B6

To view the PFR Event Report, please click the link below:
B6

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Report Details - EON-376363

ICSR:	2061172		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-01-14 17:14:59 EST		
Reported Problem:	**Problem Description:**	Eating BEG diet; developed DCM and CHF 4/11/18 Owner changed diet to Royal Canin Early Cardiac and dog has improved significantly. Will recheck again in 3 months. Have not gotten approval for you to contact owner but sent an email today	
	Date Problem Started:	04/11/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	**Product Name:**	Zignature kangaroo dry	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	**Description:**	See diet history for more details. Zignature Sept 2017-April 2017 Acana Pork/Squash before that
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	26.3 Kilogram	
	Age:	B6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6
			Phone: B6
			Email: B6
		Address:	B6 United States
	Healthcare Professional Information:	**Practice Name:**	Tufts Cummings School of Veterinary Medicine
		Contact:	**Name:** Lisa Freeman
			Phone: (508) 887-4523
			Email: lisa.freeman@tufts.edu

		Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	**Name:**	Lisa Freeman	
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	**Phone:**	5088874523
		Email:	lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			
	Attachment:	rpt_medical_record_preview_ **B6** .pdf	
	Description:	Records	
	Type:	Medical Records	

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>

To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David

Sent: 1/28/2019 3:48:02 PM

Subject: DCM-other including a cat Non-Responsive

Attachments: 1. Blue Wilderness salmon/chicken grain-free.--2 Non-Responsive Non-Responsive; 4 Health Untamed: B6 - EON-375466; 4Health beef and potato and-4health untamed lamb and Lentil: B6 - EON-375168; 4health optimal nutrition for optimal health weight management formula for dogs: B6 - EON-374758; Acana Free Run Poultry dry: Lisa Freeman - EON-374786; ACANA Lamb and Apple Singles Formula: B6 - EON-376195; Arcana lamb and apple - grain free: B6 - EON-375208; BLUE BUFFALO GRAIN FREE LAMB AND POTATO: B6 - EON-377465; BLUE Wilderness with Chicken for Adult Dogs: B6 B6 - EON-374327; Canidae Grain Free Pure Wild Dry Dog Food with Wild Boar-Grain Free Limited Ingredient Diet: B6 - EON-375880; CANIDAE Grain-Free PURE Land with Bison Limited Ingredient Diet Adult Dry Dog Food: B6 - EON-375771; CRAVE Dog Food with Protein from Salmon and Ocean White Fish: B6 - EON-376088; Diamond -Naturals-Skin & Coat-All Life Stages Dog-Salmon & Potato Formula: B6 - EON-376046; Fromm Family-From the Heartland-Grain Free-Dog Food: B6 - EON-374687; Fromm Surf & Turf dry dog food: B6 - EON-375559; GO Venison: B6 - EON-375313; Homecooked diet - see diet history in medical record: Lisa Freeman - EON-374789; Honest Kitchen Grain Free Beef Recipe (Love): B6 - EON-377314; Horizon Pulsar Chicken Flavor Dog Kibble: B6 - EON-375244; Instinct by Nature's Variety Original Grain-Free Recipe with Real Chicken Dry Dog Food: B6 - EON-375409; Merrick Good Earth Grain Free Pork Beef and Lamb Kibble: B6 - EON-376709; Merrick Grain-Free Chicken and Sweet Potato: B6 - EON-375900; Merrick Limited Ingredient Diet Grain-Free Real Lamb & Sweet Potatoes Recipe Dry Dog Food: B6 - EON-376853; Natural Balance L.I.D. Limited Ingredient Diets-Sweet Potato & Fish Dry Dog Formula: B6 - EON-375818; Natural Balance Lamb and Brown Rice: B6 - EON-377272; Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula: B6 - EON-376311; Now Fresh Grain Free Adult Dog Food-Now Fresh Grain Free Puppy Food: B6 - EON-376136; Nutrisource Small and Medium Breed Puppy Grain Free Dog Food: B6 - EON-375242; NutriSource Super Premium Pet Foods: B6 - EON-374952; NWBARBF-Beef Recipe for Dogs-Ground Bone Added-Not for Human Consumption-Made in the USA by Northwest Naturals: B6 - EON-375869; Orijen Original dry: Lisa Freeman - EON-374783; Orijen Regional Red Dry Dog Food-Fromm Beef Frittata A La Veg Dry Dog Food-From Duck & Sweet Potato Dry Dog Food-Purina Fortiflora: B6 - EON-375393; Ped: B6 - EON-376960; Pure Vita Venison & Red Lentils Grain Free Entree: B6 - EON-375203; Rachel Ray's only six - EON-377164; Solid Gold Wee Bit formula-Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food: B6 - EON-375339; Stella & Chewy's -Frozen Raw -Stellla's Super Beef -Dinner Patties: B6 - EON-375865; Taste of the Wild - EON-377564; Taste of the Wild (Pacific Stream formula): B6 - EON-377278; Taste of the Wild High Prairie grain-free with roasted bison and roasted venison: B6 - EON-377174; Taste of the Wild Prey: B6 - EON-374547; Taste of the Wild Sierra Mountain: B6 - EON-377360; Taste of the Wild Wetlands Canine Formula with roasted Fowl: B6 - EON-374534; Taste of the Wild.: B6 - EON-376466; Taste of the Wild: B6 - EON-374698; Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food: B6 - EON-377156; Wellness Core Ocean Grain Free Protein-Rich Nutrition: B6 - EON-377321; Wellness Core Ocean Grain Free Protein-Rich Nutrition: B6 - EON-377324; Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs: B6 - EON-377359

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/4/2019 7:40:21 PM

Subject: 4 Health Untamed: B6 - EON-375466

Attachments: 2060874-report.pdf

A PFR Report has been received and PFR Event [EON-375466] has been created in the EON System.

A "PDF" report by name "2060874-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375466
ICSR #: 2060874
EON Title: PFR Event created for 4 Health Untamed; 2060874

AE Date	12/08/2018	**Number Fed/Exposed**	
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Worse/Declining/Deteriorating
Breed	Shepherd Dog - German		
Age	6 Years		
District Involved	PFR-Foreign Firms DO		

Product information
Individual Case Safety Report Number: 2060874
Product Group: Pet Food
Product Name: 4 Health Untamed
Description: Since my dog was about a year or so old, he has been eating the Tractor Supply Co. brand of Dog Food, 4Health grain-free and Untamed. Starting in December 2018, my dog developed a cough, stopped eating, and experienced difficulty breathing. He was seen by a veterinarian December 20th. He had blood work done which was unremarkable, his radiograph of his chest showed an enlarged heart with pulmonary edema. He was then started on cardiac medications, and sent to a cardiologist for an echocardiogram. The echo confirmed the diagnosis of Dilated Cardiomyopathy. This is when the topic of grain-free diet associated DCM came up. My Vet recommended supplementing Taurine into his diet, switching to a mainstream brand of dog food that has participated in nutritional research, and limiting his physical activity. We are hoping for the best but he is in

rough shape. We will recheck the echocardiogram in 3 months to see if there have been any improvements. I hope this will help with any research ongoing with this issue. Please let me know if there is any more info I can provide or any additional research that has been done. Thank you. B6

Submission Type: Initial
Report Type: Both
Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4 Health Untamed		

Sender information

B6

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-375466			
ICSR:	2060874		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date:	2019-01-04 14:35:25 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	**Problem Description:**	Since my dog was about a year or so old, he has been eating the Tractor Supply Co. brand of Dog Food, 4Health grain-free and Untamed. Starting in December 2018, my dog developed a cough, stopped eating, and experienced difficulty breathing. He was seen by a veterinarian December 20th. He had blood work done which was unremarkable, his radiograph of his chest showed an enlarged heart with pulmonary edema. He was then started on cardiac medications, and sent to a cardiologist for an echocardiogram. The echo confirmed the diagnosis of Dilated Cardiomyopathy. This is when the topic of grain-free diet associated DCM came up. My Vet recommended supplementing Taurine into his diet, switching to a mainstream brand of dog food that has participated in nutritional research, and limiting his physical activity. We are hoping for the best but he is in rough shape. We will recheck the echocardiogram in 3 months to see if there have been any improvements. I hope this will help with any research ongoing with this issue. Please let me know if there is any more info I can provide or any additional research that has been done. Thank you. B6
	Date Problem Started:	12/08/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating
Product Information:	**Product Name:**	4 Health Untamed
	Product Type:	Pet Food
	Lot Number:	
	Purchase Date:	12/01/2018
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	stored in a Tupperware tote
	Product Use Information:	**Description:** fed 2-4 cups per day
		Time Interval between Product Use and Adverse Event: 6 Years
		Product Use Stopped After the Onset of the Adverse Event: Yes
		Adverse Event Abate After Product Stop: Unknown
		Product Use Started Again: No
		Perceived Relatedness to Adverse Event: Possibly related
		Other Foods or Products Given Unknown

		to the Animal During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Tractor Supply Co.
		Address:	B6
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd Dog - German	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	79 Pound	
	Age:	6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	01/03/2019
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6	
	Contact:	Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	
Additional Documents:			

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/23/2019 7:12:35 PM

Subject: Natural Balance Lamb and Brown Rice: B6 - EON-377272

Attachments: 2061634-report.pdf; 2061634-attachments.zip

A PFR Report has been received and Related PFR Event [EON-377272] has been created in the EON System.

A "PDF" report by name "2061634-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061634-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377272
ICSR #: 2061634
EON Title: Related PFR Event created for Natural Balance Lamb and Brown Rice, Merrick Lamb Peas and Ancient Grains, Zignature Fish; 2061634

AE Date	08/13/2014	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	10 Years		
District Involved	PFR-Baltimore DO		

Product information
Individual Case Safety Report Number: 2061634
Product Group: Pet Food
Product Name: Natural Balance Lamb and Brown Rice, Merrick Lamb, Peas, and Ancient Grains, Zignature Fish
Description: Presented for increased respiratory rate and effort at rest and exercise intolerance; was diagnosed with DCM and ventricular premature complexes of left bundle branch block morphology; was started on Pimobendan, enalapril, furosemide, and Taurine supplementation. 09/17/2018: B6 was changed to

NutriSource Chicken and Rice - developed diarrhea. 10/6/2018: B6 was changed to Instinct - developed diarrhea. 11/7 - 11/11/2018: B6 was transitioned to Royal Canin KP Hydrolyzed Protein.
Submission Type: Followup
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Natural Balance Lamb and Brown Rice		
Zignature Fish		
Merrick Lamb, Peas, and Ancient Grains		

This report is linked to:
Initial EON Event Key: EON-364756
Initial ICSR: 2054795

Sender information

B6

USA

Owner information

B6 USA

To view this Related PFR Event, please click the link below:
B6

To view the Related PFR Event Report, please click the link below:

B6

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Report Details - EON-377272

ICSR:	2061634
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-01-23 14:01:46 EST
Initial Report Date:	09/10/2018
Parent ICSR:	2054795
Follow-up Report to FDA Request:	Yes

Reported Problem:

Problem Description:	Presented for increased respiratory rate and effort at rest and exercise intolerance; was diagnosed with DCM and ventricular premature complexes of left bundle branch block morphology; was started on Pimobendan, enalapril, furosemide, and Taurine supplementation. 09/17/2018: B6 was changed to NutriSource Chicken and Rice - developed diarrhea. 10/6/2018: B6 was changed to Instinct - developed diarrhea. 11/7 - 11/11/2018: B6 was transitioned to Royal Canin KP Hydrolyzed Protein.
Date Problem Started:	08/13/2014
Date of Recovery:	11/03/2014
Concurrent Medical Problem:	No
Outcome to Date:	Better/Improved/Recovering

Product Information:

Product Name:	Zignature Fish	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Product Use Information:	**First Exposure Date:**	08/10/2014
	Last Exposure Date:	12/19/2014
	Product Use Stopped After the Onset of the Adverse Event:	No
	Perceived Relatedness to Adverse Event:	Possibly related
	Other Foods or Products Given to the Animal During This Time Period:	No
Manufacturer /Distributor Information:		
Purchase Location Information:		
Product Name:	Merrick Lamb, Peas, and Ancient Grains	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Product Use Information:	**Product Use Stopped After the Onset of the Adverse Event:**	Yes

		Adverse Event Abate After Product Stop:	Unknown
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	Natural Balance Lamb and Brown Rice	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	Time Interval between Product Use and Adverse Event:	5 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Unknown
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	35.1 Kilogram	
	Age:	10 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals	1	

	Reacted:		
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6 Phone: B6 Email: B6
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6 Phone: B6 Email: B6
		Address:	B6 United States
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
	Attachment:	B6	01232019 SOAP.pdf
	Description:	Most Recent Cardiac Recheck showing improvement after transition away from grain-free diet	
	Type:	Medical Records	

B6

PRELIMINARY

B6

Patient: B6 Golden Retriever, MN; DOB B6

Client: B6

Veterinarian: B6

Practice: B6

01/23/2019 **Presenting Complaint:** Cardiac Recheck

History:
B6 is presented for his six-month cardiac recheck. He has been doing well at home. His resting respiratory rates have been 14-20bpm. His appetite has been excellent; he was switched to a grain-rich in September, but he had diarrhea, so he finally settled on Royal Canin KP (Hydrolyzed) on November 11, 2018, and he was cut back to 4 cups BID on January 10, 2019 due to his increasing weight. His activity level has been increased since his diet change, though he does still tire quickly. He has been snoring, and he will still twitch in his sleep. His most recent labwork was performed November 20, 2018 (BUN 29mg/dL, Crea 1.1mg/dL, SDMA 12ug/dL). B6 would like to know if it's okay to increase B6 glucosamine amount. B6 received 75mg of trazadone at 8:00AM.

Performed Today:
Physical Exam: BAR, sweet; Weight increased 8.82# to 39.1kg/ 86.02 pounds (BCS 6/9); Temperature 100.2F; Heart rate 96bpm; Grade III/VI low frequency systolic murmur over mitral and tricuspid valves; frequent arrhythmia; Respiratory rate 30bpm; breath sounds clear (referred upper airway noise); Abdomen unremarkable: mild periodontal disease; Several cutaneous masses

Echocardiogram: Left ventricular internal diameter in systole and diastole decreased from last exam! Left ventricle no longer officially enlarged and appears less spheroid. Myocardial motion still subjectively decreased. End systolic volume index 44cm3/Ms (74.3 cm3/M2 (9/19), (58.7cm3/M2 (3/18), 39.33cm3/Ms (8/17) - 21.95 (2/16), 29 (8/16),. (54.9cm3/Ms off pimo). End diastolic volume index 115cm3/M2 (201.89 cm3/M2(9/18), (129cm3/M2 (3/18), 95.25 (8/17) - 106cm3/M2 (3/16), 148.9 off pimo. Volume indices are improved but not normal. Mild to moderate centrally directed mitral insufficiency. Normal left atrial size. EPSS decreased from 1.0cm to 0.3cm. Multiple multiform VPC, including one ventricular couplet noted on ECG gated during echocardiogram today. Pulmonary veins and Caudal vena cava unremarkable.

Holter Monitor: Pending, Results in 10-14 days

Assessment:
Reduced Systolic Function - improved on taurine, pimobendan
Progressive Dysfunction (3/18, 9/18)
Ventricular Premature Complexes
Left Bundle Branch Block Morphology
Exercise Intolerance - improved on pimobendan
Seems related to outside temperature
Increased Respiratory Rate at Rest - Wax/waning
Elevated SDMA/Minimally Concentrated Urine (5-17)

B6 heart has improved! It is not completely back to his best, but there is a clear difference. Maybe he will look even better next time around!

FAXED ☐ EMAILED
BY B6
DATE 1/23/19

Information per B6

B6

B6

It is OK if B6 wears the monitor longer than 24 hours. **Please note if there are any problems with the monitor while recording.** It is OK if a single lead dislodges - we may still obtain a valid reading. You may try to replace if you can easily find the electrode. Please do not use scissors to cut off the bandages surrounding the Holter - there are several long lead wires. Be sure to use some Goo Gone or mineral oil to remove the tape and/or ECG pads from his chest if they seems sticky. If, after removing the electrodes, the skin is red or irritated, you may apply 1% hydrocortisone cream to keep the itch and irritation down. Holter results are generally available 10-14 days after the monitor is returned to us.

Medications:

L-Carnitine: Give 1500mg orally every 24 hours.
Contact B6 research technician B6 at B6 to obtain L-carnitine.
Pimobendan 5mg: Give 1&1/2 tablets orally every 12 hours.
Enalapril 20mg: Give 1 tab(s) orally every 12 hours
Taurine 250mg: Give 2 tablets orally every 12 hours
Furosemide/Lasix 40mg: None for now
Start 1&1/2 orally every 12 hours if sleeping respiratory rate above 40bpm
Trazodone 50mg: Give 1-2 tablets orally every 12 hours as needed for anxiety.
Please give trazodone 2 hours prior to his next visit*
Glucosamine DHPlus Level 2: Give 1 tablet orally every 12 hours.
Gabapentin 800mg: Give 1/2 tablet orally every 8-12 hours as needed for pain. Can give 3/4 tablet orally every 12 hours as needed for anxiety.
or Gabapentin 300mg: Give 2 capsules orally, or as frequently as every 12 hours as needed for anxiety for thunderstorm anxiety. This drug is very effective but has an onset of action of about 2 hours.
Or Alprazolam 1mg: Give 1 tablet orally every 8-12 hours, as needed for thunderstorm anxiety. This drug is a little less effective, but does have a rapid onset of action
Fish Oil Supplement: B6 needs 1000-1400mg of the EPA component orally every 24 hours (Owners currently giving on weekdays)
Heartworm and Flea preventative recommended year-round
All medications prescribed by B6 are for long term use unless otherwise stated

Monitoring:

Diet: Normal -Avoid salty snacks (deli meats, cheese, Pupperoni or Snausages)
Consider switch from grain-free
Exercise: Avoid Overexertion/Overheating
Call us if: Status changes, Increased respiratory rate, Increase or change in cough, distended abdomen, passing out, failure to respond to medications

Recheck:

Recheck here for physical exam, abbreviated echocardiogram, in 6 months - sooner if problems;
Other recheck based upon results of Holter monitor
*****Premedicate with trazadone*****

Information for: B6

B6

B6

We appreciate your confidence in B6 We pledge to provide the clients you refer to us the same personal care that you and your pets appreciate. Please do not hesitate to call with any questions or concerns. Again, thank you for your trust.

RDVM Radiographs: ☐ Returned to Owner ☐ Mailed to B6 ☐ _____

Discharge Technician's Initials: B6

B6

B6

B6 Diplomate, ACVIM (Cardiology)

B6

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/14/2019 5:08:21 PM

Subject: Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula: B6 B6 - EON-376311

Attachments: 2061163-report.pdf

A PFR Report has been received and PFR Event [EON-376311] has been created in the EON System.

A "PDF" report by name "2061163-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376311
ICSR #: 2061163
EON Title: PFR Event created for Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula; 2061163

AE Date	11/15/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Worse/Declining/Deteriorating
Breed	Mixed (Dog)		
Age	7 Years		
District Involved	PFR-Atlanta DO		

Product information
Individual Case Safety Report Number: 2061163
Product Group: Pet Food
Product Name: Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula
Description: After about a year on Balanced Diet Grain Free Dog Food - Salmon and Sweet Potato formula - Dog started having coughing symptoms. Upon evaluation at the vet it was determined she was heart worm free with an enlarged hear upon Xray. Dog was put on two hear medications and referred for ultrasound. Ultrasound determined mitral valve disease and congestive heart failure
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-376311

ICSR:	2061163	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-14 12:02:07 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	**Problem Description:**	After about a year on Balanced Diet Grain Free Dog Food - Salmon and Sweet Potato formula - Dog started having coughing symptoms. Upon evaluation at the vet it was determined she was heart worm free with an enlarged hear upon Xray. Dog was put on two hear medications and referred for ultrasound. Ultrasound determined mitral valve disease and congestive heart failure
	Date Problem Started:	11/15/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating
Product Information:	**Product Name:**	Natural Balance LID Dry Dog Food - Sweet Potato and Fish Formula
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	26 Pound
	Purchase Date:	12/07/2018
	Number Purchased:	1
	Possess Unopened Product:	Yes
	Possess Opened Product:	Yes
	Storage Conditions:	stored in sealed container in pantry after bag is opened
	Product Use Information:	**Description:** one cup of food twice daily
		Last Exposure Date: 01/01/2019
		Time Interval between Product Use and Adverse Event: 1 Years
		Product Use Stopped After the Onset of the Adverse Event: No
		Perceived Relatedness to Adverse Event: Probably related
		Other Foods or Products Given to the Animal During This Time Period: No
	Manufacturer /Distributor Information:	
	Purchase Location Information:	**Name:** Amazon
		Address: United States
Animal Information:	**Name:**	B6

	Type Of Species:	Dog
	Type Of Breed:	Mixed (Dog)
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	65 Pound
	Age:	7 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	**Practice Name:** B6
		Contact: **Name:** B6
		Phone: B6
		Address: B6 United States
		Type of Veterinarian: Primary/regular veterinarian
		Date First Seen: 11/30/2018
		Permission to Release Records to FDA: Yes
Sender Information:	**Name:**	B6
	Address:	B6 United States
	Contact:	**Phone:** B6
		Email: B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Store/Place of Purchase
Additional Documents:		

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/11/2019 5:12:22 PM

Subject: Now Fresh Grain Free Adult Dog Food-Now Fresh Grain Free Puppy Food: B6 - EON-376136

Attachments: 2061092-report.pdf

A PFR Report has been received and PFR Event [EON-376136] has been created in the EON System.

A "PDF" report by name "2061092-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376136
ICSR #: 2061092
EON Title: PFR Event created for Now Fresh Grain Free Adult Dog Food Now Fresh Grain Free Puppy Food; 2061092

AE Date	12/03/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Retriever - Labrador		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2061092
Product Group: Pet Food
Product Name: Now Fresh Grain Free Adult Dog Food Now Fresh Grain Free Puppy Food
Description: Patient has been on Now Fresh Grain Free adult dog food/puppy dog food since purchased from breeder at approximately 16 weeks of age. P has developed, and confirmed by echocardiogram by boarded veterinary cardiologist, changes consistent with Nutritional Cardiomyopathy. P is currently on taurine supplementation and food has been changed to non grain-free diet, recheck echo planned for March/April 2019.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Now Fresh Grain Free Adult Dog Food Now Fresh Grain Free Puppy Food		

Sender information

B6

USA

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B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-376136

ICSR:	2061092	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-11 12:02:43 EST	
Reported Problem:	**Problem Description:**	Patient has been on Now Fresh Grain Free adult dog food/puppy dog food since purchased from breeder at approximately 16 weeks of age. P has developed, and confirmed by echocardiogram by boarded veterinary cardiologist, changes consistent with Nutritional Cardiomyopathy. P is currently on taurine supplementation and food has been changed to non grain-free diet, recheck echo planned for March/April 2019.
	Date Problem Started:	12/03/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Now Fresh Grain Free Adult Dog Food Now Fresh Grain Free Puppy Food
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Purchase Date:	08/01/2018
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Stored in cool dry place (garage)
	Product Use Information:	

Description:	Patient fed this food twice daily since obtained as puppy.
First Exposure Date:	09/01/2018
Last Exposure Date:	11/30/2018
Time Interval between Product Use and Adverse Event:	9 Years
Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	Unknown
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Probably related
Other Foods or Products Given to the Animal During This Time Period:	Unknown

Manufacturer /Distributor Information:	

	Purchase Location Information:	**Name:**	Chewy.com
		Address:	n/a n/a **B6** United States
Animal Information:	**Name:**	**B6**	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Labrador	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	72.8 Pound	
	Age:	**B6** Years	
	Assessment of Prior Health:	Unknown	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	**Owner Information provided:**	No
	Healthcare Professional Information:		
Sender Information:	**Name:**	**B6**	
	Address:	**B6** United States	
	Contact:	**Phone:**	**B6**
		Email:	**B6**
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	
Additional Documents:			

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/3/2019 12:52:20 AM

Subject: Nutrisource Small and Medium Breed Puppy Grain Free Dog Food: B6 B6 - EON-375242

Attachments: 2060786-report.pdf

A PFR Report has been received and PFR Event [EON-375242] has been created in the EON System.

A "PDF" report by name "2060786-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375242
ICSR #: 2060786
EON Title: PFR Event created for Nutrisource Small and Medium Breed Puppy Grain Free Dog Food; 2060786

AE Date	01/02/2019	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Unknown
Breed	Mixed (Dog)		
Age	9 Months		
District Involved	PFR-Kansas City DO		

Product information
Individual Case Safety Report Number: 2060786
Product Group: Pet Food
Product Name: Nutrisource Small and Medium Breed Puppy Grain Free Dog Food
Description: B6 9 month old labradoodle, has been fed Nutrisource grain free small/medium breed puppy food since weaning. For the past 4-5 months it had been noticed that B6 was often short of breath and had a rapid heart rate. After being taken to the vet, a grade 2 murmur was found leading to the finding of cardiomyopathy. Awaiting echocardiogram. Advised by veterinarian to switch dog food to researched and approved brand because adverse health effects related to foods with lentils, such as the one B6 was on.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)

Outcome of reaction/event at the time of last observation: Unknown
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Nutrisource Small and Medium Breed Puppy Grain Free Dog Food		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-375242

ICSR:	2060786	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-02 19:46:49 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	**Problem Description:**	B6 9 month old labradoodle, has been fed Nutrisource grain free small/medium breed puppy food since weaning. For the past 4-5 months it had been noticed that B6 was often short of breath and had a rapid heart rate. After being taken to the vet, a grade 2 murmur was found leading to the finding of cardiomyopathy. Awaiting echocardiogram. Advised by veterinarian to switch dog food to researched and approved brand because adverse health effects related to foods with lentils, such as the one B6 was on.
	Date Problem Started:	01/02/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown
Product Information:	**Product Name:**	Nutrisource Small and Medium Breed Puppy Grain Free Dog Food
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Mixed (Dog)
	Gender:	Female
	Reproductive Status:	Intact
	Pregnancy Status:	Not Pregnant
	Lactation Status:	Not lactating
	Weight:	42 Pound
	Age:	9 Months
	Assessment of Prior Health:	Unknown
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	**Contact:** **Name:** B6 **Phone:** B6
		Contact: **Name:** B6 **Phone:** B6
Sender Information:	**Name:**	B6
	Address:	B6

		B6 United States
	Contact:	Phone: B6 Email: B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
Additional Documents:		

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 12/29/2018 9:24:22 AM

Subject: NutriSource Super Premium Pet Foods: B6 - EON-374952

Attachments: 2060676-report.pdf

A PFR Report has been received and PFR Event [EON-374952] has been created in the EON System.

A "PDF" report by name "2060676-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374952
ICSR #: 2060676
EON Title: PFR Event created for NutriSource Super Premium Pet Foods; 2060676

AE Date	12/17/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	11 Years		
District Involved	PFR B6 DO		

Product information
Individual Case Safety Report Number: 2060676
Product Group: Pet Food
Product Name: NutriSource Super Premium Pet Foods
Description: Dog is a mixed breed: golden retriever and poodle hybrid (goldendoodle). He has developed heart disease (DCM) on the diet. Was told it is most likely related to taurine deficiency. Have put him on heart medication and a taurine supplement. Have already seen marked improvement in his demeanor. EKG to see if taurine supplement has reversed heart disease in 3-6 months.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
NutriSource Super Premium Pet Foods		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

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Report Details - EON-374952

ICSR:	2060676		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2018-12-29 04:20:02 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	**Problem Description:**	Dog is a mixed breed: golden retriever and poodle hybrid (goldendoodle). He has developed heart disease (DCM) on the diet. Was told it is most likely related to taurine deficiency. Have put him on heart medication and a taurine supplement. Have already seen marked improvement in his demeanor. EKG to see if taurine supplement has reversed heart disease in 3-6 months.	
	Date Problem Started:	12/17/2018	
	Date of Recovery:	12/27/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	**Product Name:**	NutriSource Super Premium Pet Foods	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	12/06/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	I only ever kept a 3-week supply. It was stored in one of those locked pet food bins at room temperature.	
	Product Use Information:	**Description:**	Fed daily to dog, per package instructions, for almost exactly 4 years (originally purchased on approximately December 15, 2014).
		First Exposure Date:	12/06/2018
		Last Exposure Date:	12/27/2018
		Time Interval between Product Use and Adverse Event:	4 Years
		Product Use Stopped After the Onset of the Adverse Event:	No
		Perceived Relatedness to Adverse Event:	Probably related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer		

	/Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	55 Pound	
	Age:	11 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
			Email: B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	12/20/2018
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
			Email: B6
		Address:	B6 United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	12/26/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6	

		B6 United States
	Contact:	**Phone:** B6 **Email:** B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	None
Additional Documents:		

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/8/2019 11:00:19 PM

Subject: NWBARBF-Beef Recipe for Dogs-Ground Bone Added-Not for Human Consumption-Made in the USA by Northwest Naturals: B6 EON-375869

Attachments: 2060992-report.pdf

A PFR Report has been received and PFR Event [EON-375869] has been created in the EON System.

A "PDF" report by name "2060992-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375869
ICSR #: 2060992
EON Title: PFR Event created for NWBARBF Beef Recipe for Dogs Ground Bone Added Not for Human Consumption Made in the USA by Northwest Naturals; 2060992

AE Date	11/14/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Unknown
Breed	Retriever - Golden		
Age	8 Years		
District Involved	PFR-Atlanta DO		

Product information
Individual Case Safety Report Number: 2060992
Product Group: Pet Food
Product Name: NWBARBF Beef Recipe for Dogs Ground Bone Added Not for Human Consumption Made in the USA by Northwest Naturals
Description: Whole Blood Taurine was 224 Plasma Taurine was 90
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Unknown

Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
NWBARBF Beef Recipe for Dogs Ground Bone Added Not for Human Consumption Made in the USA by Northwest Naturals		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

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Report Details - EON-375869

ICSR:	2060992
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-01-08 17:50:04 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description:	Whole Blood Taurine was 224 Plasma Taurine was 90
Date Problem Started:	11/14/2018
Concurrent Medical Problem:	No
Outcome to Date:	Unknown

Product Information:

Product Name:	NWBARBF Beef Recipe for Dogs Ground Bone Added Not for Human Consumption Made in the USA by Northwest Naturals
Product Type:	Pet Food
Lot Number:	
UPC:	(01)18101625NWBARF
Package Type:	BOX
Package Size:	25 Pound
Possess Unopened Product:	Yes
Possess Opened Product:	Yes
Storage Conditions:	Always in the freezer

Product Use Information:

Description:	Defrosted in refrigerator for 12 hours prior to feeding
First Exposure Date:	01/01/2018
Time Interval between Product Use and Adverse Event:	1 Years
Product Use Stopped After the Onset of the Adverse Event:	No
Perceived Relatedness to Adverse Event:	Possibly related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:	
Purchase Location Information:	

Animal Information:

Name:	**B6**
Type Of Species:	Dog
Type Of Breed:	Retriever - Golden
Gender:	Female
Reproductive Status:	Neutered

	Weight:	54 Pound
	Age:	8 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	**Name:**	B6
	Address:	B6 United States
	Contact:	**Phone:** B6 **Other Phone:** B6 **Email:** B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other
Additional Documents:		

From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>

To: Carey, Lauren; Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/4/2019 12:52:23 PM

Subject: Orijen Regional Red Dry Dog Food-Fromm Beef Frittata A La Veg Dry Dog Food-From Duck & Sweet Potato Dry Dog Food-Purina Fortiflora: B6 B6 - EON-375393

Attachments: 2060845-report.pdf; 2060845-attachments.zip

A PFR Report has been received and Related PFR Event [EON-375393] has been created in the EON System.

A "PDF" report by name "2060845-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060845-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375393
ICSR #: 2060845
EON Title: Related PFR Event created for Orijen Regional Red Dry Dog Food Fromm Beef Frittata A La Veg Dry Dog Food From Duck & Sweet Potato Dry Dog Food Purina Fortiflora; 2060845

AE Date	10/25/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR- B6 DO		

Product information
Individual Case Safety Report Number: 2060845
Product Group: Pet Food
Product Name: Orijen Regional Red Dry Dog Food Fromm Beef Frittata A La Veg Dry Dog Food From Duck & Sweet Potato Dry Dog Food Purina Fortiflora
Description: This submission is in furtherance of your nutritionally-mediated DCM investigation. My young,

energetic and very healthy Golden Retriever male had his second echocardiogram on Thursday, October 25, 2018. His first was approximately one year ago in September 2017. The 2017 echo was normal. The one from last week was not. It showed a subjective increase in sphericity of his heart, as well as mild systolic dysfunction compared with last year. ACK!!! His whole blood taurine level at U.C. Davis was 226 in September 2018. I had scheduled echocardiograms for B6 and my other two Goldens out of an abundance of caution after two (B6 and his littermate brother) tested below 250 nmol/ml for taurine in whole blood). I'm glad I did. My veterinary cardiologist is B6 DVM ACVIM (Cardiology) of B6 At last week's echocardiogram, he drew blood for CBC, chemistry, a repeat of the taurine test with paired samples, a full tick-borne disease panel, and thyroid tests. All test results are in except for the repeat taurine test from B6 B6 All B6 results were unremarkable or normal, except for a slightly low globulin level. That test will be repeated this week. I never purposely fed a "grain-free" food or an "exotic protein" food. I'm a physicist and I believe in science and common sense. HOWEVER, after FDA's investigation was announced, I noted that some of the commercial food I was feeding B6 (which I thought was perfectly conventional) met the FDA's description of "suspect diets". In addition, I had been giving my three Goldens a probiotic from Purina -- their Fortiflora product -- as a routine part of feeding after a period in which all three dogs had loose stool and diarrhea. I added the Fortiflora to their food for a period of over a year. I think the current thinking on this issue is that it's multifactorial, I wanted to mention first that I had added the Fortiflora and that while I didn't purposely choose a grain-free food (high in legumes), I've also found that the food itself has added "probiotics". I was surprised to see that. Now, I wonder if my accidental food choice for him, plus my "probiotic" supplement, changed something in how his body processed the taurine precursors and dietary taurine. In addition, he's definitely an "easy-keeper", eating nowhere near the amount of food advised on the bag. After his "equivocal" taurine level in mid-September 2018, I stopped feeding Fortiflora to all three Goldens. Their stool is perfectly fine, perhaps even better. I changed B6 diet from Fromm to Purina ProPlan Sport 30/20 at the same time. Please do get in touch if there's any further information you require or that you might provide me. Obviously, I hope this is diet-related and can be reversed. FOLLOW UP -- JANUARY 3, 2019 ECHOCARDIOGRAM Hey, good news. After 90 days of diet change, 8 weeks of taurine supplementation, and 6 weeks of l-carnitine supplementation, B6 echocardiographic findings are either within normal limits or are improving. I will attach his cardiologist's detailed report. I'm delighted, of course.

Submission Type: Followup
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Orijen Regional Red Dry Dog Food Fromm Beef Frittata A La Veg Dry Dog Food From Duck & Sweet Potato Dry Dog Food Purina Fortiflora		

This report is linked to:
Initial EON Event Key: EON-370539
Initial ICSR: 2058584

Sender information

B6

USA

To view this Related PFR Event, please click the link below:

B6

To view the Related PFR Event Report, please click the link below:

B6

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Report Details - EON-375393

ICSR:	2060845
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-01-04 07:45:14 EST
Initial Report Date:	11/08/2018
Reporter is the Animal Owner:	Yes
Parent ICSR:	2058584
Follow-up Report to FDA Request:	Yes

Reported Problem:

Problem Description:	This submission is in furtherance of your nutritionally-mediated DCM investigation. My young, energetic and very healthy Golden Retriever male had his second echocardiogram on Thursday, October 25, 2018. His first was approximately one year ago in September 2017. The 2017 echo was normal. The one from last week was not. It showed a subjective increase in sphericity of his heart, as well as mild systolic dysfunction compared with last year. ACK!!! His whole blood taurine level at U.C. Davis was 226 in September 2018. I had scheduled echocardiograms for B6 and my other two Goldens out of an abundance of caution after two (B6 and his littermate brother) tested below 250 nmol/ml for taurine in whole blood). I'm glad I did. My veterinary cardiologist is B6 DVM ACVIM (Cardiology) of B6 At last week's echocardiogram, he drew blood for CBC, chemistry, a repeat of the taurine test with paired samples, a full tick-borne disease panel, and thyroid tests. All test results are in except for the repeat taurine test from U.C. Davis. All B6 results were unremarkable or normal, except for a slightly low globulin level. That test will be repeated this week. I never purposely fed a "grain-free" food or an "exotic protein" food. I'm a physicist and I believe in science and common sense. HOWEVER, after FDA's investigation was announced, I noted that some of the commercial food I was feeding B6 (which I thought was perfectly conventional) met the FDA's description of "suspect diets". In addition, I had been giving my three Goldens a probiotic from Purina -- their Fortiflora product -- as a routine part of feeding after a period in which all three dogs had loose stool and diarrhea. I added the Fortiflora to their food for a period of over a year. I think the current thinking on this issue is that it's multifactorial, I wanted to mention first that I had added the Fortiflora and that while I didn't purposely choose a grain-free food (high in legumes), I've also found that the food itself has added "probiotics". I was surprised to see that. Now, I wonder if my accidental food choice for him, plus my "probiotic" supplement, changed something in how his body processed the taurine precursors and dietary taurine. In addition, he's definitely an "easy-keeper", eating nowhere near the amount of food advised on the bag. After his "equivocal" taurine level in mid-September 2018, I stopped feeding Fortiflora to all three Goldens. Their stool is perfectly fine, perhaps even better. I changed B6 diet from Fromm to Purina ProPlan Sport 30/20 at the same time. Please do get in touch if there's any further information you require or that you might provide me. Obviously, I hope this is diet-related and can be reversed. FOLLOW UP -- JANUARY 3, 2019 ECHOCARDIOGRAM Hey, good news. After 90 days of diet change, 8 weeks of taurine supplementation, and 6 weeks of l-carnitine supplementation, B6 echocardiographic findings are either within normal limits or are improving. I will attach his cardiologist's detailed report. I'm delighted, of course.
Date Problem Started:	10/25/2018
Date of Recovery:	01/03/2019
Concurrent Medical Problem:	No
Outcome to Date:	Better/Improved/Recovering

Product Information:

Product Name:	Orijen Regional Red Dry Dog Food Fromm Beef Frittata A La Veg Dry Dog Food From Duck & Sweet Potato Dry Dog Food Purina Fortiflora
Product Type:	Pet Food

	Lot Number:		
	Package Type:	BAG	
	Package Size:	13 Pound	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	No	
	Product Use Information:	**Description:**	I can provide a description of how I mixed this food with two others for part of B6 diet. Please let me know if you'd like me to send that. He was also fed scrambled eggs, yogurt, cottage cheese, and meats.
		First Exposure Date:	12/03/2017
		Last Exposure Date:	09/15/2018
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Unknown
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:	**Name:**	Chewy.com
Animal Information:	**Name:**	B6 -- B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	80 Pound	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	**Practice Name:**	B6
		Contact:	**Name:** B6 DVM, ACVIM (Cardiology)
			Phone: B6
			Other Phone: B6
			Email: B6
		Address:	B6

			B6 United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	10/31/2018
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact:	Name: B6 DVM
			Phone: B6
			Other Phone: B6
			Email: B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	11/08/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Other Phone:	B6
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
	Attachment:	B6 20190103 193001.pdf	
	Description:	This is B6 follow-up echocardiogram report from yesterday, January 3, 2019.	
	Type:	Echocardiogram	

B6

B6

Patient: B6 B6 **years and** B6 **months old M Canine Golden Retriever**
Client: B6
Account #: 300G
Referring Hospital: B6
Referring Doctor: B6
Referring Hospital:
Referring Doctor: Dr.
Date: Jan 03, 2019

Cardiology Consultation

Current History: B6 is a 3-year-old male Golden Retriever that presents today for a 2 month follow-up echocardiogram after the identification of a dilated cardiomyopathy phenotype and a marginal taurine level. The owner has been supplementing taurine since the last echocardiogram and carnitine for the past 6 weeks (see below). B6 was not symptomatic at the last evaluation and has remained active and energetic. The owner does not report any other noncardiac problems. He has tolerated the supplements without apparent side effects. No other new medical problems were reported.

Past medical history:
- Immature cataract, OS
- Historical dermatitis

Current Medications:
- Taurine 1g twice a day
- Carnitine 2g a.m./p.m., 1.5g "midnight snack"
- Cosequin joint supplement

Cardiopulmonary Exam: B6 is alert and friendly as usual. He is mildly overweight (38.3 kg, BCS 6/9) and has gained 1 kg since the last evaluation. Cardiac auscultation was unremarkable with no arrhythmias, gallop sounds, or murmurs. Oral mucous membrane color and refill time are within normal limits. Pulmonary auscultation was unremarkable. Arterial pulse quality was excellent and there were no pulse deficits or jugular pulsations.
General Physical Exam Abnormalities: The patient has a fractured right maxillary third incisor. An incipient cataract is present OS

Diagnostic Procedures
Electrocardiogram: A bipolar monitoring ECG recorded during the echocardiogram demonstrates a normal sinus rhythm with heart rates between 87-120 bpm. No ectopy was observed during the study.
Echocardiogram: Left ventricular internal chamber dimensions are mildly increased for a dog of this size but have remained static since the last examination. Right and left ventricular myocardial thicknesses are within normal limits, and echogenicity of the ventricular myocardium is subjectively normal as well. Left ventricular sphericity has decreased (sphericity index 1.22) although it is still mildly abnormal. Estimates of left ventricular systolic function have improved since the last exam and are now for the most part within normal

B6

B6

limits (FS 26%, EF 54-55%, EPSS 8 mm). Both atria are normal in size (LA 3.7 cm, LA/Ao 1.37). Valvular anatomy was unremarkable and color flow Doppler did not document any pathologic valvular insufficiencies, although physiologic tricuspid regurgitation was present (2.2 m/s). Ejection velocities and great vessel anatomy were normal (Ao 1.6 m/s, PA 1.1 m/s). The mitral inflow profile is normal as well (E wave 0.8 m/s, A-wave 0.5 m/s). Left ventricular IVRT is at the upper limit of normal at 95 ms. Pulsed tissue Doppler evaluation of the mitral annulus was normal (Ea 0.17 m/s). No masses or vegetations were observed.

Diagnosis/Problem List:

- Historical dilated cardiomyopathy phenotype - resolving
- Probable taurine deficiency - appropriately supplemented
- Overweight
- Fractured right maxillary I3
- Immature cataract OS

Summary/Prognosis: B6 echocardiogram has improved since the last examination with normal or near-normal estimates of LV systolic function and subjectively diminished sphericity. Atrial dimensions are still normal, and no secondary functional valvular insufficiencies were identified. The improvement in systolic function is presumably related to supplementation with taurine and carnitine. Based on today's evaluation no additional diagnostics were recommended, and B6 does not currently require any other therapy. His left ventricular internal dimensions are still slightly increased, but this may be a reflection of a physiologic change in a very active dog, since his LV dimensions have been mildly increased since his initial evaluation in 2017. He will continue to be monitored, but hopefully identification of a relative taurine deficiency early in the disease process will prevent progression to any overt clinical symptoms.

Treatment Plan:

- Continue supplements as above

Follow-up Recommendations: Recheck echocardiography in 3-4 months

B6

B6, DVM
Diplomate ACVIM (Cardiology)

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/20/2019 3:20:22 PM

Subject: Ped: B6 - EON-376960

Attachments: 2061494-report.pdf

A PFR Report has been received and PFR Event [EON-376960] has been created in the EON System.

A "PDF" report by name "2061494-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-376960
ICSR #: 2061494
EON Title: PFR Event created for Ped; 2061494

AE Date	01/02/2019	**Number Fed/Exposed**	
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Shepherd Dog - German		
Age	3 Years		
District Involved	PFR-Kansas City DO		

Product information
Individual Case Safety Report Number: 2061494
Product Group: Pet Food
Product Name: Ped
Description: My 3 y/o German Shepard, was recently dx with dilated cardiomyopathy (DCM) and Congestive Heart Failure. I feel the dog food I fed her was Pedigree grain free, with main ingredients being, potatoes, peas and Legumes. She ate that food for about 2 years. During that time, she had a minor cough which progressed to a bad hacking cough. I took her to the vet and did a Chest x-ray which revealed an enlarged heart with fluid in her lungs. The first vet I took her to just prescribed an antibiotic and told me to follow up with a specialist in B6 B6 condition worsened to the point where I though I would have to put her down. I, immediately took her to another vet. She recognized B6 condition, and administered Lasix immediately and observed B6 for 4 hours. B6 improved to the point I could take her home however, she will be on meds for

DCM and CHF for the rest of her life. I feel the dog food I fed B6 is responsible for her condition.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Ped		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-376960

ICSR:	2061494
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-01-20 10:10:37 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description:	My 3 y/o German Shepard, was recently dx with dilated cardiomyopathy (DCM) and Congestive Heart Failure. I feel the dog food I fed her was Pedigree grain free, with main ingredients being, potatoes, peas and Legumes. She ate that food for about 2 years. During that time, she had a minor cough which progressed to a bad hacking cough. I took her to the vet and did a Chest x-ray which revealed an enlarged heart with fluid in her lungs. The first vet I took her to just prescribed an antibiotic and told me to follow up with a specialist in B6 B6 condition worsened to the point where I though I would have to put her down. I, immediately took her to another vet. She recognized B6 condition, and administered Lasix immediately and observed B6 for 4 hours. B6 improved to the point I could take her home however, she will be on meds for DCM and CHF for the rest of her life. I feel the dog food I fed B6 is responsible for her condition.
Date Problem Started:	01/02/2019
Date of Recovery:	01/20/2019
Concurrent Medical Problem:	No
Outcome to Date:	Better/Improved/Recovering

Product Information:

Product Name:	Ped
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Package Size:	30 Pound
Purchase Date:	11/30/2018
Number Purchased:	1
Possess Unopened Product:	No
Possess Opened Product:	No
Storage Conditions:	Air tight plastic container.

Product Use Information:

Description:	Dog food bowl full 2 times a day.
Last Exposure Date:	01/01/2019
Time Interval between Product Use and Adverse Event:	2 Years
Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	No
Product Use Started Again:	No
Perceived Relatedness to	Definitely related

		Adverse Event:	
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Petsmart
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd Dog - German	
	Gender:	Female	
	Reproductive Status:	Intact	
	Pregnancy Status:	Not Pregnant	
	Lactation Status:	Not lactating	
	Weight:	50 Pound	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:		
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
	Reported to Other Parties:	None	
Additional Documents:			

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/2/2019 8:12:39 PM

Subject: Pure Vita Venison & Red Lentils Grain Free Entree B6 - EON-375203

Attachments: 2060773-report.pdf; 2060773-attachments.zip

A PFR Report has been received and PFR Event [EON-375203] has been created in the EON System.

A "PDF" report by name "2060773-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2060773-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-375203
ICSR #: 2060773
EON Title: PFR Event created for Pure Vita Venison & Red Lentils Grain Free Entree, Whole Life Pet Just One Ingredient Pure Beef Liver Treat; 2060773

AE Date	10/05/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Retriever - Golden		
Age	8 Years		
District Involved	PFR- B6 DO		

Product information
Individual Case Safety Report Number: 2060773
Product Group: Pet Food
Product Name: Pure Vita Venison & Red Lentils Grain Free Entree, Whole Life Pet Just One Ingredient Pure Beef Liver Treat
Description: Low whole blood taurine noted 10/05/18 (135 nmol/mL). Mild decrease in systolic function noted on echocardiogram 10/06/18. Generally asymptomatic but seems heat intolerant and tires easily on walks (not a new finding).

Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Whole Life Pet Just One Ingredient Pure Beef Liver Treat		
Pure Vita Venison & Red Lentils Grain Free Entree		

Sender information

B6

USA

Owner information

B6 USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-375203		
ICSR:	2060773	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-02 15:05:36 EST	
Reported Problem:	**Problem Description:**	Low whole blood taurine noted 10/05/18 (135 nmol/mL). Mild decrease in systolic function noted on echocardiogram 10/06/18. Generally asymptomatic but seems heat intolerant and tires easily on walks (not a new finding).
	Date Problem Started:	10/05/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Past history of vomiting/diarrhea - IBD suspected but not confirmed. History of struvite crystalluria, dental calculus.
	Outcome to Date:	Stable
Product Information:	**Product Name:**	Whole Life Pet Just One Ingredient Pure Beef Liver Treat
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Possess Unopened Product:	Unknown
	Possess Opened Product:	Unknown
	Storage Conditions:	Unknown
	Product Use Information:	**Description:** 1 treat given monthly
		Product Use Stopped After the Onset of the Adverse Event: Unknown
		Perceived Relatedness to Adverse Event: Unrelated
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	Pure Vita Venison & Red Lentils Grain Free Entree
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Possess Unopened Product:	Unknown
	Possess Opened Product:	Unknown
	Storage Conditions:	Unknown
	Product Use Information:	**Description:** 1.25 cup fed 2x/day since 9/2017
		First Exposure Date: 09/01/2017
		Time Interval between Product Use and Adverse Event: 2 Years
		Product Use Stopped After the Yes

		Onset of the Adverse Event:	
		Adverse Event Abate After Product Stop:	Unknown
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	60 Pound	
	Age:	8 Years	
	Assessment of Prior Health:	Fair	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6 Phone: B6 Other Phone: B6 Email: B6
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6 Phone: B6 Email: B6
		Address:	B6 United States
		Type of Veterinarian:	Referred veterinarian
		Permission to	Yes

	Release Records to FDA:	
	Practice Name:	B6
	Contact:	Name: B6
		Phone: B6
	Address:	B6 United States
	Type of Veterinarian:	Referred veterinarian
	Date First Seen:	10/06/2018
	Permission to Release Records to FDA:	Yes
	Practice Name:	B6
	Contact:	Name: B6
		Phone: B6
	Address:	B6 United States
	Type of Veterinarian:	Primary/regular veterinarian

Sender Information:	Name:	B6
	Address:	B6 United States
	Contact:	Phone: B6
		Email: B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None

Additional Documents:	Attachment:	B6 _2019-01-02_Converted medical history for B6 .pdf
	Description:	Older medical history
	Type:	Medical Records
	Attachment:	B6 _2018-10-21_17.50_care instructions.pdf
	Description:	Diet recommendations
	Type:	Medical Records
	Attachment:	B6 __2019-01-02_Echo .pdf
	Description:	Echocardiogram report
	Type:	Echocardiogram
	Attachment:	B6 __2019-01-02_Ref Recs- B6 2) taurine results.pdf
	Description:	Whole blood taurine results from B6
	Type:	Laboratory Report

Attachment:	B6 _Medical history 2018-09-09 to 2018-12-06.pdf
Description:	More recent medical history (B6)
Type:	Medical Records

Client: B6
Patient: B6

Doctor: B6
Record Date: 12-Jun-2014 to 19-Oct-2016

Medical Records

Client		Patient		
B6	B6	B6	B6	B6
Phone: B6		Canine Retriever, Golden	Golden Female Spayed	0 pounds

Diagnostic History

Date	Code	Diagnosis

Medical History

Visit Info Date Start: 2016-10-19 Date End: 2016-10-19 Notes:

Date	Type	Description	Qty	Resource
19-Oct-2016	Converted History	B6	1	B6
19-Oct-2016	Converted Rx	B6	5	B6

Visit Info Date Start: 2016-10-18 Date End: 2016-10-18 Notes:

Date	Type	Description	Qty	Resource
18-Oct-2016	Converted History	• Entered: B6	1	B6
18-Oct-2016	Converted History	Syringe - 1cc x 25g (6)	6	B6
18-Oct-2016	Converted History	Cyanocobalamine 1000mcg/ml for Rx (5)	5	B6

Visit Info Date Start: 2016-10-17 Date End: 2016-10-17 Notes:

Date	Type	Description	Qty	Resource
17-Oct-2016	Converted History	Needle - 18g x 1"	1	B6
17-Oct-2016	Converted History	Vitamin B Complex Inj. (5)	5	B6
17-Oct-2016	Converted History	* Entered: B6	1	B6
17-Oct-2016	Converted Rx	B6	1	B6
17-Oct-2016	Converted Rx		5	B6

Visit Info Date Start: 2016-09-28 Date End: 2016-09-28 Notes:

Date	Type	Description	Qty	Resource

28-Sep-2016	Converted History	Client Communication	1	B6

History:
Client Communication:

B6

28-Sep-2016	Converted History	Client Communication	1	Other, Doctor

B6

28-Sep-2016	Converted History	B6	6	B6
28-Sep-2016	Converted History	* Entered: B6	1	B6
28-Sep-2016	Converted History	B6	5	B6
28-Sep-2016	Converted Rx	B6	5	B6

Visit Info		Date Start:	2016-09-26	Date End:	2016-09-26	Notes:		
Date	Type	Description					Qty	Resource
26-Sep-2016	Converted History	B6					4	B6
26-Sep-2016	Converted History						1	B6
26-Sep-2016	Converted Rx						4	B6

Visit Info		Date Start:	B6	Date End:	B6	Notes:		
Date	Type	Description					Qty	Resource

History:

B6

Physical Exam:

B6

Objective:
Wt-30.9 kg, T-102 F, P-128 bpm, R-pant

Abdominal ultrasound:

B6

No significant findings

CBC: WBC 10.9 K/uL (6-17), HCT 53.5% (37-55) and platelets 265 K/uL (200-500)

PCV/TP: 52%, 6.8 g/dL

Chemistry panel: ALP <5 U/L (20-150), phosphorus 2.8 mg/dL (2.9-6.6)

Fecal PCR: results pending

Cobalamin/folate/PLI: results pending

Assessment:

B6

Body condition score:
BCS 7/9

Pain Score:
0/4

Prognosis:
Undetermined

Follow-up with Primary Care Veterinarian:
Plan:

B6

History:
Ultrasound Findings:

B6

Conclusion:
No significant findings

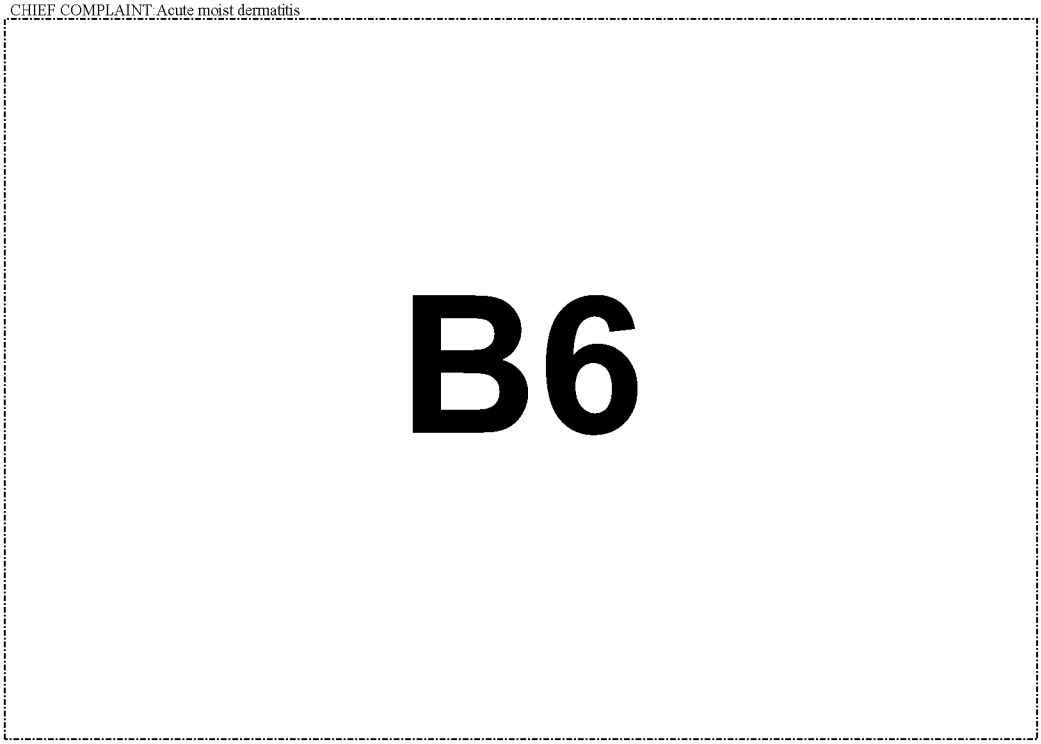
B6	Converted History	Mailing Fee - B6	1	Other, Doctor
B6	Converted History	B6	21	B6
B6	Converted History		4	B6
B6	Converted History	B6 to B6	1	B6
B6	Converted History	GI Profile FastPanel PCR Canine #T950	1	B6
B6	Converted History	* Entered: B6	1	B6
B6	Converted History	Consultation - Internal Medicine	1	B6
B6	Converted History	B6 CBC STAT	1	B6
B6	Converted History	Ultrasound, Abdomen - CG	1	B6
B6	Converted History	B6 (10.01)	10.01	B6
B6	Converted History	Consultation - Emergency CHIEF COMPLAINT:Vomiting blood. To transfer to B6 History:	1	B6
B6	Converted Rx	B6	4	B6
B6	Converted Rx		21	B6
B6	Converted Rx	B6	4	B6
B6	Converted Rx		21	B6

Visit Info	Date Start: B6	Date End: B6	Notes:

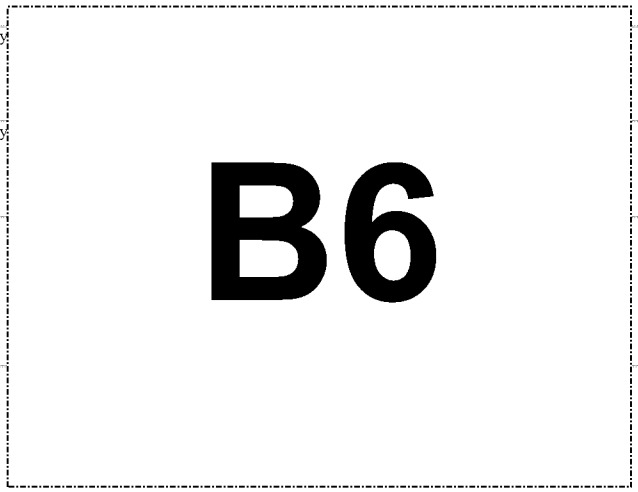
Date	Type	Description	Qty	Resource

B6	Converted History	Consultation - Emergency	1	B6

CHIEF COMPLAINT:Acute moist dermatitis



B6	Converted History	* To Go Home: B6	1	B6
B6	Converted History	* Entered: B6	1	B6
B6	Converted History	Wound Care Level I	1	B6
B6	Converted History	Consultation - Emergency	1	B6
B6	Converted History	• Entered: B6	1	B6
B6	Converted History		10	B6
B6	Converted History		13.33	B6
B6	Converted Rx		10	B6
B6	Converted Rx		10	B6

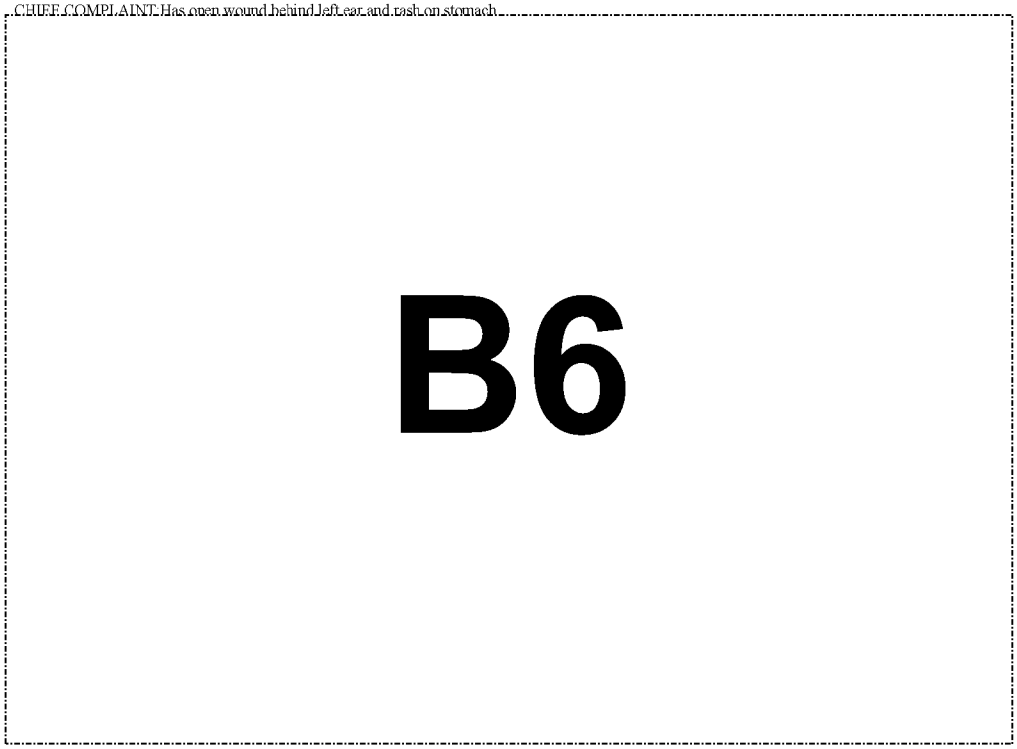


Visit Info	Date Start:	2014-06-15	Date End:	2014-06-15	Notes:		
Date	Type	Description				Qty	Resource
15-Jun-2014	Converted History	Client Communication (emergency serv)				1	B6

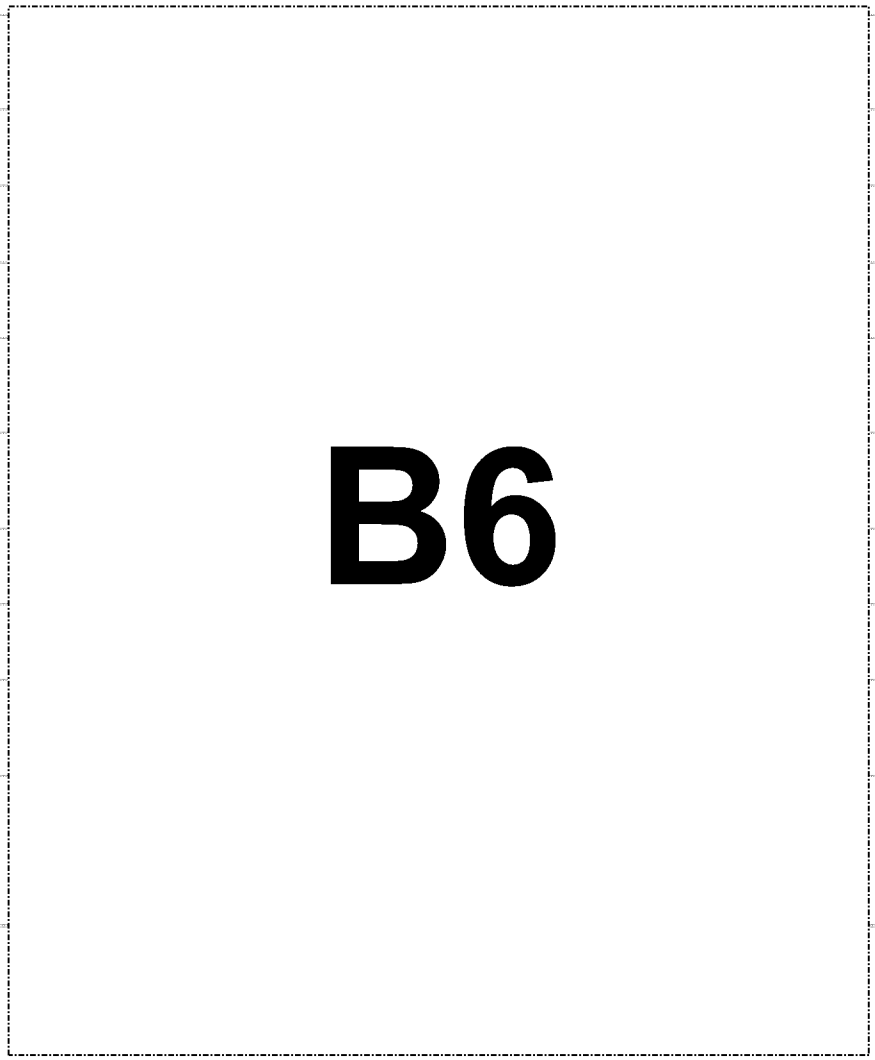
History:Hot spots
Client Communication:1445 - SW B6 B6 is doing very well and owner is happy.

Visit Info	Date Start:	2014-06-12	Date End:	B6	Notes:		
Date	Type	Description				Qty	Resource

B6	Converted History	Consultation - Emergency {10:54 PM} CHIEF COMPLAINT Has open wound behind left ear and rash on stomach	1	B6



B6	Converted History		10	B6
B6	Converted History		1	B6
B6	Converted History		1	B6
B6	Converted History		1	B6
B6	Converted History		10	B6
B6	Converted History		8	B6
B6	Converted History		1	B6
B6	Converted History		1	B6
B6	Converted History		21.44	B6
B6	Converted Rx		1	B6
B6	Converted Rx		10	B6



B6 Converted Rx

B6

8 B6

B6 Converted Rx

10 B6

B6

B6

Name B6
Patient Id B6
Birthdate B6
Age 8
Sex/Breed FS GOLDEN RETRIEVER
Weight 27.5 kg

Date 10/06/2018

Physician B6

2D
Ao Diam
LA Diam
LA/Ao
Ao/LA
LVLd A4C
LVEDV MOD A4C
LVLs A4C
LVESV MOD A4C
LVEF MOD A4C
SV MOD A4C

B6

M-Mode
IVSd
LVIDd
LVPWd
IVSs
LVIDs
LVPWs
EDV(Teich)
ESV(Teich)
EF(Teich)
%FS
SV(Teich)

B6

Doppler
MV E Vel
MV A Vel
MV E/A Ratio
E/IVRT
IVRT
E/IVRT
AV Vmax
AV maxPG

B6

Subjective Findings
NORMAL CHAMBER DIMENSIONS, ALL VALVES COMPETENT, MILD DECREASE IN SYSTOLIC FUNCTION.

B6

Print Date: 10/06/2018

22555

Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory
1089 Veterinary Medicine Drive
Davis, Ca 95616
Telephone: 530-752-5058, Fax: 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

Veterinarian Contact: B6

Clinic/Company Name: B6

Address: B6

Email: B6

Telephone: B6 **Fax:** B6

Billing Contact: B6 **Email:** B6

Patient Name: B6 **Species:** Canine.

Breed: Golden Retriever **Owner's Name:** B6

Current Diet : Pure Vita Venison & red lentil

Sample type: ~~☒ Plasma~~ ☒ Whole Blood ~~☒ Urine~~ ~~☒ Food~~ ~~☒ Other~~ _____

Test: ☒ Taurine ~~☒ Complete Amino Acids~~ ~~☒ Other:~~ _____

Taurine Results (lab use only)

Plasma: _____ Whole Blood: B6 Urine: _____ Food: _____

	Plasma (nMol/ml)		Whole Blood (nMol/ml)	
	Normal Range	No known risk for deficiency	Normal Range	No known risk for deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

* Please note with the recent increase in the number of dogs screened for taurine deficiency, we are seeing dogs with values within the reference ranges (or above the "no known risk for deficiency range") yet are still exhibiting signs of cardiac disease. Veterinarians are welcome to contact our laboratory for assistance in evaluating your patient's results.

MEDICAL HISTORY

09-Sep-2018 to 06-Dec-2018

Client

B6

Home: B6

Patient

B6

Canine

Retriever, Golden

B6 (B6)

Golden

Female / Spayed - 60 lb (10-Oct-2018)

Most recent visit date: 10-Oct-2018

Microchip No.: n/a

Rabies tag ID / date : n/a

Patient Alerts: n/a

Current medical overview: as of B6

Weight by Age		Wt.	Record date
B6	27.22 kg	60 lb	10-Oct-2018
	27.5 kg	60.63 lb	06-Oct-2018

Active Concerns	Established
Urinary crystal, struvite	10-Oct-2018
Dental calculus	10-Oct-2018
Overweight	10-Oct-2018
Gastroenteritis	10-Oct-2018
Taurine deficiency	10-Oct-2018
Systolic dysfunction	06-Oct-2018

Inactive Concerns	Established
n/a	

Resolved Concerns (since 09-Sep-2018)	Established	Resolved
n/a		

Medications (since 06-Dec-2017)	Amount	Disp. Date
n/a		

Documents*

09-Sep-2018 • B6 _2019-01-02_Converted medical history for B6 .pdf

Communication logs

	Source	From	To	Created by/date
05-Oct-2018 17:54	Email	B6	B6	B6 /05-Oct-2018

Appointment Confirmation for B6 **at** B6

B6

Dear B6

This email is to confirm your appointment at B6 for B6 Please review the appointment details below for accuracy:

Reason for Appointment: Medical
Appointment Date: Saturday, October 6, 2018
Appointment Time: 10:30 AM
If you have any questions or need to reschedule your appointment, please contact us at B6

Thank you,

B6

Map & Directions
Please use attached .ics file to add appointment to your calendar.
Please do not reply to this email as we do not receive mail sent to this address.

Echocardiogram report

06-Oct-2018 10:30 **Echocardiogram** B6 **DVM**

Order item: Echocardiogram [23.38]

Findings

Mitral Valve: Unremarkable valve morphology
Valve insufficiency: not present

Tricuspid Valve: anatomically unremarkable morphology
Valve insufficiency: not present
Pulmonary Hypertension is not present

Aorta
Aortic valve: Unremarkable morphology
Blood flow velocity is within normal limits
Aortic insufficiency: is not present
Heart base mass was not present

Pulmonic valve: Unremarkable morphology
Blood flow velocity is within normal limits

Left atrium: Normal in size and not dilated

Right atrium: Normal in size and not dilated
No mass was seen

Left ventricle:
Diastolic diameter: Normal in size
Systolic function: Mild systolic myocardial failure
Wall thickness: Within normal limits

Right ventricle
Diastolic diameter: Normal in size

*Documents are available as separate attachments or files.

Wall thickness: Subjectively normal

Pericardium: No pericardial effusion present

Pleural space: Unremarkable

Abdomen/ hepatic veins: Not visualized

Interpretation: Mild systolic dysfunction with normal chamber dimensions. All valves competent.

Outpatient visit (06-Oct-2018 to 06-Oct-2018)

Appointment Type: **New Consult Only-** B6 Provider: B6 **, DVM** Sex / age / weight: **Female - Spayed /** B6 **/ 27.5 kg** (06-Oct-2018)

Concerns (Problem List)

Active

- **Systolic dysfunction** (06-Oct-2018)

06-Oct-2018 10:35 **Exam** — B6 **DVM**

Assisted by: B6

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain	BCS
10:35	not taken	100	pant	--	< 2	Pink	--	--

CLIENT INTERVIEW

General findings: **History** - B6 presented for a cardiology consultation due to recently diagnosed taurine deficiency (135 whole blood), her breed and history of being fed a grain free diet raised concern for taurine deficiency DCM. B6 is overall asymptomatic at this time. She does seen heat intolerant and tires easily on walks yet this is not new.
B6 has a history of severe IBD, which prompted the grain free diet.

Presenting concerns: **Taurine Deficiency**

Past medical history: **Referring DVM Diagnostics**

Medication history: **Digestive Enzymes Probiotic**; **Allertech** - 1 T SID

Diet history: **PurVita Venison and Lintels**

EXAM FINDINGS

Whole body

Eyes

Thorax

Abdomen

Musculoskeletal

B6

ASSESSMENTS

Systolic dysfunction

Suspect secondary to taurine deficiency give recent bloodwork. Systolic dysfunction is mild at this time with normal chamber dimensions.
Taurine deficiency DCM has been documented more commonly in Golden Retrievers and linked to diets containing novel proteins, grain-free, and/or boutique diets. The exact cause of taurine deficiency is unknown, given the over representation of GR dogs it is thought that they might have something in their genetic make-up that makes them less efficient at making taurine. It is also suspected that certain diets may have fewer building blocks for taurine or food components may inhibit

06-Oct-2018 10:35 **Exam** — B6, **DVM**

Assisted by: B6

synthesis. Given that the issue is not fully understood, the typically recommendation is to start taurine supplementation and alter diet (pending current diet profile). Pimobendan may be recommended in more severe cases.

Due to B6 history of severe IBD, I recommend consulting your primary veterinarian regarding diet or our nutritionist Dr. B6 here at B6. I feel we need to be mindful in how we switch her diet to avoid causing a significant flare up of IBD.

PLANS

Systolic dysfunction

Recommend starting taurine supplementation 500mg PO q12h for 1-2 weeks, increase to 1000mg PO q12h if stools remain normal.

Recommend recheck taurine level 1 month after starting supplementation.

Recommend recheck echocardiogram in 4-6 months.

06-Oct-2018 **Order items**

- Exam/Consultation Cardiology [3.19]: 1.00 each
- Echocardiogram [23.38]: 1.00 proc
  - Specialty Interpretation of Ultrasound Study [23.134]: 1.00 proc

Documents*

B6
- B6_2019-01-02_Echo .pdf
- B6_2019-01-02_Ref Recs-B6.pdf
- B6_2019-01-02_Ref Recs-B6.pdf

Outpatient visit (10-Oct-2018 to 10-Oct-2018)

Appointment Type: **Consultation** Provider: B6 **DVM, DACVN** Sex / age / weight: **Female - Spayed** / B6 / **60 lb** (10-Oct-2018)

Concerns (Problem List)

Active

- **Urinary crystal, struvite** (10-Oct-2018)
- **Dental calculus** (10-Oct-2018)
- **Overweight** (10-Oct-2018)
- **Gastroenteritis** (10-Oct-2018)
- **Taurine deficiency** (10-Oct-2018)
- **Systolic dysfunction** (06-Oct-2018)

10-Oct-2018 09:10 **Exam** — B6 **DVM, DACVN**

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain	BCS
09:10	**102.4**	110	pant	--	< 2	Pink	0	6

CLIENT INTERVIEW

General findings

History - Systolic dysfunction, taurine deficiency (135 whole blood). Generally asymptomatic; seems heat intolerant and tires easily on walks but this is not a new finding.
Chronic history of sensitive stomach - owner reports suspected IBD but biopsies not performed; full elimination diet trial with challenge testing has not been performed to confirm or rule out food allergy. History of soft stool with mucus - resolved on current diet. Still has occasional episodes of bilious vomiting; possibly related to eating poop from feral cats.
Seasonal allergies, well-managed with Allertec. Past history of calcium oxalate crystalluria per owner, recent struvite crystalluria with negative culture. No pollakiuria, hematuria, stranguria.
Lifestyle: Indoor, moderate activity, no other pets at home. Fed 2x/day, finishing all food offered.

*Documents are available as separate attachments or files.

10-Oct-2018 09:10 **Exam** — B6, DVM, DACVN

Stable weight, no current nausea/vomiting. Good drinker.

Presenting concerns: **Taurine Deficiency**

Medication history: **Cetirizine** - (Aller-Tec) 10 mg PO q24h; **Heartgard** - Monthly

Diagnostic history:

Summary of prior diagnostics -
09/19/16: ALP <10 u/L. PT wnl. Snap cPL wnl.
09/20/16: AXR: No radiopaque GIFB, possible decreased serosal detail in mid/cranial abdomen
06/23/16: CBC wnl. ALP <5 u/L, phos 2.8.
09/23/16: AUS – no significant abnormalities noted.
09/28/16: Fecal PCR negative. TAMU GI Panel: low B12; no abnormal folate/PLI results recorded.
09/20/18: USG 1.030, pH 9, 2+ struvite crystalluria. UMIC negative.
10/05/18: UC Davis whole blood taurine: 135 nmol/mL (200-350)
10/06/18: Echo – Normal chamber dimensions, all valves competent, mild decrease in systolic function

Diet history:

Diet history -
Current diet: Pure Vita Venison & Red Lentils Entrée Grain Free dry, 1.25 cup 2x/day fed since 9/2017. 429 kcal/cup = 1073 kcal/day. 6.8 g protein, 4 g fat, 77 mg sodium/100 kcal, 22.9 mg taurine/100 kcal. Contains venison, lentil, garbanzo beans, sunflower, alfalfa, pumpkin, chia seed, various fruits/vegetables
Previous diet:
- Wellness Complete Health Deboned Chicken & Oatmeal - d/c due to hematemesis, low B12. Contains chicken, oatmeal, barley, pea, rice, sweet potato, fruits/vegetables.
- Royal Canin Veterinary Diet Selected Protein Adult PV dry - started 12/2016; some vomiting, developed UTI; d/c due to venison shortage
- Royal Canin Veterinary Diet Selected Protein Adult PR dry - started 7/2017; diarrhea, fever, infection after change
- Home-cooked chicken and rice fed during recent GI upset - got better; chicken well-tolerated
Treats: Whole Life Pet Just One Ingredient Pure Beef Liver Treat (freeze dried), 1 treat/month; well-tolerated. Switch Pumpkin 1 tsp used when transitioning between diets.
Supplements:
- NaturVet Digestive Enzymes, 1/4 tsp q12h with meals.
- Country Life Taurine with B6 500 mg capsules sprinkled over food - gave twice; discontinued due to uncertainty about B6. Concerned about "fillers" in supplements
- Hx Henry Schein Omega Tri-V caps Large Dogs fish oil - discontinued.
Daily calorie intake: 1073 kcal/day

Prior ingredient exposures include: chicken, beef, venison, rabbit, oat, barley, pea, rice, sweet potato, lentil, garbanzo beans, pumpkin

Weight history:

Past weights -
09/26/16: 30.9 kg = 68 lbs, BCS 7/9
09/20/18: 28 kg = 61.9 lbs, BCS 4/9
10/10/18: 27.2 kg = 60 lbs, BCS 6/9 (lots of motion)

EXAM FINDINGS

Whole body

Eyes

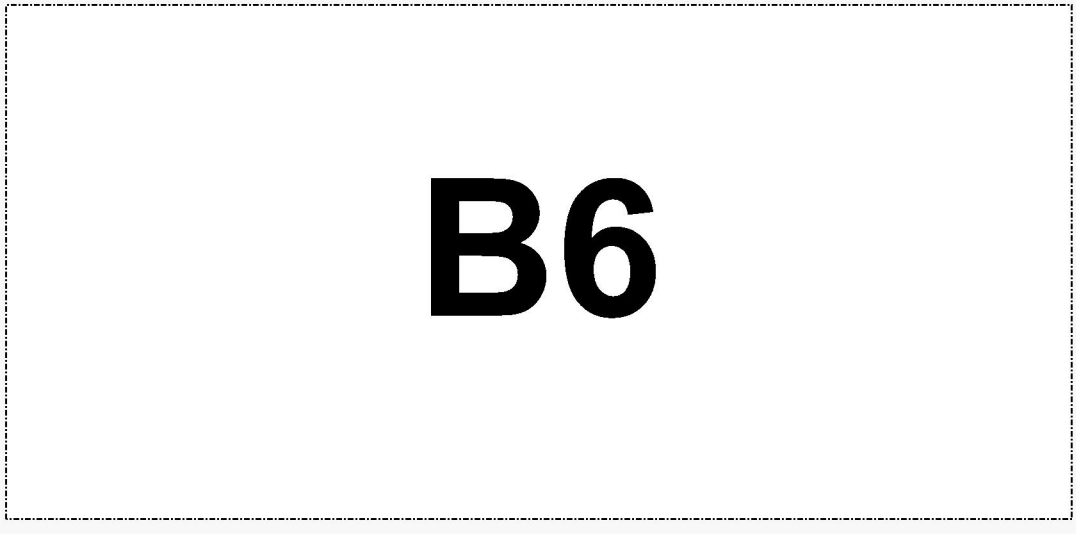
Ears

Mouth

Thorax

Abdomen

Pelvic region



*Documents are available as separate attachments or files.

B6 **Exam** B6, DVM, DACVN

09:10

Integument
Lymphatic system
Musculoskeletal
Nervous system

B6

ASSESSMENTS

Systolic dysfunction
Mild decrease in systolic function noted on echo 10/06/18

Taurine deficiency
Low taurine while fed grain-free diet
10/05/18: UC Davis whole blood taurine: 135 nmol/mL (200-350)

B6

PLANS

Gastroenteritis, Taurine deficiency, Systolic dysfunction

- Discussed nutritional management of DCM, current concerns about DCM/taurine deficiency/diet, nutritional management of chronic GI signs. Discussed elimination diet trial procedure including challenge testing.
- Recommend feeding limited ingredient diet from reputable manufacturer; can try more readily available protein sources (e.g., fish, hydrolyzed protein) and try products with higher fiber content to help with stool quality.
- Specific urinary diet not indicated at this time.
- Recommend reporting case to FDA to help with ongoing investigation.
- Nutrition plan to follow by email within 2 weeks.

10-Oct-2018 **Order items**

- Nutrition Consultation [3.48]: 1.00 each

Documents*

10-Oct-2018 • B6 /__2019-01-02_Nutrition intake form .pdf

Communication logs

	Source	From	To	Created by/date
10-Oct-2018 15:25	Phone	B6 DVM, DACVN	B6	B6

FDA reporting

Spoke with B6 by phone to discuss reporting to the FDA safety reporting portal. O had questions about privacy of data/information. Plan to email O with FDA links so she can investigate further and consider; O will email back to confirm whether she would like to move forward with FDA reporting or decline to participate.

Confirmed ok to do gradual introduction of taurine if B6 seems to have an upset stomach.

*Documents are available as separate attachments or files.

	Source	From	To	Created by/date
15:29	Email	B6 DVM, DACVN	B6	B6 /10-Oct-2018

Emailed FDA portal information

From: B6
Sent: Wednesday, October 10, 2018 3:25 PM
To: B6
Subject: FDA reporting portal

Hi B6

Here's the website with instructions for the FDA's safety reporting portal for reporting pet food complaints:
https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ B6 htm

FAQs on reporting a pet food complaint:
https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ B6 htm

Best,

B6 DVM, DACVN

B6

31-Oct-2018 15:15	Email	B6	B6 DVM, DACVN	B6 /31-Oct-2018

O question about recommended diet

From: B6 <B6>
Sent: Wednesday, October 31, 2018 3:05:14 PM
To: B6
Subject: B6 -diet

Hi B6

Thank you for the list of authorized diets for B6

B6

Thank you very much,

B6

From: B6
Sent: Wednesday, October 31, 2018 3:15 PM
To: B6
Subject: Re: B6 -diet

*Documents are available as separate attachments or files.

	Source	From	To	Created by/date
		Hi B6, Yes, you have linked the correct product. B6 DVM, DACVN B6		
06-Dec-2018 20:08	Email	B6	B6, DVM, DACVN	B6 /06-Dec-2018

O grants permission to report case to FDA

From: B6 [mailto: B6]
Sent: Wednesday, December 05, 2018 3:28 PM
To: B6 < B6 >
Subject: B6 follow up

Hi B6,
I just realized that I hadn't gotten back to you regarding reporting B6 condition to the FDA.

Please feel free to share this info with them. I hope it helps in their investigation into this condition.
I will be scheduling a follow up with you soon. I just completed the transition to the new food.
Please feel free to contact me with any questions. Thank you for your time. B6

==========

From: B6
Sent: Thursday, December 06, 2018 8:10 PM
To: B6 < B6 >
Subject: RE: B6 follow up

Hi B6,

Thanks for the update. I'll be able to work on B6 FDA case reporting when I'm back at B6 next Wednesday.

Sincerely,

B6, DVM, DACVN

B6

B6 | B6 | Canine (Retriever, Golden) | Golden | F: S | B6

B6 **Nutrition Plan**- October 21, 2018

Medical Concerns:

Systolic dysfunction - mild
Taurine deficiency
History of gastroenteritis, large bowel diarrhea - improved with limited-ingredient diet; chicken/beef allergy unlikely
Struvite crystalluria - asymptomatic, urine culture negative. Owner reports past history of calcium oxalate crystalluria.
Overweight (27.3 kg = 60 lbs, BCS 6/9)
- Estimated ideal weight: 24.8 kg = 54.6 lbs
Seasonal allergies
Dental calculus

Nutritional Goals:

Complete and balanced diet
Taurine supplementation
Consider elimination diet trial to evaluate for food allergy
Consider fiber supplementation
Encourage moisture intake
Maintain body condition score (BCS) 5-6/9

A strict elimination diet trial is the only reliable way to diagnose food allergy in dogs. This procedure involves feeding a special diet using either novel ingredients (ones that have never been eaten before) or hydrolyzed proteins (ones where the proteins are very small and less likely to stimulate an immune system response). This special diet would need to be fed exclusively for at least 4 weeks for gastrointestinal signs or at least 8 weeks for skin signs. If signs improve, then challenge tests can be done to determine which food(s) may be causing a food allergy. If signs do not improve during the trial or do not return with a return to the previous diet, then food allergy is unlikely.
In B6 case, she has been on a diet with unusual ingredients for quite some time. This diet may also differ from her past diets in other ways (e.g., digestibility, fiber content, etc.) rather than just its ingredients. Our plan is to transition her to a diet made by a well-established manufacturer, which should allow us to complete an elimination diet trial with less concern for issues related to DCM and taurine deficiency. Then, if her signs remain stable on the new diet, we can proceed with challenge testing to confirm or rule out food allergy.

Daily calorie goal: 1000 Calories per day, with 980 Calories/day from a balanced main diet and up to 20 Calories/day from treats.

Commercial diets: Veterinary therapeutic diets are available through a veterinarian or with a prescription. Daily feeding amounts can be divided into smaller meals as desired. You can mix and match diets as desired; adjust feeding amounts as needed to meet the daily calorie goal listed above.

- Royal Canin Veterinary Diet Selected Protein Adult PW Moderate Calorie dry (260 Calories/cup) - Feed 3 & 3/4

cups per day
- Royal Canin Veterinary Diet Hydrolyzed Protein Moderate Calorie dry (286 Calories/cup) - Feed 3 & 1/2 cups per day
- Hill's Prescription Diet i/d Sensitive dry (380 Calories/cup) - Feed 2 & 1/2 cups per day

Water: Fresh water should be available at all times. Water can be added to dry, canned, or home-cooked food to further increase water intake. Monitoring urine specific gravity (USG) will help determine whether more water should be added.

Diet transitions: A slow transition to a new diet plan may help with acceptance and tolerance. Gradually decrease the amount of old food while gradually increasing the amount of new food over about 7 days. Stop feeding a diet if it is not tolerated (refusal to eat, vomiting and/or diarrhea, etc.).

Treats: Treats should be limited to 20 Calories per day. The treats below are compatible with B6 elimination diet trial.

- Royal Canin Veterinary Diet Hydrolyzed Protein treats: 6 Calories per treat
- Purina ProPlan Veterinary Diets Gentle Snackers: 15 Calories per treat

Supplements:

- Taurine: Give 1000 mg orally twice daily. Suggested brands include NOW Foods, Solgar, and GNC.
- Fiber supplementation can be helpful for some pets with diarrhea. If soft stool is noted after transitioning to the new diet, you can try gradually adding about 1 teaspoon of ground psyllium husk to food 1-2 times daily; start low and increase as needed. You can mix psyllium with water or a small amount of canned pumpkin to help with consistency. One product without added flavors or sweeteners is NOW Foods Psyllium Husk Powder.
- Omega-3 fatty acids: There is some evidence that omega-3 fatty acid supplementation using fish oil can be helpful for animals with some types of heart disease. However, side effects can include stomach upset and soft stool. Please discontinue fish oil for now; we can consider gradual reintroduction of a concentrated fish oil supplement after determining the best main diet for B6 .
- Probiotic supplementation can be helpful for some pets with soft stool. If needed, choose from the following recommended products and administer according to package directions.
    - Nutramax Proviable DC: This product comes in a sprinkle capsule that can be opened so you can sprinkle the contents over food. Give one capsule per day.
    - Visbiome Vet: Give 2 capsules per day. Handling instructions: Visbiome Vet should be refrigerated. If stored under refrigeration, the product is guaranteed through "Best if used by" date. Visbiome can be stored at room temperature for up to one week without adversely affecting potency. Available online through www.VetRxDirect.com .
- Digestive enzyme supplementation is not indicated for B6 at this time.

Foods to avoid:

- Avoid any foods with ingredients that are not included in the selected elimination diet trial diet. This includes any treats, people foods, or flavored medications. Ask your regular veterinarian about topical or unflavored flea, tick, and heartworm medications.
- Avoid high salt foods including most dairy and bread products, potato chips, deli meats, fast food, and pizza.
- Avoid macadamia nuts, garlic, onions, grapes, raisins, and other foods that are toxic to dogs.
- Avoid xylitol, a sweetener found in some sugar-free gum, candy, and peanut butter.
- Avoid fresh, frozen, and freeze-dried raw foods and treat (including bully sticks, pig ears, and raw meaty bones) due to risk for bacterial contamination and other health concerns.
- Avoid bones, antlers, hooves, and other very hard chews; if a chew cannot be indented by your fingernail, it is too hard and can cause dental damage.

Monitoring and Follow Up:

- **Tracking progress**: Please keep a journal or calendar of B6 diet, medications, supplements, and clinical signs (food intake, any vomiting, stool quality - please see fecal score chart handout). This will help us to monitor her response to changes in our treatment plan.
- **Weight**: Please weigh B6 every 1-2 weeks and contact us with an update if she is gaining or losing weight.
- **Urinary signs**: Monitor for lower urinary tract signs, including blood in the urine, urinating frequently in small amounts, or straining to urinate. If B6 is ever straining and unable to pass urine, please have her evaluated immediately; urinary obstruction is a medical emergency.
- **Cardiac:** Continue heart monitoring as directed by B6
- **Recheck**: A progress evaluation with B6 is recommended about 4 weeks after transitioning to the new diet plan. At this appointment, we will discuss whether calorie goals and diet recommendations need to be adjusted.
- **FDA reporting:** Reporting taurine-deficient DCM cases to the FDA is strongly recommended in order to help investigators learn more about this problem. Per your request, we have not yet initiated an FDA report for B6 If you would like to proceed with FDA reporting, please visit the following website: https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm182403.htm . It is recommended that you keep B6 old food or packaging materials in case the FDA needs these for further investigation.
- Diet recommendations may require adjustment in the future if diets are not tolerated, if there are changes to B6 health, or if she will not eat any of the recommended foods.

Please contact us with any questions about B6 nutrition plan.

Sincerely,

B6

B6

B6 | B6 | Canine (Retriever, Golden) | Golden | F: S | B6

B6, DVM
Diplomate, American College of Veterinary Nutrition

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/22/2019 10:12:20 PM

Subject: Rachel Ray's only six - EON-377164

Attachments: 2061580-report.pdf

A PFR Report has been received and PFR Event [EON-377164] has been created in the EON System.

A "PDF" report by name "2061580-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377164
ICSR #: 2061580
EON Title: PFR Event created for Rachel Ray's only six; 2061580

AE Date	09/12/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	2
Animal Species	Dog	**Outcome to Date**	Worse/Declining/Deteriorating
Breed	Chihuahua		
Age	10 Years		
District Involved	PFR- B6 DO		

Product information
Individual Case Safety Report Number: 2061580
Product Group: Pet Food
Product Name: Rachel Ray's only six
Description: dog began coughing at night. very did x-ray and listened; heart murmur which wasn't evident six months earlier, enlarged heart and connection which was also new. began feeding dog grain free food one year ago. dogs heart was healthy at that time at vet visit. have since been prescribed vetmedin and am switching back to mixed diet.
Submission Type: Initial
Report Type: Both
Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating
Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Rachel Ray's only six		

Sender information

B6
USA

To view this PFR Event, please click the link below:
B6

To view the PFR Event Report, please click the link below:
B6

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Report Details - EON-377164

ICSR:	2061580
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-01-22 17:05:34 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description:	dog began coughing at night. very did x-ray and listened; heart murmur which wasn't evident six months earlier, enlarged heart and connection which was also new. began feeding dog grain free food one year ago. dogs heart was healthy at that time at vet visit. have since been prescribed vetmedin and am switching back to mixed diet.
Date Problem Started:	09/12/2018
Concurrent Medical Problem:	No
Outcome to Date:	Worse/Declining/Deteriorating

Product Information:

Product Name:	Rachel Ray's only six
Product Type:	Pet Food
Lot Number:	
UPC:	unknown
Package Type:	BAG
Package Size:	15 Pound
Purchase Date:	08/01/2018
Number Purchased:	1
Possess Unopened Product:	No
Possess Opened Product:	Yes
Storage Conditions:	stored in a closed container.

Product Use Information:

Description:	free feeding.
Last Exposure Date:	01/08/2019
Time Interval between Product Use and Adverse Event:	6 Months
Product Use Stopped After the Onset of the Adverse Event:	Unknown
Perceived Relatedness to Adverse Event:	Definitely related
Other Foods or Products Given to the Animal During This Time Period:	No

Manufacturer /Distributor Information:

Purchase Location Information:

Name:	petco
Address:	B6

		B6 United States
Animal Information:	**Name:**	Chihuahua, dachshund
	Type Of Species:	Dog
	Type Of Breed:	Chihuahua
	Gender:	Mixed Population of Female and Male
	Reproductive Status:	Neutered
	Weight:	6 Pound
	Age:	10 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	2
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	**Name:**	
	Address:	B6 United States
	Contact:	
	Reporter Wants to Remain Anonymous:	Yes
	Reported to Other Parties:	Other
Additional Documents:		

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/3/2019 8:56:20 PM

Subject: Solid Gold Wee Bit formula-Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food: B6 - EON-375339

Attachments: 2060822-report.pdf

A PFR Report has been received and PFR Event [EON-375339] has been created in the EON System.

A "PDF" report by name "2060822-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375339
ICSR #: 2060822
EON Title: PFR Event created for Solid Gold Wee Bit formula Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food; 2060822

AE Date	B6	**Number Fed/Exposed**	3
Best By Date		**Number Reacted**	3
Animal Species	Dog	**Outcome to Date**	Not Applicable
Breed	Terrier - Yorkshire		
Age	6 Years		
District Involved	PFR B6 DO		

Product information
Individual Case Safety Report Number: 2060822
Product Group: Pet Food
Product Name: Solid Gold Wee Bit formula Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food
Description: There are 3 of my dogs that have been diagnosed with Enlarged heart. None of theses dogs are related. B6 died of diagnosed enlarged heart (via xray) at age 14 in B6 B6 was diagnosed (xray) with an enlarged heart on 4/12/18 measured 10.7 heart score. B6 is now on 3 heart meds twice a day. Indefinitely B6 was recently diagnosed on 12/31/18 with an enlarged heart measured 11.5 heart score. B6 is now on 3 heart meds twice a day. Indefinitely.

Submission Type: Initial
Report Type: Both
Outcome of reaction/event at the time of last observation: Not Applicable
Number of Animals Treated With Product: 3
Number of Animals Reacted With Product: 3

Product Name	Lot Number or ID	Best By Date
Solid Gold Wee Bit formula Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

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Report Details - EON-375339

ICSR:	2060822
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-01-03 15:48:03 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description:	There are 3 of my dogs that have been diagnosed with Enlarged heart. None of theses dogs are related. B6 died of diagnosed enlarged heart (via xray) at age 14 in B6 B6 was diagnosed (xray) with an enlarged heart on 4/12/18 measured 10.7 heart score. B6 is now on 3 heart meds twice a day. Indefinitely B6 was recently diagnosed on 12/31/18 with an enlarged heart measured 11.5 heart score. B6 is now on 3 heart meds twice a day. Indefinitely.
Date Problem Started:	B6
Concurrent Medical Problem:	No
Outcome to Date:	Not Applicable

Product Information:

Product Name:	Solid Gold Wee Bit formula Bison & Brown Rice Recipe with Pearled Barley Small Breed Dry Dog Food
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Package Size:	12 Pound
Purchase Date:	12/03/2018
Number Purchased:	1
Possess Unopened Product:	No
Possess Opened Product:	No
Storage Conditions:	Always removed from bag and put in a sterilite bin. Note date first given would actually be since)5/01/2001 It would not let me enter that year.

Product Use Information:

Description:	I have fed this formula to my yorkies for 18 years. This not a specific bag instance. They were fed 1/4 cup twice a day dry.
Last Exposure Date:	12/30/2018
Time Interval between Product Use and Adverse Event:	18 Years
Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	No
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Possibly related
Other Foods or Products Given	No

		to the Animal During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Terrier - Yorkshire	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	4.4 Pound	
	Age:	6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	3	
	Number of Animals Reacted:	3	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	04/12/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
	Reported to Other Parties:	Manufacturer	

Additional Documents:

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/8/2019 10:44:21 PM

Subject: Stella & Chewy's -Frozen Raw -Stellla's Super Beef -Dinner Patties: B6 B6 - EON-375865

Attachments: 2060990-report.pdf

A PFR Report has been received and PFR Event [EON-375865] has been created in the EON System.

A "PDF" report by name "2060990-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-375865
ICSR #: 2060990
EON Title: PFR Event created for Stella & Chewy's Frozen Raw Stellla's Super Beef Dinner Patties; 2060990

AE Date	11/14/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Not Applicable
Breed	Retriever - Golden		
Age	3 Years		
District Involved	PFR-Atlanta DO		

Product information
Individual Case Safety Report Number: 2060990
Product Group: Pet Food
Product Name: Stella & Chewy's Frozen Raw Stellla's Super Beef Dinner Patties
Description: Whole Blood Taurine Level was 204 Plasma Taurine Level was 79
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Not Applicable
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Stella & Chewy's Frozen Raw Stellla's Super Beef Dinner Patties		

Sender information

B6

USA

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Report Details - EON-375865

ICSR:	2060990
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-01-08 17:40:09 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description:	Whole Blood Taurine Level was 204 Plasma Taurine Level was 79
Date Problem Started:	11/14/2018
Concurrent Medical Problem:	No
Outcome to Date:	Not Applicable

Product Information:

Product Name:	Stella & Chewy's Frozen Raw Stellla's Super Beef Dinner Patties
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Package Size:	12 Pound
Purchase Date:	01/03/2019
Number Purchased:	1
Possess Unopened Product:	Yes
Possess Opened Product:	No
Storage Conditions:	Always stored in the freezer

Product Use Information:

Description:	Removed from freezer and put in refrigerator 12 hours prior to feeding
Time Interval between Product Use and Adverse Event:	1 Years
Product Use Stopped After the Onset of the Adverse Event:	No
Perceived Relatedness to Adverse Event:	Possibly related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:

Purchase Location Information:

Address:	United States

Animal Information:

Name:	**B6**
Type Of Species:	Dog
Type Of Breed:	Retriever - Golden
Gender:	Female
Reproductive Status:	Neutered
Weight:	44 Pound

	Age:	3 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	**Name:**	B6
	Address:	B6 United States
	Contact:	**Phone:** B6 **Other Phone:** B6 **Email:** B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other
Additional Documents:		

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/26/2019 1:54:30 AM

Subject: Taste of the Wild - EON-377564

Attachments: 2061774-report.pdf

A PFR Report has been received and PFR Event [EON-377564] has been created in the EON System.

A "PDF" report by name "2061774-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377564
ICSR #: 2061774
EON Title: PFR Event created for Taste of the Wild, 4 health; 2061774

AE Date	12/04/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Worse/Declining/Deteriorating
Breed	Bulldog - American		
Age	3 Years		
District Involved	PFR- B6 DO		

Product information
Individual Case Safety Report Number: 2061774
Product Group: Pet Food
Product Name: Taste of the Wild, 4 health
Description: We have been feeding B6 grain free food his whole life. Around christmas he developed a cough. Since he had stayed at the vet for surgery, they treated him for kennell cough. I brought him to the vet today for a follow up as the cough had progressed. He HATES the vet so on order to get an xray, they wanted to sedate him. As soon as they did they had to use counter medicine to get him out of it Nd admitted iter oxygen. He was on oxygen for an hour as they were B6 to emergency veterinarian 1 hour away. They weren't sure he would make it to the other vet. He was diagnosed Congestive heart failure, secondary to dialated cardiomyopathy (DCM) . His heart is so enlarged, its pumping blood into his lungs. He is now being with heart medication, medication to dry out his lungs, and high doses of the vitamins(taurine) that he was starved of with

the grain free food. The veterinarian is certain it was caused by lack of these nutrients with the grain free diet.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
4 health		
Taste of the Wild		

Sender information

B6
USA

To view this PFR Event, please click the link below:
B6

To view the PFR Event Report, please click the link below:
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Report Details - EON-377564

ICSR:	2061774		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-01-25 16:57:34 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	**Problem Description:**	We have been feeding B6 grain free food his whole life. Around christmas he developed a cough. Since he had stayed at the vet for surgery, they treated him for kennell cough. I brought him to the vet today for a follow up as the cough had progressed. He HATES the vet so on order to get an xray, they wanted to sedate him. As soon as they did they had to use counter medicine to get him out of it Nd admitted iter oxygen. He was on oxygen for an hour as they were B6 to emergency veterinarian 1 hour away. They weren't sure he would make it to the other vet. He was diagnosed Congestive heart failure, secondary to dialated cardiomyopathy (DCM) . His heart is so enlarged, its pumping blood into his lungs. He is now being with heart medication, medication to dry out his lungs, and high doses of the vitamins(taurine) that he was starved of with the grain free food. The veterinarian is certain it was caused by lack of these nutrients with the grain free diet.
	Date Problem Started:	12/04/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Worse/Declining/Deteriorating	
Product Information:	**Product Name:**	4 health	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In original bag.	
	Product Use Information:	**Description:**	2 cups, twice a dsy
		Time Interval between Product Use and Adverse Event:	2 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	No
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Probably related
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer		

	/Distributor Information:		
	Purchase Location Information:	Name:	Tractor Supply
		Address:	United States
	Product Name:	Taste of the Wild	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in original bag. In the pantry.	
	Product Use Information:	Description:	2 cups twice a day
		Perceived Relatedness to Adverse Event:	Probably related
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog - American	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	56 Pound	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	12/04/2018
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	01/25/2019

		Permission to Release Records to FDA:	Yes
Sender Information:	**Name:**		
	Address:	**B6** United States	
	Contact:		
	Reporter Wants to Remain Anonymous:	Yes	
	Reported to Other Parties:	None	
Additional Documents:			

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/23/2019 7:40:22 PM

Subject: Taste of the Wild (Pacific Stream formula): B6 - EON-377278

Attachments: 2061637-report.pdf; 2061637-attachments.zip

A PFR Report has been received and PFR Event [EON-377278] has been created in the EON System.

A "PDF" report by name "2061637-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061637-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377278
ICSR #: 2061637
EON Title: PFR Event created for Taste of the Wild (Pacific Stream formula); 2061637

AE Date	08/22/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Recovered Completely
Breed	Retriever - Golden		
Age	6 Years		
District Involved	PFR B6 DO		

Product information
Individual Case Safety Report Number: 2061637
Product Group: Pet Food
Product Name: Taste of the Wild (Pacific Stream formula)
Description: B6 had been fed two brands of grain-free kibble since I purchased him at 8 weeks of age. In August 2018, I became aware of a possible link between this type of food and a taurine deficiency which could lead to heart disease. A blood test was performed at B6 at that time, and his whole blood taurine result of 222 was below the recommended level for a Golden Retriever. An echocardiogram a few weeks later confirmed DCM, moderate dilation of the left ventricle. His diet was changed to a grain inclusive kibble. He was also given daily heart medications and a taurine supplement. Four months later, another echocardiogram showed his heart to

be completely normal.
Submission Type: Initial
Report Type: Both
Outcome of reaction/event at the time of last observation: Recovered Completely
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild (Pacific Stream formula)		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-377278		
ICSR:	2061637	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-23 14:31:35 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	**Problem Description:**	B6 had been fed two brands of grain-free kibble since I purchased him at 8 weeks of age. In August 2018, I became aware of a possible link between this type of food and a taurine deficiency which could lead to heart disease. A blood test was performed at UCDavis at that time, and his whole blood taurine result of 222 was below the recommended level for a Golden Retriever. An echocardiogram a few weeks later confirmed DCM, moderate dilation of the left ventricle. His diet was changed to a grain inclusive kibble. He was also given daily heart medications and a taurine supplement. Four months later, another echocardiogram showed his heart to be completely normal.
	Date Problem Started:	08/22/2018
	Date of Recovery:	01/10/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Recovered Completely
Product Information:	**Product Name:**	Taste of the Wild (Pacific Stream formula)
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	28 Pound
	Purchase Date:	08/06/2018
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	It was stored in its original bag, in a closed plastic storage container in the basement.
	Product Use Information:	**Description:** It was kibble fed to B6 twice a day, moistened with water.
		Last Exposure Date: 08/30/2018
		Time Interval between Product Use and Adverse Event: 3 Years
		Product Use Stopped After the Onset of the Adverse Event: Yes
		Adverse Event Abate After Product Stop: Yes
		Product Use Started Again: No
		Perceived Relatedness to Adverse Event: Definitely related
		Other Foods or Yes

		Products Given to the Animal During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	**Name:**	chewy.com
Animal Information:	**Name:**	**B6**	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	74 Pound	
	Age:	6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	**Practice Name:**	**B6**
		Contact:	**Name:** **B6**
			Phone: **B6**
			Email: **B6**
		Address:	**B6** United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	09/06/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	**Name:**	**B6**	
	Address:	**B6** United States	
	Contact:	**Phone:**	**B6**
		Email:	**B6**
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			
	Attachment:	img088.jpg	
	Description:	follow-up echocardiogram	
	Type:	Echocardiogram	
	Attachment:	img076.jpg	
		initial echocardiogram	

Description:	
Type:	Echocardiogram

B6

B6

Name: B6
Weight: 33.0 kg (72.8 lbs)
Age: 6
Sex: Male
Breed: Canine

Date: 09/06/2018
Cardiologist: B6 DVM, DACVIM (Cardiology)
Ref. Hosp.: B6
Patient ID: B6

B6

History & Cardiovascular Examination:
Indication: low blood taurine on recent exam. Screen for DCM. Diet was salmon based originally and changed to chicken based diet.

PE: panting; no murmur; regular

Echocardiographic Findings:

Comprehensive echocardiographic descriptions::
ECG: sinus rhythm
Left ventricle: moderate dilation in diastole and systole; adequate fractional shortening
Left atrium: normal size.
Right ventricle: normal size and function
Right atrium: normal size.
Mitral valve: normal appearance without regurgitation.
Tricuspid valve: normal appearance without regurgitation.
Aortic valve: normal appearance without regurgitation nor stenosis
Pulmonic valve: normal appearance without regurgitation nor stenosis.
Aorta: normal size and appearance.
Pulmonary arteries: normal size and appearance.
Pericardium: normal appearance without pericardial effusion.
Pleural space: no effusion noted

Cardiac Diagnoses & Assessment:
1) Left ventricular dilatio n - r/o DCM vs nutritional/malabsorptive vs myocarditis
2) Low blood taurine

DCM is a rule out diagnosis and given the recent low taurine levels and diet changes, a nutritional cardiomyopathy seems more likely than primary DCM. Future exams will better prognosticate.

Recommendations:
1) Start pimobendan 10mg PO BID
2) Add taurine 1 gram PO BID
3) Add enalapril 15mg PO BID (check renal values in 5-7 days)
3b) 2 weeks recheck taurine, renal, tick panel and thyroid
4) Continue a commercial, non-novel protein based diet

Print Date: 9/6/2018

B6

Name: B6

Weight: 33.0 kg (72.8 lbs)

Age: 7

Sex: Male

Breed: Canine

B6

Date: 01/10/2019

Ref. B6

Patient ID: B6

B6

History & Cardiovascular Examination:
Indication: taurine level is low

Echo 9/2018
LVIDd = 60mm
LVIDs = 40 mm

PE: no murmur; regular; eupneic/clear lungs; 100 bpm

Echocardiographic Findings:

Comprehensive echocardiographic descriptions::
Left ventricle: normal size and function.
Left atrium: normal size.
Right ventricle: normal size and function
Right atrium: normal size.
Mitral valve: normal appearance without regurgitation.
Tricuspid valve: normal appearance without regurgitation.
Aortic valve: normal appearance without regurgitation nor stenosis
Pulmonic valve: normal appearance without regurgitation nor stenosis.
Aorta: normal size and appearance.
Pulmonary arteries: normal size and appearance.
Pericardium: normal appearance without pericardial effusion.
Pleural space: no effusion noted

Cardiac Diagnoses & Assessment:
1) Resolved left ventricular dilation - r/o nutritional/malabsorptive
2) Low blood taurine - resolved

improved/normalized LV dimensions indicated likely nutritional cardiomyopathy. Good long-term prognosis without any contraindications.

Recommendations:
1) Continue pimobendan 10mg PO BID until next echo
2) taurine 1 gram PO BID. No taurine level indicated.
3) Stop enalapril & carnitine
4) Continue a commercial, non-novel protein based diet

Print Date: 1/10/2019

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/22/2019 11:08:32 PM

Subject: Taste of the Wild High Prairie grain-free with roasted bison and roasted venison: B6 - EON-377174

Attachments: 2061583-report.pdf

A PFR Report has been received and PFR Event [EON-377174] has been created in the EON System.

A "PDF" report by name "2061583-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377174
ICSR #: 2061583
EON Title: PFR Event created for Taste of the Wild High Prairie grain-free with roasted bison and roasted venison; 2061583

AE Date	B6	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Mixed (Dog)		
Age	11 Years		
District Involved	PFR B6 DO		

Product information
Individual Case Safety Report Number: 2061583
Product Group: Pet Food
Product Name: Taste of the Wild High Prairie grain-free with roasted bison and roasted venison
Description: Anorexia, lethargy and abdominal distention noted 6 days before presentation to the ER. He was diagnosed with chronic degenerative valve disease, Dilated cardiomyopathy, myocardial dysfunction, congestive heart failure, both left- and right-sided, atrial fibrillation,
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering

Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild High Prairie grain-free with roasted bison and roasted venison		

Sender information

B6

USA

Owner information

B6 USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-377174

ICSR:	2061583	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-22 17:58:32 EST	
Reported Problem:	**Problem Description:**	Anorexia, lethargy and abdominal distention noted 6 days before presentation to the ER. He was diagnosed with chronic degenerative valve disease, Dilated cardiomyopathy, myocardial dysfunction, congestive heart failure, both left- and right-sided, atrial fibrillation,
	Date Problem Started:	B6
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering
Product Information:	**Product Name:**	Taste of the Wild High Prairie grain-free with roasted bison and roasted venison
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Possess Unopened Product:	Unknown
	Possess Opened Product:	Unknown
	Product Use Information:	**Description:** Fed daily for 5-6 years
		Product Use Stopped After the Onset of the Adverse Event: Yes
		Adverse Event Abate After Product Stop: Unknown
		Product Use Started Again: No
		Perceived Relatedness to Adverse Event: Possibly related
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	**Name:**	B6
	Type Of Species:	Dog
	Type Of Breed:	Mixed (Dog)
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	27 Kilogram
	Age:	11 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	**Owner** Yes

		Information provided:	
		Contact:	Name: B6
			Phone: B6
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
			Other Phone: B6
			Email: B6
		Address:	B6 United States
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Other Phone:	B6
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 12/22/2018 10:28:56 PM

Subject: Taste of the Wild Prey B6 - EON-374547

Attachments: 2060525-report.pdf

A PFR Report has been received and PFR Event [EON-374547] has been created in the EON System.

A "PDF" report by name "2060525-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374547
ICSR #: 2060525
EON Title: PFR Event created for Taste of the Wild Prey; 2060525

AE Date	B6	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Died Naturally
Breed	Terrier - Bull - Staffordshire		
Age	2 Years		
District Involved	PFR B6 DO		

Product information
Individual Case Safety Report Number: 2060525
Product Group: Pet Food
Product Name: Taste of the Wild Prey
Description: Patient presented on B6 with a 10 day history of reduced appetite and an episode of diarrhea 2 weeks prior. Prior to presentation he was found to be very lethargic with a distended abdomen. Patient was found to have changes consistent with dilated cardiomyopathy were severe pump dysfunction and biventricular congestive heart failure. Had been given a grain free diet for over a year (Tate of the Wild Prey). The abdomen was drained of about 2.6 L for comfort. The patient initially responded favorably but died suddenly the next morning with an acute onset of respiratory difficulty. Contacted Jennifer Jones, DVM who recommended a complaint be submitted and obtained tissue samples from the pet even though a full necropsy was unable to be performed.

Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Died Naturally
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Prey		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-374547

ICSR:	2060525
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-12-22 17:18:45 EST

Reported Problem:

Problem Description:	Patient presented on B6 with a 10 day history of reduced appetite and an episode of diarrhea 2 weeks prior. Prior to presentation he was found to be very lethargic with a distended abdomen. Patient was found to have changes consistent with dilated cardiomyopathy were severe pump dysfunction and biventricular congestive heart failure. Had been given a grain free diet for over a year (Tate of the Wild Prey). The abdomen was drained of about 2.6 L for comfort. The patient initially responded favorably but died suddenly the next morning with an acute onset of respiratory difficulty. Contacted Jennifer Jones, DVM who recommended a complaint be submitted and obtained tissue samples from the pet even though a full necropsy was unable to be performed.
Date Problem Started:	B6
Concurrent Medical Problem:	No
Outcome to Date:	Died Naturally
Date of Death:	B6

Product Information:

Product Name:	Taste of the Wild Prey
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Product Use Information:	**Description:** Meal feeding **Time Interval between Product Use and Adverse Event:** 1 Years **Perceived Relatedness to Adverse Event:** Probably related
Manufacturer /Distributor Information:	
Purchase Location Information:	

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Terrier - Bull - Staffordshire
Gender:	Male
Reproductive Status:	Intact
Weight:	26 Kilogram
Age:	2 Years
Assessment of Prior Health:	Good
Number of Animals Given the Product:	1
Number of Animals Reacted:	1
Owner Information:	**Owner Information provided:** No
Healthcare Professional	

	Information:	
Sender Information:	Name:	B6
	Address:	B6 United States
	Contact:	Phone: B6 Other Phone: B6 Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:		

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/24/2019 4:28:19 PM

Subject: Taste of the Wild Sierra Mountain: B6 - EON-377360

Attachments: 2061702-report.pdf

A PFR Report has been received and PFR Event [EON-377360] has been created in the EON System.

A "PDF" report by name "2061702-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-377360
ICSR #: 2061702
EON Title: PFR Event created for Taste of the Wild Sierra Mountain; 2061702

AE Date	07/01/2018	**Number Fed/Exposed**	5
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Died Euthanized
Breed	Bulldog		
Age	10 Years		
District Involved	PFR B6 DO		

Product information
Individual Case Safety Report Number: 2061702
Product Group: Pet Food
Product Name: Taste of the Wild Sierra Mountain
Description: Diet for entire life consisted of grain free food. Started in July to have labored breathing with an occasional gag. Activity level had decreased. X-rays showed displacement of trachea. Vet treated for pneumonia due to white areas of lung. Finally got an echocardiogram and the diagnosis was Dilated Cardiomyopathy. Tests also showed his liver, spleen, and caudal vena cava were enlarged. The last week of life, he could not lay down but would just stand and pant. When it got so bad, I chose to let him be euthanized.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Died Euthanized

Number of Animals Treated With Product: 5
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Sierra Mountain		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-377360

ICSR:	2061702		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-01-24 11:22:19 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	**Problem Description:**	Diet for entire life consisted of grain free food. Started in July to have labored breathing with an occasional gag. Activity level had decreased. X-rays showed displacement of trachea. Vet treated for pneumonia due to white areas of lung. Finally got an echocardiogram and the diagnosis was Dilated Cardiomyopathy. Tests also showed his liver, spleen, and caudal vena cava were enlarged. The last week of life, he could not lay down but would just stand and pant. When it got so bad, I chose to let him be euthanized.	
	Date Problem Started:	07/01/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Died Euthanized	
	Date of Death:	B6	
Product Information:	**Product Name:**	Taste of the Wild Sierra Mountain	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Product Use Information:	**Time Interval between Product Use and Adverse Event:**	4 Years
		Product Use Stopped After the Onset of the Adverse Event:	No
		Perceived Relatedness to Adverse Event:	Definitely related
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	56 Pound	
	Age:	10 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	5	

	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	08/02/2018
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	08/22/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 12/22/2018 3:44:09 PM

Subject: Taste of the Wild Wetlands Canine Formula with roasted Fowl: B6 - EON-374534

Attachments: 2060519-report.pdf

A PFR Report has been received and PFR Event [EON-374534] has been created in the EON System.

A "PDF" report by name "2060519-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374534
ICSR #: 2060519
EON Title: PFR Event created for Taste of the Wild Wetlands Canine Formula with roasted Fowl; 2060519

AE Date	B6	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Died Euthanized
Breed	Retriever - Golden		
Age	6 Years		
District Involved			

Product information
Individual Case Safety Report Number: 2060519
Product Group: Pet Food
Product Name: Taste of the Wild Wetlands Canine Formula with roasted Fowl
Description: On third and final visit to vet due to heavy panting, difficulty breathing, and collapse the vet started an IV to hydrate her and found excessive fluid around the heart in x-ray. Sent us to emergency pet hospital which eventually asked us if we wanted to have them insert breathing tube to aid her struggle to breathe. Eventually, put her down because decided to discontinue breathing assistance.
Submission Type: Initial
Report Type: Both
Outcome of reaction/event at the time of last observation: Died Euthanized

Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Wetlands Canine Formula with roasted Fowl		

Sender information

B6

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-374534

ICSR:	2060519
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-12-22 10:35:42 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description:	On third and final visit to vet due to heavy panting, difficulty breathing, and collapse the vet started an IV to hydrate her and found excessive fluid around the heart in x-ray. Sent us to emergency pet hospital which eventually asked us if we wanted to have them insert breathing tube to aid her struggle to breathe. Eventually, put her down because decided to discontinue breathing assistance.
Date Problem Started:	B6
Concurrent Medical Problem:	Yes
Pre Existing Conditions:	In and out of vet for past 3 months leading to event for various symptoms. First visit (Mar 2018) was for lethargy, weakness in hind legs. Vet prescibed Gabepentin and Carprofen and Dasuquin supplment. Secon visit was for puffy face, which we thought was allergies. Vet suggested Benadryl. Third visit was for excessive panting and difficulty breathing.
Outcome to Date:	Died Euthanized
Date of Death:	B6

Product Information:

Product Name:	Taste of the Wild Wetlands Canine Formula with roasted Fowl
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Package Size:	15 Pound
Number Purchased:	1
Possess Unopened Product:	No
Storage Conditions:	Stored in large tin with a lid

Product Use Information:

Description:	1/4 cup was given in bowl in combination with rice, a fruit or vegetable, and protein (typically cottage cheese, eggs, or meat).
First Exposure Date:	04/01/2012
Last Exposure Date:	B6
Product Use Stopped After the Onset of the Adverse Event:	No
Perceived Relatedness to Adverse Event:	Definitely related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:

Purchase Location Information:

Name:	B6
Address:	B6

		B6 United States
Animal Information:	**Name:**	
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	65 Pound
	Age:	6 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	**Name:**	B6
	Contact:	**Email:** B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
Additional Documents:		

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/15/2019 11:08:32 PM

Subject: Taste of the Wild.: B6 - EON-376466

Attachments: 2061221-report.pdf; 2061221-attachments.zip

A PFR Report has been received and PFR Event [EON-376466] has been created in the EON System.

A "PDF" report by name "2061221-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061221-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-376466
ICSR #: 2061221
EON Title: PFR Event created for Taste of the Wild.; 2061221

AE Date	B6	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	4 Years		
District Involved	PFR-New England DO		

Product information
Individual Case Safety Report Number: 2061221
Product Group: Pet Food
Product Name: Taste of the Wild.
Description: B6 presented on emergency for lethargy, hyporexia, and tachypnea. Diagnostics testing (echocardiogram) revealed Dilated Cardiomyopathy. It was discovered that B6 had been on a grain free diet.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild.		

Sender information

B6

USA

Owner information

B6 USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-376466

ICSR:	2061221	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-15 17:57:25 EST	
Reported Problem:	**Problem Description:**	B6 presented on emergency for lethargy, hyporexia, and tachypnea. Diagnostics testing (echocardiogram) revealed Dilated Cardiomyopathy. It was discovered that B6 had been on a grain free diet.
	Date Problem Started:	B6
	Date of Recovery:	11/09/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering
Product Information:	**Product Name:**	Taste of the Wild.
	Product Type:	Pet Food
	Lot Number:	
	Product Use Information:	

Description:	Taste of the Wild is a dry dog kibble. B6 has been on this diet and only this diet since he was a puppy.
First Exposure Date:	01/01/2015
Time Interval between Product Use and Adverse Event:	3 Years
Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	Yes
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Probably related

Manufacturer /Distributor Information:	
Purchase Location Information:	
Animal Information:	**Name:** B6
Type Of Species:	Dog
Type Of Breed:	Retriever - Golden
Gender:	Male
Reproductive Status:	Intact
Weight:	79 Pound
Age:	4 Years
Assessment of Prior Health:	Excellent
Number of Animals Given the Product:	1
Number of Animals Reacted:	1

	Owner Information:	**Owner Information provided:**	Yes
		Contact:	**Name:** B6 **Phone:** B6 **Email:** B6
		Address:	B6 United States
	Healthcare Professional Information:		
Sender Information:	**Name:**	B6	
	Address:	B6 United States	
	Contact:	**Phone:** B6 **Email:** B6	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	
Additional Documents:			
	Attachment:	B6 _Taurine T_22752.pdf	
	Description:	Taurine level from the diagnostic lab at UC Davis. They are investigating "grain free" diets and DCM, suspecting Taurine deficiency. The UC Davis lab considers B6 level low according to what they are seeing with grain free diets.	
	Type:	Laboratory Report	

27752

Sample Submission Form

Amino Acid Laboratory
University of California, Davis
1020 Vet Med 3B
1089 Veterinary Medicine Drive
Davis, CA 95616
Tel: (530)752-5058, Fax: (530)752-4698

http://www.vetmed.ucdavis.edu/vmb/aal/aal.html

UC CUSTOMERS ONLY:
Non-federal funds ID/Account Number to bill:_____

Vet/Tech Contact: B6
Company Name: B6
Address: B6
Email: B6
Tel: B6 **Fax:** B6

Billing Contact:_____ **TAX ID:**_____
Email:_____ **Tel:**_____

Patient Name: B6 (Not fasted)
Species: Golden Retriever
Owner's Name: B6

Sample Type: ☐ Plasma ☒ Whole Blood ☐ Urine ☐ Food ☐ Other:_____
Test Items: ☒ Taurine ☐ Complete Amino Acid ☐ Other:_____

Taurine Results (nmol/ml)

Plasma:_____ Whole Blood B6 Urine:_____ Food:_____

Reference Ranges (nmol/ml)

	Plasma		Whole Blood	
	Normal Range	No Known Risk for Taurine Deficiency	Normal Range	No Known Risk for Taurine Deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 12/26/2018 4:36:21 PM

Subject: Taste of the Wild: B6 - EON-374698

Attachments: 2060561-report.pdf

A PFR Report has been received and PFR Event [EON-374698] has been created in the EON System.

A "PDF" report by name "2060561-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-374698
ICSR #: 2060561
EON Title: PFR Event created for Taste of the Wild; 2060561

AE Date	03/01/2016	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Died Other
Breed	Boxer (German Boxer)		
Age	B6 Years		
District Involved	PFR- B6		

Product information
Individual Case Safety Report Number: 2060561
Product Group: Pet Food
Product Name: Taste of the Wild
Description: Started feeding him Taste of the Wild bison formula on 03/2016. On 11/2016 we started to notice a decrease in his activity level and his health in general. After undergoing several test on 05/2018 we were told that he had now an enlarged heart. Something that was not detected previously. We finally determined that it was the food we were feeding him that was causing all the problems. We change the food we were feeding him but the damage had already been done. Sadly he passed away on B6 while playing in the park.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Died Other

Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-374698

ICSR:	2060561
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-12-26 11:24:57 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description:	Started feeding him Taste of the Wild bison formula on 03/2016. On 11/2016 we started to notice a decrease in his activity level and his health in general. After undergoing several test on 05/2018 we were told that he had now an enlarged heart. Something that was not detected previously. We finally determined that it was the food we were feeding him that was causing all the problems. We change the food we were feeding him but the damage had already been done. Sadly he passed away on B6 while playing in the park.
Date Problem Started:	03/01/2016
Concurrent Medical Problem:	Yes
Pre Existing Conditions:	Had a slightly herniated disc and was taking 400 mg of Gabapentin 2 times a day while under going rehab. Also had 2 melanomas removed from his leg. The first in 2014. The second in the same location in 02/2018.
Outcome to Date:	Died Other
Date of Death:	B6

Product Information:

Product Name:	Taste of the Wild
Product Type:	Pet Food
Lot Number:	
UPC:	NA
Package Type:	BAG
Package Size:	30 Pound
Number Purchased:	1
Possess Unopened Product:	No
Possess Opened Product:	No
Storage Conditions:	Sealed plastic container.

Product Use Information:

Description:	Feed 2 times a day.
First Exposure Date:	03/01/2016
Last Exposure Date:	05/18/2018
Time Interval between Product Use and Adverse Event:	8 Months
Product Use Stopped After the Onset of the Adverse Event:	No
Perceived Relatedness to Adverse Event:	Definitely related

Manufacturer /Distributor Information:

Purchase Location Information:

Name:	Several locations

Animal Information:	**Name:**	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Boxer (German Boxer)	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	90 Pound	
	Age:	B6 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	**Practice Name:**	B6
		Contact:	**Name:** Staff Vet
			Phone: B6
			Other Phone: B6
		Address:	B6 United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	05/18/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	**Name:**	B6	
	Address:	B6 United States	
	Contact:	**Phone:**	B6
		Other Phone:	B6
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/22/2019 9:08:23 PM

Subject: Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food: B6 - EON-377156

Attachments: 2061571-report.pdf; 2061571-attachments.zip

A PFR Report has been received and PFR Event [EON-377156] has been created in the EON System.

A "PDF" report by name "2061571-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061571-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377156
ICSR #: 2061571
EON Title: PFR Event created for Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food 23.5-lb bag by CANIDAE, Zignature Turkey Limited Ingredient Formula Grain-Free Dry Dog Food 27-lb bag; 2061571

AE Date	12/26/2018	**Number Fed/Exposed**	1
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Unknown
Breed	Shepherd Dog - Australian		
Age	11 Years		
District Involved	PFR- B6 DO		

Product information
Individual Case Safety Report Number: 2061571
Product Group: Pet Food
Product Name: Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food, 23.5-lb bag by CANIDAE, Zignature Turkey Limited Ingredient Formula Grain-Free Dry Dog Food, 27-lb bag
Description: B6 has NEVER had a heart issue and has been fed a grain free diet for several years at least (two different brands, which I purchased from Chewy.com) - and she developed a heart murmur just recently (valve issue), and an irregular heartbeat just recently. This was first noticed in December 2018, at a mostly routine visit;

and then the specialist told me that the grain free diets could be linked. We visited the specialist in January 2019.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Unknown
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food, 23.5-lb bag by CANIDAE		
Zignature Turkey Limited Ingredient Formula Grain-Free Dry Dog Food, 27-lb bag		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

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Report Details - EON-377156

ICSR:	2061571
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-01-22 15:59:06 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description:	B6 has NEVER had a heart issue and has been fed a grain free diet for several years at least (two different brands, which I purchased from Chewy.com) - and she developed a heart murmur just recently (valve issue), and an irregular heartbeat just recently. This was first noticed in December 2018, at a mostly routine visit, and then the specialist told me that the grain free diets could be linked. We visited the specialist in January 2019.
Date Problem Started:	12/26/2018
Concurrent Medical Problem:	No
Outcome to Date:	Unknown

Product Information:

Product Name:	Zignature Turkey Limited Ingredient Formula Grain-Free Dry Dog Food, 27-lb bag
Product Type:	Pet Food
Lot Number:	
UPC:	unknown
Package Type:	BAG
Package Size:	27 Pound
Purchase Date:	07/01/2014
Number Purchased:	1
Possess Unopened Product:	No
Possess Opened Product:	No
Storage Conditions:	In an airtight container at room temperature in the house.

Product Use Information:

Description:	Served as regular dog food morning and night.
First Exposure Date:	07/24/2014
Last Exposure Date:	02/01/2015
Time Interval between Product Use and Adverse Event:	5 Years
Product Use Stopped After the Onset of the Adverse Event:	Unknown
Perceived Relatedness to Adverse Event:	Possibly related
Other Foods or Products Given to the Animal During This Time Period:	Unknown

Manufacturer /Distributor Information:

Purchase Location

Name:	Chewy.com

	Information:	Address:	unknown B6 unknown United States
	Product Name:	Under the Sun Grain-Free Lamb Recipe Adult Dry Dog Food, 23.5-lb bag by CANIDAE	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	unknown	
	Package Type:	BAG	
	Package Size:	23.5 Pound	
	Purchase Date:	05/05/2017	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Stored in an airtight container at room temperature in the house.	
	Product Use Information:	Description:	Fed to my dog morning and night as her normal food.
		First Exposure Date:	05/05/2017
		Last Exposure Date:	01/16/2019
		Time Interval between Product Use and Adverse Event:	21 Months
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Unknown
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Probably related
		Other Foods or Products Given to the Animal During This Time Period:	Unknown
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Chewy.com
		Address:	unknown B6 unknown United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd Dog - Australian	
	Gender:	Female	

	Reproductive Status:	Neutered
	Weight:	55 Pound
	Age:	11 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	**Practice Name:** B6
		Contact: **Name:** B6
		Phone: B6
		Address: B6 United States
		Type of Veterinarian: Primary/regular veterinarian
		Date First Seen: 12/26/2018
		Permission to Release Records to FDA: Yes
		Practice Name: B6
		Contact: **Name:** B6
		Phone: B6
		Address: B6 United States
		Type of Veterinarian: Referred veterinarian
		Date First Seen: 01/17/2019
		Permission to Release Records to FDA: Yes
Sender Information:	**Name:**	B6
	Address:	B6 United States
	Contact:	**Phone:** B6
		Email: B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Distributor
Additional Documents:		
	Attachment:	Vet record 1-17-19 B6 pdf
	Description:	Record of the visit to B6 (cardiac specialist) detailing her condition.

	Type: Medical Records

B6

B6

CARDIOLOGY

B6 DVM, DACVIM-Cardiology
DVM, DACVIM-Cardiology

Date: Thursday, B6
Patient: B6 - Shepherd, Australian, Spayed Female, B6
Owner: B6

Referring Veterinarian:

B6

Phone: B6 **Fax**: B6

Chief Concern: B6 is here for further evaluation of a heart murmur noted at her exam with B6 in December. At home, she's showing no clinical signs suggestive of cardiac disease. She will have an intermittent hacking cough, but is breathing comfortably.

Weight: 24.9 kilograms

Current Medications: None

Diagnosis:
Degenerative valvular disease - mild (no left atrial enlargement)
Ventricular premature complexes - mild (infrequent, single beats)
Moderate hypertension - possibly excitement-related, recommend recheck

Procedures:

Physical exam:
BAR, nervous. MM pink, moist, CRT<2s. III-IV/VI left apical systolic murmur auscultated. Pulses strong and synchronous. No arrhythmias noted during physical exam. Lung sounds normal, eupneic. HR = B6 bpm, RR = B6 brpm

Echocardiogram:

B6

Comments:
The left atrium is normal in size. The left ventricle is normal in size and LV systolic function is normal. The mitral valve is mildly thickened and prolapses. The tricuspid valve is mildly thickened. All other valves are subjectively normal in appearance. The right atrium and right ventricle are both subjectively normal in size and function. No masses or effusions are noted. The main and branch pulmonary arteries are subjectively normal in size. ECG shows sinus rhythm/sinus tachycardia when anxious - intermittent, sometimes very infrequent single ventricular premature complexes are noted (no couplets, triplets, or runs of ventricular tachycardia observed).

B6

Comments:
Mild mitral regurgitation is noted. Mild tricuspid valve regurgitation is noted. Based on the TR

velocity, there is no evidence of significant pulmonary hypertension. No other valvular regurgitations are noted. Normal, laminar flow is noted across the aortic and pulmonic valves during systole.

Assessment:

Based on today's evaluation, the murmur that is heard is due to degenerative valvular disease and a resultant leak across the mitral valve. The mitral valve is located on the left side of the heart and lies in between the atrium (top chamber) and ventricle (bottom chamber). As dogs age, the degenerative process causes a progressive thickening of the valve and the leaflets that make up the valve do not completely close. When the ventricle pumps, a small amount of blood is leaking backwards across the mitral valve and this is what we hear as a murmur. Currently, the leak across the valve is small and is causing no heart enlargement. The remainder of the heart is very normal and the muscle of the heart is functioning normally. Due to the lack of heart enlargement and an otherwise normal heart, no treatment is indicated at this time as significant clinical signs of heart disease are not likely to be present. Structural heart disease is not present to result in the ventricular premature complexes. They could be due to stress (most likely), hypertension, or non-cardiac disease. Recheck ecg in 1-2 months with blood pressure.

Additionally, there is minimal (if any) risk of anesthesia, so any procedures (surgery or dental cleaning) that must be performed in the near future have no cardiac contraindications.

Blood pressure: #4 cuff left front limb, Doppler; 175mmHg. She was nervous during her blood pressure and this could be the cause of moderate hypertension. Prior to any therapy, I recommend rechecking this in 1-2 months.

Client Instructions:

CAUSE OF MURMUR:

Degenerative valve disease (DVD) is the most common acquired heart disease in dogs. It is especially common in older, small breed dogs. DVD is typically a slowly progressive condition and not all dogs will develop clinical signs associated with degenerative valve disease. Any valve in the heart can be affected by DVD, but the most common valve involved is the mitral valve. This is the valve that sits between the left ventricle and the left atrium. As it becomes degenerative and starts to fail, it can allow blood to leak back into the left atrium (top chamber on left). If severe enough, this 'backing up' of blood can affect the pulmonary circulation as well, resulting in fluid accumulation inside the lungs (pulmonary edema). When this occurs, it is referred to as "congestive heart failure" or CHF. Pulmonary edema makes breathing very difficult since normally the lungs should be filled with air, rather than fluid.

At this time, B6 heart disease is not progressed to the point of congestive heart failure, but we should periodically monitor for further progression and the above clinical signs - as the disease worsens over time. Much of this monitoring can be performed at B6 B6 as chest x-rays will be a good screening tool. Less frequently, echocardiograms will allow for more specific assessment of heart valvular and muscle function as well as chamber sizes.

Clinical signs associated with CHF include lethargy, weakness, decreased activity level, coughing and/or increased breathing rate (>40 breaths per minute AT REST) or increased breathing effort. If any of these signs are noted, a veterinarian should be contacted immediately.

OCCASIONAL ARRHYTHMIA:

Based on today's testing, B6 has abnormal heart beats coming from the bottom heart chambers (ventricles). Normally, the heart has a very organized electrical system that tells the muscle when/where to contract. Occasionally, diseases will disrupt the heart's electrical system and cause inappropriate areas of the heart to fire off electrical signals that can affect the heartbeat. In B6 case, these arrhythmias do not appear overly dangerous and are only occurring as single premature beats (ventricular premature complexes/VPC). There are many causes of mild ventricular arrhythmias and include both cardiac and non-cardiac disease. While some breeds (Boxers and Dobermans) are prone to primary heart diseases, most other breeds have non-cardiac disease as the primary cause of arrhythmias. Based on the echocardiogram performed today, there is no evidence of structural heart disease in B6 We cannot completely rule out that a tiny, microscopic area of the heart is producing these beats because that will not show up on any available testing.

More likely, non-cardiac disease could be affecting heart rhythm. These include benign causes like anxiety/stress. Or other issues like increased blood pressure, systemic inflammatory conditions, abdominal diseases (tumors of spleen, liver, adrenal glands), or nervous system diseases. We checked a blood pressure today and it was a little increased - but still within the range of what can be seen with stress. I recommend rechecking blood pressure in 1-2 months to make sure it is repeatably high. Also, if not performed recently, full bloodwork is recommended to make sure there's no evidence of inflammation in her body or kidney disease (which can cause high blood pressure). From the next recheck, we can discuss if further treatment or evaluation is needed for the arrhythmias or persistent hypertension.

Medications: No cardiac medications are warranted at this time.

Recheck:

For arrhythmia/hypertension:
Consider full bloodwork with B6 to check for any evidence of kidney or inflammatory diseases

Recheck ECG and blood pressure in 1-2 months to make sure arrhythmias/hypertension are persistently noted - further therapy may be discussed at that time based on testing results

For mild valvular disease:
Recheck thoracic radiographs (x-rays) every 12 months, sooner if clinical signs occur - this may be performed with B6, or here at B6

Recheck echocardiogram in 1-2 years

Call & ask to speak w/ Cardio in order to schedule recheck

Thank you,

B6

B6 DVM, DACVIM-Cardiology

B6

Client ID: B6
Invoice #: 1413284
Date: B6

B6

Patient ID: B6 | Species: Canine | Weight: 24.90 kilograms
Patient Name: B6 | Breed: Shepherd, Australian | Birthday: B6 | Sex: Spayed Female

	Description	Staff Name		Quantity	Total
B6	Consultation, Cardiology	B6	DVM, DA	0.95	B6
	Echocardiogram Complete			0.95	
	Blood Pressure, Indirect			0.50	
	For Office Use Only			1.00	

Patient Subtotal:

Invoice Total:

Total:
Balance Due:
Previous Balance:
Balance Due:
American Express 1:
Less Payment:
Balance Due:

B6 supports B6, a foundation that assists the neediest families with their pets' life-saving medical treatments. We can accept your tax-deductible donation or visit B6

Sample Submission Form

UC CUSTOMERS ONLY:
Non-federal funds ID/Account Number to bill:_____

Amino Acid Laboratory
University of California, Davis
1020 Vet Med 3B
1089 Veterinary Medicine Drive
Davis, CA 95616
Tel: (530)752-5058, Fax: (530)752-4698

http://www.vetmed.ucdavis.edu/vmb/aal/aal.html

Vet/Tech Contact: B6 B6
Company Name: B6
Address: B6

Email: B6
Tel: B6 **Fax:**

Billing Contact B6 **TAX ID:**
Email: B6 **Tel:** B6

Patient Name: B6 B6
Species: Canine
Owner's Name: B6

Sample Type: ☐ Plasma ☒ Whole Blood ☐ Urine ☐ Food ☐ Other:
Test Items: ☒ Taurine ☐ Complete Amino Acid ☐ Other:

Taurine Results (nmol/ml)

Plasma:_____ Whole Blood: B6 Urine:_____ Food:_____

Reference Ranges (nmol/ml)

	Plasma		Whole Blood	
	Normal Range	No Known Risk for Taurine Deficiency	Normal Range	No Known Risk for Taurine Deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

239 29

Sample Submission Form

UC CUSTOMERS ONLY:
Non-federal funds ID/Account Number to bill:_____

Amino Acid Laboratory
University of California, Davis
1020 Vet Med 3B
1089 Veterinary Medicine Drive
Davis, CA 95616
Tel: (530)752-5058, Fax: (530)752-4698

http://www.vetmed.ucdavis.edu/vmb/aal/aal.html

Vet/Tech Contact: B6
Company Name: B6
Address: B6

Email: B6
Tel: B6 **Fax:**

Billing Contact: B6 **TAX ID:**
Email: B6 **Tel:** B6

Patient Name: B6
Species: k-9
Owner's Name: B6

Sample Type: ☐ Plasma ☒ Whole Blood ☐ Urine ☐ Food ☐ Other:_____
Test Items: ☒ Taurine ☐ Complete Amino Acid ☐ Other:_____

Taurine Results (nmol/ml)

Plasma:_____ Whole Blood: B6 Urine:_____ Food:_____

Reference Ranges (nmol/ml)

	Plasma		Whole Blood	
	Normal Range	No Known Risk for Taurine Deficiency	Normal Range	No Known Risk for Taurine Deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

ple Submission Form

UC CUSTOMERS ONLY:
Non-federal funds ID/Account Number to bill:_____

o Acid Laboratory
rsity of California, Davis
Vet Med 3B
Veterinary Medicine Drive
CA 95616
30)752-5058, Fax: (530)752-4698

www.vetmed.ucdavis.edu/vmb/aal/aal.html

ech Contact: B6 / B6

any Name: B6

ess: B6

B6

B6 Fax:

g Contact: TAX ID:

Tel:

nt Name: B6

es: canine

r's Name: B6

le Type: ☐ Plasma ☒ Whole Blood ☐ Urine ☐ Food ☐ Other:

tems: ☒ Taurine ☐ Complete Amino Acid ☐ Other:

ne Results (nmol/ml)

a:_____ Whole Blood: B6 Urine:_____ Food:_____

ence Ranges (nmol/ml)

	Plasma		Whole Blood	
	Normal Range	No Known Risk for Taurine Deficiency	Normal Range	No Known Risk for Taurine Deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

23929

Sample Submission Form

UC CUSTOMERS ONLY:
Non-federal funds ID/Account Number to bill:_____

Amino Acid Laboratory
University of California, Davis
1020 Vet Med 3B
1089 Veterinary Medicine Drive
Davis, CA 95616
Tel: (530)752-5058, Fax: (530)752-4698

http://www.vetmed.ucdavis.edu/vmb/aal/aal.html

Vet/Tech Contact: B6
Company Name: B6
Address: B6

Email: B6
Tel: B6 **Fax:**_____

Billing Contact: B6 **TAX ID:**_____
Email: B6 **Tel:** B6

Patient Name: B6
Species: Canine
Owner's Name: B6

Sample Type: ☐ Plasma ☒ Whole Blood ☐ Urine ☐ Food ☐ Other:_____
Test Items: ☒ Taurine ☐ Complete Amino Acid ☐ Other:_____

Taurine Results (nmol/ml)

Plasma:_____ Whole Blood: B6 Urine:_____ Food:_____

Reference Ranges (nmol/ml)

	Plasma		Whole Blood	
	Normal Range	No Known Risk for Taurine Deficiency	Normal Range	No Known Risk for Taurine Deficiency
Cat	80-120	>40	300-600	>200
Dog	60-120	>40	200-350	>150

From: PFR Event <pfreventcreation@fda.hhs.gov>

To: Cleary, Michael *; HQ Pet Food Report Notification; B6

Sent: 1/24/2019 4:20:22 PM

Subject: Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs: B6 - EON-377359

Attachments: 2061700-report.pdf; 2061700-attachments.zip

A PFR Report has been received and PFR Event [EON-377359] has been created in the EON System.

A "PDF" report by name "2061700-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2061700-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-377359
ICSR #: 2061700
EON Title: PFR Event created for Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs; 2061700

AE Date	12/23/2018	**Number Fed/Exposed**	2
Best By Date		**Number Reacted**	1
Animal Species	Dog	**Outcome to Date**	Stable
Breed	Shepherd Dog - German		
Age	3 Years		
District Involved	PFR B6 DO		

Product information
Individual Case Safety Report Number: 2061700
Product Group: Pet Food
Product Name: Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs
Description: B6 began vomiting once a day for a few days, then it progressed to a couple of times a day. Her energy seemed to dissipate too...she was lethargic, depressed. I was contacting the vet via email and inquiring on ideas of what was going on. We put her on a bland rice/egg diet for a week, but no change was noted...other than

a new symptom occurred of her panting a lot. When B6 started to noticeably lose weight, I immediately took her into the vet for a physical exam. She had dropped 9 lbs from the previous visit of two months earlier! The vet kept us there most of the day running blood work, etc. Everything came back fine. When xrays were performed, it was clear what the problem was.. B6 heart was clearly enlarged. Where it normally was supposed to be within 3 ribs, it was over 5 ribs and encroaching on her other organs! The vet immediately suspected it was the grain-free kibble (Wholesomes Food For Dogs Chickmeal and Chickpea formula:Grain-free/Gluten-free that I purchased at Tractor Supply) that I had her on....and she prescribed her heart meds, an antibiotic (going the remedial course as if peritonitis as a secondary diagnosis), and a medication to alleviate the nausea. We purchased Purina dogfood and immediately fed it to her...and she is still on it to this very day. B6 is still throwing up occasionally, but the vet assured me that if her heart heals this will lessen.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs		

Sender information

B6

USA

To view this PFR Event, please click the link below:

B6

To view the PFR Event Report, please click the link below:

B6

==========

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

Report Details - EON-377359

ICSR:	2061700
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-01-24 11:11:03 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description:	B6 began vomiting once a day for a few days, then it progressed to a couple of times a day. Her energy seemed to dissipate too...she was lethargic, depressed. I was contacting the vet via email and inquiring on ideas of what was going on. We put her on a bland rice/egg diet for a week, but no change was noted...other than a new symptom occurred of her panting a lot. When B6 started to noticeably lose weight, I immediately took her into the vet for a physical exam. She had dropped 9 lbs from the previous visit of two months earlier! The vet kept us there most of the day running blood work, etc. Everything came back fine. When xrays were performed, it was clear what the problem was. B6 heart was clearly enlarged. Where it normally was supposed to be within 3 ribs, it was over 5 ribs and encroaching on her other organs! The vet immediately suspected it was the grain-free kibble (Wholesomes Food For Dogs Chickmeal and Chickpea formula:Grain-free/Gluten-free that I purchased at Tractor Supply) that I had her on....and she prescribed her heart meds, an antibiotic (going the remedial course as if peritonitis as a secondary diagnosis), and a medication to alleviate the nausea. We purchased Purina dogfood and immediately fed it to her...and she is still on it to this very day. B6 is still throwing up occasionally, but the vet assured me that if her heart heals this will lessen.
Date Problem Started:	12/23/2018
Concurrent Medical Problem:	No
Outcome to Date:	Stable

Product Information:

Product Name:	Wholesomes Grain-free Food for Dogs: Grain-Free/Gluten-Free. Chicken Meal & Chickpeas Formula Net Wt. 35lbs
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Package Size:	35 Pound
Number Purchased:	1
Possess Unopened Product:	No
Possess Opened Product:	No
Storage Conditions:	I purchased it from Tractor Supply, took it home and put it in a dogfood container (plastic) and threw out the bag

Product Use Information:

Description:	I give 2 cups of food to B6 in the morning and 2 cups of food at night.
First Exposure Date:	11/26/2018
Last Exposure Date:	01/14/2019
Time Interval between Product Use and Adverse Event:	3 Weeks
Product Use Stopped After the Onset of the Adverse Event:	Yes

		Adverse Event Abate After Product Stop:	Yes
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Tractor Supply
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd Dog - German	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	64 Pound	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6 Phone: B6 Email: B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	01/14/2019
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6 United States	

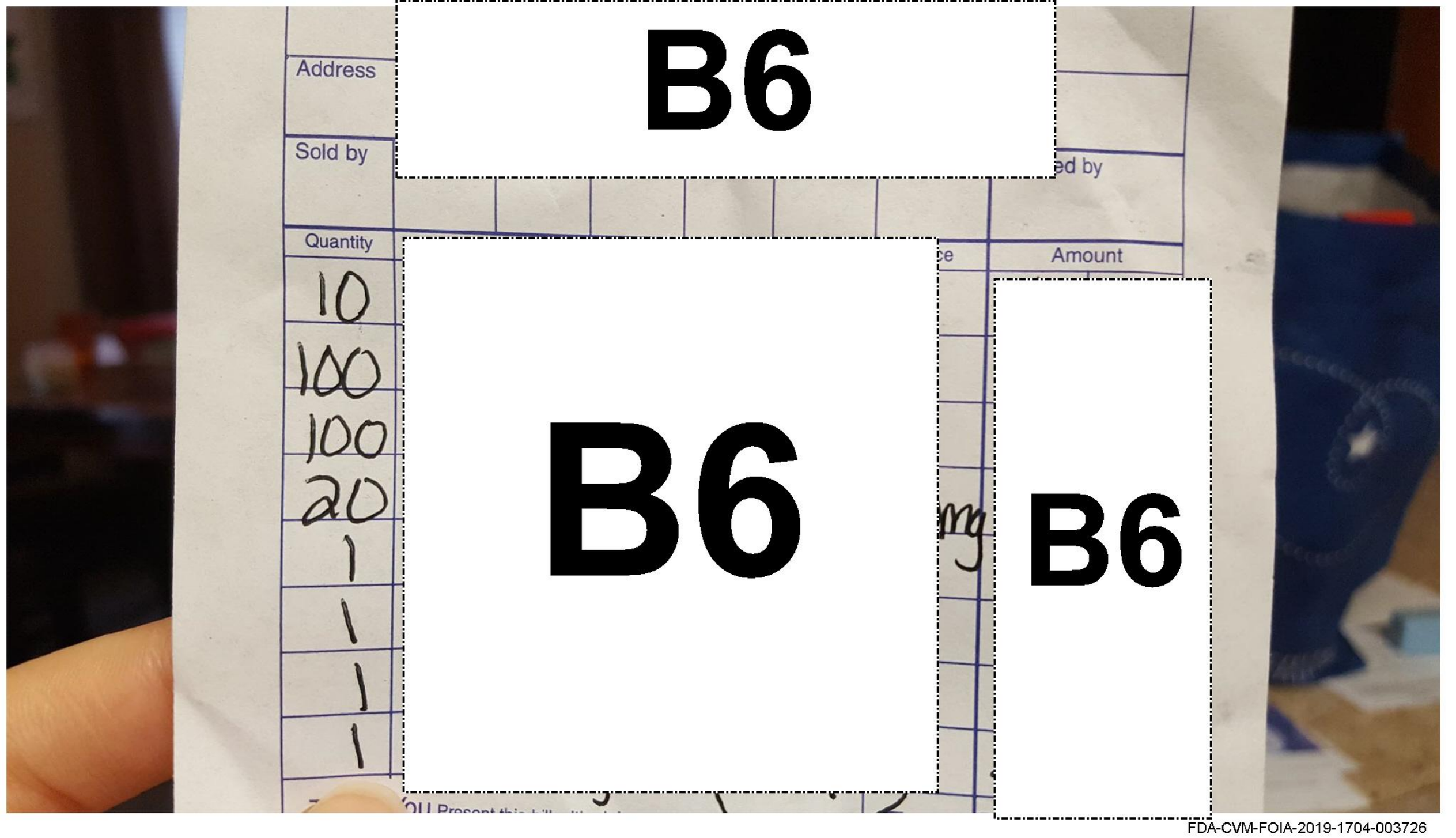
	Contact:	**Phone:** B6 **Email:** B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other
Additional Documents:		

Attachment:	daily log on B6 jpg
Description:	Daily log on B6
Type:	Photograph

Attachment:	meds that B6 is on.jpg
Description:	Meds that B6 is currently on
Type:	Photograph

Attachment:	B6 food.jpg
Description:	picture of dogfood purchased
Type:	Photograph

B6



From: Darcy Adin <dbadin@ncsu.edu>
To: Lisa Freeman; B6 jstern@ucdavis.edu; rfries@illinois.edu;
B6
CC: Jones, Jennifer L
Sent: 4/18/2018 11:09:14 AM
Subject: Diet DCM Call

Hi All,

We had originally proposed B5
B5 would work for you all.

I'm going to pick B5 - please let me know if you can talk then or if a different time is better. I'm available throughout the day.

Thanks Everyone!
Darcy

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L; Darcy Adin; Joshua A Stern; Fries, Ryan C; B6
CC: Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 5/24/2018 7:21:01 PM
Subject: diet related DCM - a couple forms
Attachments: diet history form 5-24-18 external.doc; protocol NP 5-17-18.docx

Hi everyone

B5

I'm working on the editorial which will include a writable pdf version of the diet history form (Josh and Darcy – you'll be hearing from me soon)
Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]
Sent: Friday, April 20, 2018 3:50 PM
To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <Lisa.Freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; B6 B6 <B6
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: hold-call with Dr. Adin re: DCM cases
Importance: High

My apologies for the repeat email. After further internal discussion, B5 you can just email me a spreadsheet with the data.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Jones, Jennifer L
Sent: Friday, April 20, 2018 1:19 PM
To: 'Darcy Adin' <dbadin@ncsu.edu>; Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; B6 <B6 B6
<B6
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: hold-call with Dr. Adin re: DCM cases

Thank you again for joining us on the call and providing the information about your cases. To help us catalogue and potentially act on these adverse events, please file an official consumer complaint. Instructions on how to report a pet food report can be found at: https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm. The complaint can be submitted through the Safety Reporting Portal: https://www.safetyreporting.hhs.gov. You can attach documents already created that compile your case data. We will review the data and may contact you for possible follow-up.

In the meantime, if you have a dog with DCM on a grain free diet that dies or is euthanized, please do not dispose of the animal's body or any remaining food. Please submit an individual consumer complaint for that dog, and mention that you have been instructed to submit the report by Vet-LIRN. We will review the complaint for potential follow-up and may be able to offer a necropsy. I attached a copy of our Vet-LIRN network procedures that describe how we operate. I also included a version for animal owners.

Please email or call me with any questions. Thank you again for your time and expertise,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Thursday, April 19, 2018 11:00 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; B6 B6 B6 Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: Fwd: hold-call with Dr. Adin re: DCM cases

Dear Dr. Jones,

We are all able to meet tomorrow, Friday April 20th at 11 am EST to discuss our clinical observations and concerns surrounding a potential relationship between grain-free canine diets and Dilated Cardiomyopathy.

Drs. B6 Freeman, B6 Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

B6
Dr. Lisa Freeman is a Professor of Clinical Nutrition at Tufts University, College of Vet Med

B6
Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med
Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

Thank you everyone for making time in your schedule! I am looking forward to this.

Sincerely,
Darcy Adin

---------- Forwarded message ----------
From: **Jones, Jennifer L** <Jennifer.Jones@fda.hhs.gov>
Date: Thu, Apr 19, 2018 at 7:16 AM
Subject: hold-call with Dr. Adin re: DCM cases
To: "Rotstein, David" <David.Rotstein@fda.hhs.gov>, "Norris, Anne" <Anne.Norris@fda.hhs.gov>, "DeLancey, Siobhan" <Siobhan.Delancey@fda.hhs.gov>, Darcy Adin <dbadin@ncsu.edu>

-- Do not delete or change any of the following text. --

Join WebEx meeting

Meeting number (access code): B6
Meeting password: B6

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

Can't join the meeting?

If you are a host, go here to view host information.

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

CARDIOLOGY DIET HISTORY FORM
Please answer the following questions about your pet

B5

Document properties

Author: Reed Elsevier
Company: Reed Elsevier
Template: Normal.dotm
Page count: 1
Paragraph count: 62
Line count: 112
Word count: 438
Character count (spaces excluded): 3088
Character count (spaces included): 3638

DCM Protocol (canine and feline)

B5

Document properties

Author: Freeman, Lisa
Template: Normal.dotm
Page count: 1
Paragraph count: 29
Line count: 39
Word count: 268
Character count (spaces excluded): 1160
Character count (spaces included): 1406

From:	Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
Sent:	5/11/2018 10:05:00 PM
To:	Rotstein, David <David.Rotstein@fda.hhs.gov>; B6 Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>
Subject:	Dilated Cardiomyopathy
Start:	5/18/2018 5:00:00 PM
End:	5/18/2018 6:00:00 PM
Recurrence:	(none)
Meeting Status:	Accepted
Required Attendees:	Rotstein, David; B6 Jones, Jennifer L; Hartogensis, Martine; Carey, Lauren; Burkholder, William; Palmer, Lee Anne; Norris, Anne; DeLancey, Siobhan; Lovell, Randall A
Optional Attendees:	Atkinson, Krisztina Z

Good Afternoon,

Please join us for a discussion of dilated cardiomyopathy cases and current knowledge.

Agenda:

1. Roll Call and Introduction (CVM)
2. CVCACase discussion (CVCA)
3. CVM/CVM Vet-LIRN Case Information (Vet-LIRN/DVPS/CERT)
4. Open Discussion

-- Do not delete or change any of the following text. --

Join WebEx meeting

Meeting number (access code): B6
Meeting password: B6

Join by phone

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

Can't join the meeting?

If you are a host, go here to view host information.

From: B6

To: Peloquin, Sarah; B6

CC: Jones, Jennifer L; jstern@ucdavis.edu

Sent: 3/8/2019 12:37:17 AM

Subject: B6

Attachments: B6 B6 3.7.19.Cardiology Echocardiogram Report (recheck)sarah.peloquinFDA.hhs.gov.pdf

B6

B6

Date **03/07/2019**

B6

Age **7 years**
Gender **Male**
Weight **34.1 kg**
Species/Breed **K9 Golden Retriever**

2D
IVSd
LVIDd
LVPWd
LVIDs
%FS
Ao Diam
LA Diam
LA/Ao
RPAs
RPAd
RPA
Distensibility
LVLd A4C
LVEDV MOD A4C
LVLs A4C
LVESV MOD A4C
LVEF MOD A4C
SV MOD A4C

M-Mode

B6

Doppler
MV E Vel
MV A Vel
MV E/A Ratio
MR Vmax
MR maxPG
AV Vmax
AV maxPG
PV Vmax
PV maxPG
PV AccT
PV Acc Slope
PVET
PV AccT/ET

B6

Case History
Recheck. Hx of R-CHF, DCM, mild PH, taurine deficiency in association with grain-free diet consumption (lifelong) under my care at AERA in 2018 (initial dx in July). CHF resolved with therapy, taurine level normalized with supplementation. Slight improvement in systolic function suspected on November recheck echo, not significant. Clinically stable at home, excellent energy level as per owner, E/D well, eupneic.

Current medications:
Taurine 1000 mg PO q 12h
L-carnitine 2000 mg PO q 8h
Furosemide 40 mg PO q 12h
Pimobendan 10 mg PO q 12h
Benazepril 15 mg PO q 24h
Current diet: Purina Pro Plan Chicken dry, 2 cups BID

Cardiovascular Examination
BAR! Panting, excited. T: 101.2F. MM pk/m, CRT 1-2s. RR: panting, eupneic. HR: 130 bpm, sinus arrhythmia, no murmur/arr. Lungs clear all fields. Femoral pulses mod/synch. Abd soft/compliant w/no distension. LN wnl. Amb x 4. BCS 6/9, MCS 5/9.

Electrocardiography
Sinus rhythm in lead II during echocardiogram.

Print Date: 03/07/2019

Thoracic Radiography

B6

Additional Diagnostic Testing

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Diagnosis
Hx of congestive heart failure, right sided (July 2018 - controlled)
Hx of pulmonary hypertension (mild) (resolved)
Dilated cardiomyopathy (DCM) - taurine deficiency associated
Mitral regurgitation (mild)
Taurine deficiency - hx of grain-free diet consumption

Assessment/Prognosis
Patient remains clinically stable with excellent QOL. No further improvement in left ventricular systolic function is noted thus far, which remains poor overall.

Treatment/Outcome

Medications at Discharge
Continue current medications/doses

Follow-up
Taurine, renal profile pending
Recheck echocardiogram in 4-6 months

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: CVM Vet-LRN-OR; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
Sent: 10/22/2014 10:16:29 AM
Subject: EON-183693-ICSR-1036446 B6 Purina Whisker lickins
Attachments: 1036446-report.pdf.html

This is an interesting one!!!

11 YO NM

Product Information:

LIVER, WHEAT FLOUR, CORN GLUTEN MEAL, CHICKEN BY-PRODUCT MEAL, WATER, BEEF TALLOW PRESERVED WITH BHA, GLYCERIN, PHOSPHORIC ACID, CALCIUM SULFATE, HYROGENATED STARCH HYDROLYSATE, SALT, SOY PROTEIN ISOLATE, SORBIC ACID (PRESERVATIVE), ADDED COLOR (RED 40 AND OTHER COLOR), POTASSIUM PHOSPHATE, DRIED CHEESE POWDER, CHOLINE CHLORIDE, PROPIONIC ACID (PRESERVATIVE), TAURINE, ZINC SULFATE, FERROUS SULFATE, NIACIN, CALCIUM PANTOTHENATE, ETHOXYQUIN (PRESERVATIVE), VITAMIN SUPPLEMENTS (E, B12, D3), MANGANESE SULFATE, RIBOFLAVIN SUPPLEMENT, BIOTIN, FOLIC ACID, COPPER SULFATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE MONONITRATE, MENADIONE SODIUM BISULFITE COMPLEX (SOURCE OF VITAMIN K ACTIVITY), CALCIUM IODATE, SODIUM SELENITE.

Analysis:

Moisture (maximum)34.00%
Crude Fat (minimum)8.50%
Crude Fiber (maximum)1.00%
Crude Protein (minimum)23.00%<BR< div>

Comment:

Site of manufacture- couldn't find this, but that won't tell us about the ingredients (e.g., glycerin).

Recommend:
MRx
Urine
Exposure history (make sure no other exposures)
Treat collection with lot code evaluation*
*If this case pans out and we have lot information, we may be able to get the district to find out about product manufacture/ingredient sources

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM OSC/DC/ICERT
7519 Standish Place, RM 120

240-276-9213 (Office and Fax)
B6

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Tuesday, October 21, 2014 6:20 PM
To: B6
Subject: Purina Whisker lickins: B6

A PFR Report has been received and PFR Event [EON-183693] has been created in the EON System

A "PDF" report by name "1036446-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report

EON Key: EON-183693
EON Title: PFR Event created for Purina Whisker lickins chicken and cheese flavors soft and delicious; 1036446

To view this PFR Event, please click the link below:
B6
To view the PFR Event Report, please click the link below:
B6

Product information
Individual Case Safety Report Number: 1036446
Product Group: Pet Food
Product Name: Purina Whisker lickins, chicken and cheese flavors, soft and delicious
Description: In August I started to give Purina Whisker lickings soft treats on a regular basis (twice a day). After a month I noticed that B6 had excessive urinations. Urinalysis on 9/9/14 showed 4+ glucose in urine, protein in urine - 30; bloodwork was normal 9normal glucose). There have been no other changes in what he eats/takes. I stopped the treats. After a few week, the excessive urination stopped. recheck urinalysis on 10/21/14 showed no glucose.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Recovered Completely
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Sender information
B6

B6

==========

This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.

From:	Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To:	'Jones, Jennifer L (Jennifer.Jones@fda.hhs.gov)'
CC:	Norris, Anne
BCC:	ajfascetti@ucdavis.edu; jstern@ucdavis.edu; Freeman, Lisa; ADIN,DARCY BRITTAIN; Steven Rosenthal
Sent:	6/27/2019 3:10:45 PM
Subject:	FDA DCM Update Links-Live 6/27/2019

Good morning,
I wanted to let you know that FDA Consumer update about DCM when live this morning. Here are the links:
CVM Update

Web Update – DCM Investigation

Web QA (Updated)

Vet-LIRN Update

DCM Complaint Spreadsheet – 1/1/14 - 4/30/19

If you have any questions about the content, please direct them to: AskCVM@fda.hhs.gov

Thank you and take care,
Jen

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Hartogensis, Martine; Jones, Jennifer L; Rotstein, David; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/5/2018 6:59:03 PM
Subject: RE: Redacted complaint file for the DCM webposting
Attachments: Slides for MH.pptx

B5

Thanks, Lee Anne

From: Palmer, Lee Anne
Sent: Thursday, July 5, 2018 1:50 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Redacted complaint file for the DCM webposting

Hello – **B6** and working my way through emails. To answer these 2 questions:

B5

Martine

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help **B5**

B5

Thanks,
Anne

B5

B5

Please ask me questions you have if I haven't made sense.

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Awesome! Thank you Jen!!

Martine

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Subject: RE: Redacted complaint file for the DCM webposting

It's possible we are B5

B5

I'll put together some slides for AVMA that you can choose from.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
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To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
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Also, would it be possible to get a few high level slides for me to present at AVMA? I will be there July 15th and I

am pretty sure DCM will come up B5 but I defer to the experts J

Thanks again for all the excellent work!

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B5

https://academic.oup.com/jn/article/131/2/276/4687012

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Please check your calendar, if you don't see it, I'll resend the invite.

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 3, 2018 at 8:19:29 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
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B5

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U.S. FOOD & DRUG ADMINISTRATION

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Sent: Monday, July 02, 2018 5:59 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

I just double checked our database and these are all complaints that came directly to FDA through our reporting portals, not CVCA complaints.

Thanks,
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To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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B5

Martine

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To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help. **B5**

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point…

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Palmer, Lee Anne; Jones, Jennifer L; Rotstein, David; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/5/2018 7:28:56 PM
Subject: RE: Redacted complaint file for the DCM webposting

Thank you so very much Lee Anne! Looks like the advisory is going out early next week, so this may be perfect timing J

From: Palmer, Lee Anne
Sent: Thursday, July 05, 2018 2:59 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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B5

B5

Martine

Hi Jen and Dave,

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B5

Thanks,
Anne

Lauren is correct, the complaint file is ONLY for complaints that came into FDA (all had come via the SRP) as of the end-date they were pulled – B5

B5

Please ask me questions you have if I haven't made sense.

Thanks, Lee Anne

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Awesome! Thank you Jen!!

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Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
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Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

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To:	Hartogensis, Martine; Palmer, Lee Anne; Rotstein, David; Carey, Lauren; Norris, Anne
CC:	DeLancey, Siobhan; Burkholder, William
Sent:	7/6/2018 2:27:31 PM
Subject:	RE: Redacted complaint file for the DCM webposting
Attachments:	2018-AVMA-VetLIRN DCM.pptx

Hi Martine,
Here are some updated slides you can pick from. I'm fine if you want to **B5**
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Thursday, July 05, 2018 3:29 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

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B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

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Thanks again for all the excellent work!

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https://academic.oup.com/jn/article/131/2/276/4687012

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Date: July 3, 2018 at 8:19:29 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
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From: Carey, Lauren
Sent: Monday, July 02, 2018 5:59 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

B5

Thanks,
Lauren

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Sent: Monday, July 02, 2018 5:28 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein,

David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
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From: Norris, Anne
Sent: Monday, July 02, 2018 3:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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Subject: FW: Redacted complaint file for the DCM webposting
Importance: High

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B5

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Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

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Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Jones, Jennifer L; Palmer, Lee Anne; Rotstein, David; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/6/2018 5:14:43 PM
Subject: RE: Redacted complaint file for the DCM webposting

These are excellent! Thank you so much Jen and I think they will work well with Lee Anne's slides very nicely!! Should be an interesting session!

Martine

From: Jones, Jennifer L
Sent: Friday, July 06, 2018 10:28 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,
Here are some updated slides you can pick from. I'm fine if you want to l **B5**
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

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Martine – if any of these slides are useful for your talk, please use them. They're part of what I put together for

B5

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I updated the slide deck with a summary from some great articles. B5

B5

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Center for Veterinary Medicine
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Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

Convention 2019 Submission for FDA CVM Update on DCM (Team leader: Dr. Siobhan DeLancey)

1) Speaker Information notes:
    a. Speakers:
        i. Lauren Carey, D.V.M. (FDA Center for Veterinary Medicine, Division of Veterinary Product Safety)
        ii. Jennifer Jones, D.V.M. (FDA Center for Veterinary Medicine, Veterinary Laboratory Investigation and Response Network)
        iii. Lee Anne M. Palmer, V.M.D., M.P.H. (FDA Center for Veterinary Medicine, Division of Veterinary Product Safety, Veterinary Epidemiologist)
2) Title:
    a. Update from FDA on Canine Dilated Cardiomyopathy Investigation and Potential Diet Association.
3) Abbreviated Title:
    a. FDA Update: Dilated Cardiomyopathy Investigation
4) Description:
    a. In recent years, veterinary cardiologists nationwide have reported an uptick in cases of Dilated Cardiomyopathy (DCM) in dogs, including occurrences in breeds not normally expected to develop it. Canine DCM was traditionally thought of as a genetic condition of specific large and giant breed dogs, including the Doberman Pinscher, Newfoundland and Great Dane. Subsequently, additional breeds such as Cocker Spaniels and Golden Retrievers were identified to have a predisposition to taurine deficiency associated with DCM. However, more recently, FDA has been investigating a potential link between certain diets and cases of DCM in dogs, some small-breed, without a genetic predisposition to the disease. FDA veterinarians and researchers have been collecting and studying case reports, including extensive dietary histories, medical records, product samples, and diagnostic samples. This session will share what FDA has learned thus far in its investigation and highlight ways that practitioners can help advance the agency's investigation.

5) Objectives:
    a. Attendees should recognize that recent cases of DCM include a variety of dog breeds that are not traditionally associated with a genetic predisposition to DCM.
    b. Attendees should understand what dietary factors FDA is currently investigating.
    c. Attendees should understand what data is most helpful to submit to aid FDA in its investigation.

1-1999

Familial Dilated Cardiomyopathy of Young Portuguese Water Dogs

Donna M. Dambach

Anne Lannon

Meg M. Sleeper

James W. Buchanan
University of Pennsylvania, jwb@vet.upenn.edu

Familial Dilated Cardiomyopathy of Young Portuguese Water Dogs

Abstract

A novel dilated cardiomyopathy (DCM) in 12 related Portuguese Water Dogs was identified by retrospective analysis of postmortem and biopsy case records. Male and female puppies born to clinically healthy parents typically died at 13 (± 7.3) weeks of age (range, 2–32 weeks) because of congestive heart failure. Puppies died suddenly without previous signs or with mild depression followed by clinical signs of congestive heart failure 1–5 days before death. There was no sex predilection. The hearts were enlarged and rounded, with marked left ventricular and atrial dilation. No other significant structural cardiac defects were noted. The histologic changes in the myocardium were diffuse and characterized by myofibers of irregular sizes separated by an edematous interstitium. The myofibers had multifocal swollen, cleared segments often involving perinuclear areas that contained granular, phosphotungstic-acid-hematoxylin-positive material consistent with mitochondria. There was loss of the cross-striation pattern, and intercalated discs were difficult to identify. There was no evidence of concurrent myocardial fibrosis; rare chronic inflammatory infiltrates were noted in one dog. Noncardiac skeletal muscles were not affected. The underlying cause is unknown. From the pedigree analysis, an autosomal recessive pattern of inheritance is suspected. Based on the histologic findings, this DCM is most likely due to an underlying molecular (biochemical or structural) defect. The early onset and rapid progression of the disease makes this a clinically distinctive form of canine DCM.

Keywords

Dog, Idiopathic dilated cardiomyopathy

J Vet Intern Med 1999;13:65–71

Familial Dilated Cardiomyopathy of Young Portuguese Water Dogs

Donna M. Dambach, Anne Lannon, Meg M. Sleeper, and James Buchanan

A novel dilated cardiomyopathy (DCM) in 12 related Portuguese Water Dogs was identified by retrospective analysis of postmortem and biopsy case records. Male and female puppies born to clinically healthy parents typically died at 13 (± 7.3) weeks of age (range, 2–32 weeks) because of congestive heart failure. Puppies died suddenly without previous signs or with mild depression followed by clinical signs of congestive heart failure 1–5 days before death. There was no sex predilection. The hearts were enlarged and rounded, with marked left ventricular and atrial dilation. No other significant structural cardiac defects were noted. The histologic changes in the myocardium were diffuse and characterized by myofibers of irregular sizes separated by an edematous interstitium. The myofibers had multifocal swollen, cleared segments often involving perinuclear areas that contained granular, phosphotungstic-acid-hematoxylin–positive material consistent with mitochondria. There was loss of the cross-striation pattern, and intercalated discs were difficult to identify. There was no evidence of concurrent myocardial fibrosis; rare chronic inflammatory infiltrates were noted in one dog. Noncardiac skeletal muscles were not affected. The underlying cause is unknown. From the pedigree analysis, an autosomal recessive pattern of inheritance is suspected. Based on the histologic findings, this DCM is most likely due to an underlying molecular (biochemical or structural) defect. The early onset and rapid progression of the disease makes this a clinically distinctive form of canine DCM.

Key words: Dog; Idiopathic dilated cardiomyopathy.

Dilated cardiomyopathy (DCM) is the most commonly reported form of canine cardiomyopathy.[1,2] DCM is most often associated with large and giant breed dogs and the Doberman Pinscher, Boxer, and English and American Cocker Spaniel breeds.[3–7] In all breeds, the age range of affected dogs is wide (6 months to 15 years), although the typical age range of clinical presentation is 4–8 years.[1] For the Boxer, Doberman Pinscher, and Great Dane breeds, less than 1% of cases are made up of dogs younger than 1 year of age.[8] There is a 2 : 1 male predilection reported in the affected breeds.[8] Survival is poor after onset of signs ranging from 6 weeks to 2 years, and death is due to congestive heart failure or fatal arrhythmias. The predisposition of specific breeds for DCM suggests a heritable basis for the disease, but the exact underlying molecular or biochemical mechanism(s) for canine DCM in all cases is unknown. Many of the structural and biochemical changes noted may be secondary manifestations of the failing heart. This is the first report of DCM in the Portuguese Water Dog breed. This disease appears to be familial, but it has features that distinguish it from other canine dilated cardiomyopathies.

Materials and Methods

The 12 cases of DCM in Portuguese Water Dogs (POWD) were identified by review of the records of the Necropsy and Surgical Pathology Services of the School of Veterinary Medicine, University of Pennsylvania, for the period 1987–1996. Postmortem examinations were performed on 5 pups, and heart weight and heart : body weight ratio were recorded in 3 pups. Heart weight was determined after removal of the pericardium and great vessels and after all heart chambers were opened and blood clots were removed. Body weight and condition were recorded at postmortem to allow calculation of heart : body weight ratios. Tissues and information from the remaining 7 cases of DCM were obtained through submissions to the Surgical Pathology Service. Hearts from clinically normal age- and breed-matched pups were also examined histologically. All tissues were fixed in 10% neutral buffered formalin, routinely processed, embedded in paraffin, and sectioned at 3–5 μm for light microscopy. Tissue sections were stained with hematoxylin and eosin, Masson's trichrome for collagen, alcian blue (pH 2.7) for mucopolysaccharides, phosphotungstic acid–hematoxylin for mitochondria, and periodic acid–Schiff for glycogen. Formalin-fixed, frozen tissue from 1 pup (10) was stained with oil red O for lipid. When whole hearts were submitted for evaluation, the following were examined histologically: sections through the entire left and right free walls (atria, atrioventricular valves, and ventricles) and sections through the entire interventricular septum, including right atrioventricular valve and aortic valve.

Clinical and historical data were obtained either by examination of the clinical records from affected pups at the Veterinary Hospital, University of Pennsylvania, or from the referring veterinarians. Two pups (4, 10) were clinically evaluated with radiographs, EKG, and echocardiography prior to death. Results of serum clinicopathologic analysis and CBCs were available for 1 pup (10). Urinary metabolic screening was performed on pup 10 using spot tests and 1-dimensional paper chromatography to analyze the types of amino acids, organic acids, and carbohydrates in urine.[9] Pedigree analysis was performed using 4–6-generation predigree information from affected pups provided by owners and breeders.

Results

Clinical Findings

The clinical courses of the 12 pups were similar. The affected pups were 13 ± 7.3 (SD) weeks of age (range, 2–32 weeks) at the time of death. The longest clinical course was 5 days and was characterized by depression and decreased appetite, collapse, and death. The remainder of the pups presented with either an acute onset of respiratory distress leading to death within hours or sudden unexpected collapse and death (Table 1). There was no evidence of protracted disease, even in the 32-week-old male. Because

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Table 1. Characteristics of Portuguese Water Dog pups with dilated cardiomyopathy.

Pup No.	Age (weeks)	Gender	Heart Weight (g) (% body weight)	Clinical History
1[a]	12	Female		Several days depression, anorexia; sudden collapse, death
2[a]	12	Female		24-hour respiratory distress, death; cardiomegaly, pulmonary edema
3	32	Male	174 (1.06%)	Acute onset respiratory distress; enlarged heart, pulmonary edema
4	14	Female	73 (1.3%)	Few hours of weakness, then respiratory distress, cyanosis, death; pup from previous litter from same parents died with similar signs
5	2	Male		Respiratory distress; failure to thrive
6	7	Male		Sudden, unexpected death
7[b]	9	Male		Not available
8[b]	11	Female	44	Respiratory distress; severe interstitial pattern
9	8	Female	32	Lethargic, decreased appetite on day of death; died suddenly while playing; breeder reported another littermate died
10[c]	14	Female	67 (1.09%)	Quiet pup; echocardiography showed dilated heart; all other clinical data normal; euthanized
11[c]	13	Male	73	Sudden onset respiratory distress; exercise intolerance; died 4 hours later
12[c]	17	Female	83	Sudden onset respiratory distress; died 30 minutes later

Pups with same superscript are littermates.

of the unexpected onset of the clinical signs and the rapid decline, 10 of 12 pups lacked clinicopathologic data. Two pups (4, 10) were evaluated and followed clinically from the onset of clinical signs to death. Pup 4 was presented because of respiratory distress. Physical examination revealed a grade III/VI soft systolic murmur at the left cardiac apex. The cardiac rhythm was regular; however, weak pulses and pale mucous membranes were detected. Crackles were auscultatable over all lung fields, and the pup was markedly dyspneic. Radiographs revealed left-sided cardiomegaly and a hilar alveolar pattern consistent with pulmonary edema. The vertebra : heart ratio measurement was 11.9 (normal = 8.6–10.6).[10] Echocardiography revealed a severely dilated left ventricle with a shortening fraction of 10% (normal = 27–48%)[11] (Fig 1). The pup was treated with furosemide (2 mg/kg IV q8h), nitroglycerine (0.6mL sc q6h), digoxin (0.04 mg PO q12h), and increased inspired oxygen tension via an oxygen cage. The pup underwent cardiac arrest later that day, and resuscitation attempts were not successful.

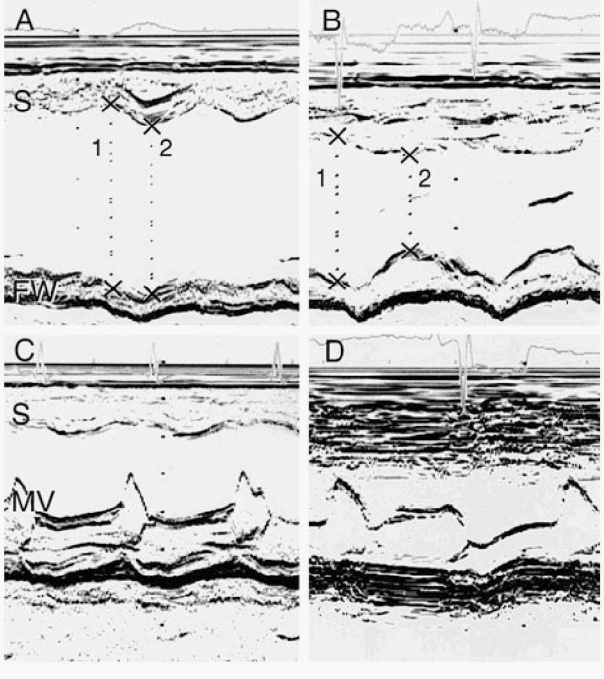

Fig 1. M-mode echocardiographs from affected pup 10 **(A, C)** and a normal age-, breed-, and weight-matched pup **(B, D)**. The affected pup had increased left ventricular end-diastolic diameter (1) (3.7 cm) and increased end-systolic diameter (2) (3.4 cm), yielding a shortening fraction of 10%. Respective values in the normal pup **(B)** were 2.3 cm, 1.5 cm, and a shortening fraction of 35%. An echocardiogram of the affected pup **(C)** showed mitral valve (MV) motion and increased E-point septal separation (EPSS) of 1.1 cm. EPSS in the normal pup **(D)** was 0.5 cm. S = interventricular septum, FW = left ventricular free wall.

Pup 10 was presented because a littermate (pup 11) died suddenly, and cardiomyopathy was diagnosed at postmortem. Physical examination of pup 10 at the time of presentation revealed a slightly muffled 1st heart sound; however, no murmur was detected. Normal bronchovesicular lung sounds were auscultated over all lung fields. Radiographs revealed a heart size at the upper limit of normal, with a vertebra : heart ratio of 10.7. The right cranial pumonary arteries and veins were enlarged. All variables on an EKG examination were within normal limits (PR = 80 ms; QRS = 40 ms; QT = 200 ms; RII = 1.7 mV; mean electrical axis = normal), although a sinus tachycardia was present (heart rate [HR] = 180beats/minute). An echocardiogram revealed cardiomegaly, with a left ventricular end diastolic diameter of 3.7 cm and a left ventricular systolic diameter of 3.4 cm (respective normal values from an age-, breed-, and size-matched control animal: 2.3 and 1.5 cm). The shortening fraction was 10%. E-point septal separation was 1.1 cm (normal, 0.3 cm), and the aortic ejection time was 0.135 seconds (normal, 0.185 seconds) (Sleeper, unpublished data). Mild mitral regurgitation was detected with Doppler investigation.

The following day, the pup remained tachycardic, and a faint, intermittent diastolic gallop was occasionally auscultatable. By that evening, the pup was slightly weak and had a decreased appetite. Bronchovesicular sounds were in-

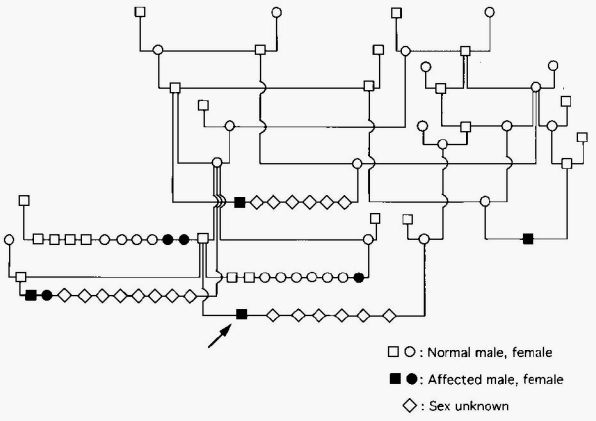

Fig 2. Pedigree analysis of 8 pups affected with dilated cardiomyopathy (DCM). The arrow indicates the propositus (pup 10). Pedigree analysis reveals common ancestry of the 8 POWD affected with DCM. Both genders are affected and were produced by phenotypically normal parents. In another family of POWD sharing no common ancestor with the propositus within 6 generations, there are 4 affected dogs (1 male, 3 females). These results are highly suggestive of an autosomal recessive mode of inheritance.

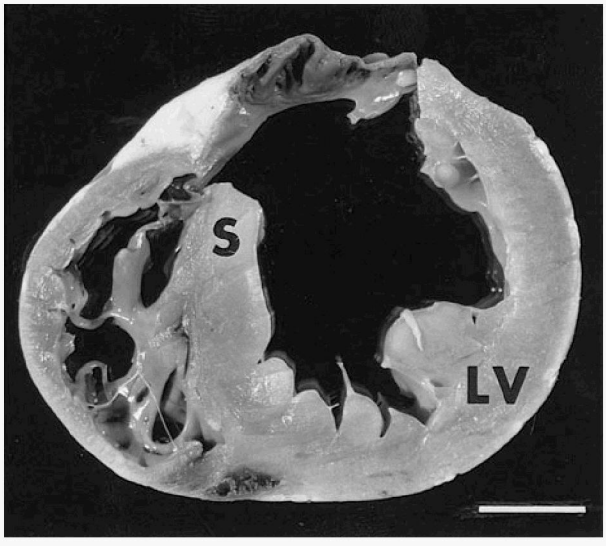

Fig 3. Transverse section of heart from pup 10 with dilated cardiomyopathy. The heart is globoid due to diffuse chamber dilation, which is most pronounced for the left ventricle and atrium. S = septum; LV = left ventricular free wall. Bar = 1 cm.

creased; however, no distinct crackles were auscultatable. Mild end expiratory effort was noted. The 2nd day after presentation as a clinically normal pup, the dog was weaker and anorectic. Auscultation revealed a grade V/VI pansystolic murmur with the point of maximal intensity at the left apex. A prominent gallop rhythm was also noted, and pulses were of a short duration and weak. Crackles became auscultatable bilaterally in the thorax several hours later, and a bolus of 1 mg/kg furosemide was administered IV. Over the following 2 hours, crackles became more prominent, as did tachypnea and dyspnea. During this period, the pup vomited and remained severely depressed. An EKG exam demonstrated sinus tachycardia (HR=190 beats/minute) but was otherwise unremarkable. Another bolus of IV furosemide was administered; however, the pup remained in respiratory distress and was euthanized and submitted for postmortem. A CBC and serum and urinary biochemical analyses on pup 10 did not reveal any abnormalties. Radiographic abnormalities for pups 4, 10, and 11 included pulmonary interstitial patterns characteristic of edema in all 3 pups and cardiomegaly in 2.

The treatment for 7 pups consisted of emergency supportive care to stabilize the cardiovascular system, including 1 or more of the following: cardiopulmonary resuscitation (n = 3); digoxin (n = 1), furosemide (n = 3), nitroglycerine (n = 1), oxygen (n = 3), corticosteroids (n = 1), fluids (n = 1), epinephrine (n = 2), and aminophylline (n = 1).

Pedigree Analysis

Pedigree analysis revealed common ancestry of 8 of the POWD affected with DCM (Fig 2). One female was the dam of 4 affected pups, the granddam of 2 affected pups, the great-granddam of 1 pup, and a half-sister to the remaining affected pup. Another family of POWD sharing no common ancestor to pup 10 within 6 generations did include the 4 additional affected pups. All 12 affected pups were produced by phenotypically normal parents. Both males (n = 5) and females (n = 7) were affected. Based upon these findings, the pedigree is most consistent with an autosomal recessive mode of inheritance, but a polygenic mode of inheritance cannot be ruled out without further test breedings. Although there are several anecdotal reports of pups dying with clinical signs similar to those reported here, the true incidence of this disease in the POWD breed cannot be determined at this time.

Postmortem Results

Entire hearts of 9 pups were available for examination, but only sections of heart were submitted for the remaining 3 pups. Of the 9 hearts examined, all had similar changes (Fig 3). The hearts were enlarged and globoid with rounding of the apex. The left auricle was markedly dilated, often larger than the right auricle. The left ventricle was dilated and easily compressible from the epicardial surface. On cut section, the left ventricular lumen was expanded with flattening of papillary muscles. The left ventricular free wall thickness was noticeably reduced (measurements of thickness were not routinely made). The endocardium of the left ventricle was diffusely opaque, corresponding histologically to endocardial fibrosis. The right ventricle and atrium were also dilated, but these changes were not as pronounced at that seen in the left hemiportion of the heart. A patent foramen ovale (1 × 0.4 cm) was noted in case pup 2. No other structural abnormalities were found in the remaining 8 hearts.

Lung changes were noted grossly at postmortem in 5 pups; lungs were wet and rubbery, congested, and slightly firm. Lungs from 11 pups were examined histologically. Interstitial edema and alveolar histiocytosis were noted in all pups, and in 7 pups there was minimal to mild acute interstitial pneumonia with infiltrates of neutrophils and the presence of alveolar fibrin and necrosis of individual cells

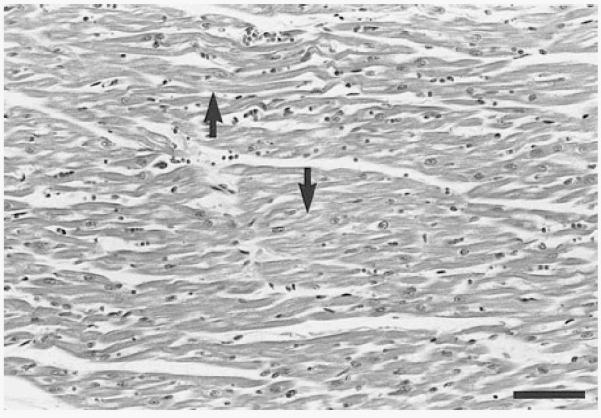

Fig 4. Histologic section of myocardium from pup affected with dilated cardiomyopathy. The interstitial space between the myofibers is prominent. The myofibers are generally thinner than normal and disorganized; their size varies markedly. The swollen, cleared areas of the sarcoplasm are obvious at this magnification (arrows). Hematoxylin and eosin. Bar = 61 μm.

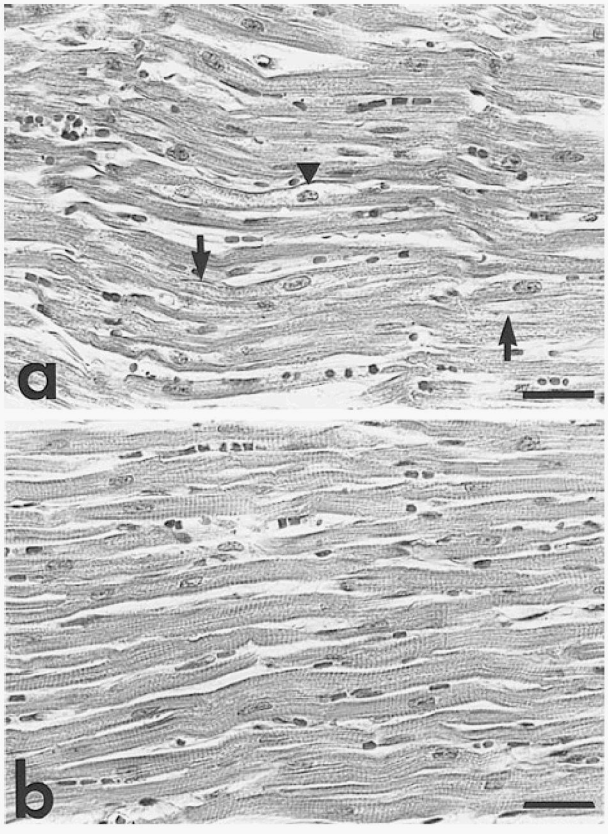

Fig 5. Histologic appearance of myocardium from POWD affected with DCM **(a)** and from a clinically normal pup **(b)**. The myocardiocytes from the affected dog **(a)** are expanded segmentally by cleared areas of the sarcoplasm, which are typically prominent in perinuclear regions (arrowhead) but extend to affect large areas of the fibers, leading to loss of regular cross-striations (arrows). There is greater nuclear size/shape variability in the affected heart when compared with tissue from a breed/age-matched control dog **(b)**. Hematoyxlin and eosin. Bars = 57 μm.

in the septa. Erythrophagocytosis was noted in only 1 pup (9); however, red blood cells were noted in alveoli in all 11 pups examined. The changes are consistent with those found in congestive heart failure and secondary hypoxia. The mild acute interstitial inflammation may have also been the result of mild aspiration during the bouts of dyspnea.

Other changes noted at postmortem or from tissues submitted were consistent with those resulting from heart failure. Hepatic congestion was found histologically in the 6 pups where liver was available for evaluation. Hepatomegaly was reported in 6 pups; hepatic capsular fibrin was also reported in 1 pup. These gross findings are consistent with passive hepatic congestion of cardiac origin. Peritoneal cavity ascites was reported in 2 pups, and pleural effusion (transudate) was reported in 1 pup.

Histologic Examination

Heart tissue from 5 normal breed-matched dogs (4 pups 6–18 weeks of age and one 4-year-old adult dog) were compared with that of affected pups. The changes in the myocardium from affected pups were most obvious upon examination of longitudinal sections of myofibers. The myofibers were accentuated by an interstitium expanded by clear space that did not stain with special stains for mucopolysaccharides, lipid, or glycogen and was therefore consistent with edema. The myofibers often appeared irregular in thickness and wavy to bent; many myofibers appeared to taper or branch. These changes created a disorganized appearance of the myofibers in some areas when examined at low magnification (Fig 4). There was a generalized loss of the normal pattern of cross-striations in affected myofibers, and intercalated discs were not seen. The irregularity in myofiber thickness was due predominately to swelling and clearing of the sarcoplasm, which resulted in an overall decrease in staining intensity when compared with normal myocardium (Fig 5). The zones of clearing in the myofibers were multifocal and segmental and typically included prominent perinuclear staining with pinpoint eosinophilic granular material (Fig 5). This granular material stained dark blue with phosphotungstic acid–hematoxylin, which is consistent with mitochondria. However, the cleared areas of the myofiber sarcoplasm did not stain with special stains for mucopolysaccharides, lipid, or glycogen, which suggests that the swelling was due to accumulation of intracellular fluid (hydropic change).

There was no histologic evidence of myocardial fibrosis in any pup when tissues were examined with a trichrome stain. Myofiber nuclei had marked size variability, with karyomegaly and occasional indented nuclei. The nuclei also were slightly more hyperchromatic when compared with the nuclei from normal myocardium. These nuclear changes are consistent with those described in cases of myocardial hypertrophy.[12] On cross-section, the changes in the myofibers were more difficult to appreciate when compared with normal myocardium; the most prominent changes included nuclear hyperchromasia and myofibers of irregular shape and size that often appeared more angular.

Myocardial inflammation was absent in all except pup 2, in which rare mixed inflammatory cells (neutrophils, lymphocytes, and macrophages) were noted associated with the endocardium and perivascularly. Rare Anitchkow cells

were noted in the interstitium of case pup 12. Myofiber degeneration and necrosis were also absent in all pups examined. Coronary arterial and venous vasculatures were histologically normal. Skeletal muscle obtained from the extremities was also histologically normal.

Discussion

DCM is characterized by generalized dilation of both atria and ventricles of the heart.[2] Clinical manifestations of DCM result from decreased pump function leading to reduced cardiac output. A narrow pulse pressure may be detected on physical examination, and ventricular gallops typically develop once cardiac decompensation occurs. Body cavity and pulmonary fluid accumulation and hepatomegaly result from a compensatory increase in preload and the decreased forward movement of the blood through the heart to the arterial system. The most striking clinical signs are related to hypoxia and hypoperfusion, with weakness, exercise intolerance, syncope, coughing, respiratory distress, and tachypnea frequently observed. The development of these clinical signs typically occurs late in the course of disease and is ominous.[13] Murmurs due to consequent valvular insufficiency occur if dilation is severe enough to enlarge the valve annulus. Arrhythmias are a common finding, as are radiographic and echocardiographic evidence of heart enlargement. Echocardiographic findings consistent with cardiac enlargement include increased end-diastolic and end-systolic ventricular volumes and increased atrial diameter; changes are more frequently detected on the left side. The shortening fraction is typically lowered, with a decreased left ventricular free wall thickness. An additional common feature is a reduced left ventricular ejection time. Death is due to congestive heart failure or fatal arrhythmias.

The histologic changes noted in cases of DCM are not pathognomonic for DCM nor are they indicative of a specific cause. In the dog, as in humans, the histologic changes differ among individuals, but several changes are commonly found in all DCM cases, including 1 or more of the following: myofiber degeneration (vacuoles or fracturing) and necrosis, interstitial fibrosis in areas of myofiber loss, mononuclear (lymphoplasmacytic and histiocytic) inflammation, infiltration of adipocytes, and myofiber atrophy. Myofiber hypertrophy is also a common compensatory occurrence because the affected hearts have increased weights. Variable myofiber size with thin and wavy fibers has also been reported.[14]

Ultrastructural changes are also inconsistent among cases of canine DCM and include myofibrillysis (disorientation and loss of myofibrils), increased intermyofibrillar space, sarcoplasmic reticulum dilation, interstitial edema, thickening of Z-bands, mitochondria of irregular shape and size, and increases in the numbers of mitochondria, glycogen granules, lysosomes, lipofuscin granules, and lipid vacuoles.[14–17] Additional mitochondrial changes include swollen and disrupted cristae, myelin figure formation, and spherical intramitochondrial inclusions. In general, the ultrastructural changes are also nonspecific and have been noted in a variety of chronic cardiac diseases. Some changes indicate an increase in cell breakdown products, ie, lipofuscin and myelin figures. Other changes are most likely compensatory and related to deranged energy metabolism (mitochondrial changes, lipid and glycogen accumulation) and hypertrophy (Z-band thickening).[15]

The causes of DCM can be divided into 2 major categories: primary (idiopathic) and secondary. Secondary DCM is the result of cardiac dysfunction due to extracardiac factors that affect cardiac function. These factors are usually systemic in origin and include infectious agents, toxins, and inflammatory or neoplastic conditions that result in destruction of the myocardium and acquired or inherited metabolic diseases that affect myofiber function.[1] Primary or idiopathic DCM principally or exclusively affects the myocardium, and the etiology is unknown. The clinical determination of idiopathic DCM is based upon the absence of underlying systemic, coronary, valvular, structural (congenital), hypertensive, or pericardial disease. Suspected causes of idiopathic DCM include inherited (genetic) defects, infectious agents (enteroviral), immunologic disease, and endstage disease of unknown origin (toxic, infectious, inflammatory).[12,18,19] The latter proposed etiologies are based upon the finding of inflammatory infiltrates in the myocardium. The only definitive virus-induced DCM described in the dog is parvoviral myocarditis. Pups affected with parvoviral myocarditis are between 2 and 16 weeks of age with no apparent familial, breed, or sex predilection.[20] Histologically, the changes in the myocardium correspond to a lymphocytic, end-stage myocarditis with myofiber loss and replacement by extensive fibrosis. In early stages of disease, viral inclusions are noted in myofibers, often without concurrent inflammation. Subacute changes include myofiber necrosis and mild inflammatory infiltrates.

Immune-mediated myocarditis leading to endstage DCM has also been suggested as a possible etiological subset of human DCM,[18,19] but an immune-mediated cause of canine DCM has not been proved. A subset of human DCM appears to have a genetic basis. Inherited DCM can be further subdivided into disorders of substrate and energy metabolism, storage diseases, and disorders of mechanisms yet to be determined that are classified as heritable because of evidence of familial relatedness.[19,21,22] In other forms of human cardiomyopathy, such as hypertrophic cardiomyopathy, genetic defects have been related to contractility proteins (cardiac beta-myosin heavy chain), cytoskeletal proteins, and proteins involved in either signal transduction or metabolism.[19] Similar defects have not been found to date for DCM in dogs.

Other etiologies that have been considered for DCM in humans and animals revolve around defects in energy metabolism or decreased levels of compounds that protect against oxidative damage. These problems include deficiencies in magnesium, thiamine, selenium, vitamin E, and taurine.[23–25] Deficiencies of these compounds have not been thoroughly explored in the dog.[26] Catecholamine excess has also been suggested in human DCM because DCM has been identified in patients with actively secreting pheochromocytomas and in animals given catecholamines.[27] The exact mechanism of catecholamine-induced cardiomyopathy is unknown.

In dogs, idiopathic DCM is generally suspected to be heritable based upon the various breed predilections, but heterogeneous underlying biochemical/metabolic defects

are suspected. Substantive evidence supporting the possible underlying causes or mechanisms is quite limited. Decreased myocardial L-carnitine concentrations have been noted in related Boxer dogs with DCM and in some Doberman Pinschers with DCM.[28,29] However, L-carnitine concentrations are also lowered with advanced cardiac disease of any cause, and therefore a lower concentration is not a definitive indicator of underlying cause.[23] Supplementation may serve to enhance remaining cardiac function.

Decreased cardiac myosin levels have been noted in clinically normal Doberman Pinschers and Doberman Pinschers affected with DCM when compared with cardiac myosin levels in other dog breeds.[30] Lower myosin levels may predispose the heart to failure due to diminished protective effects against cellular hypoxia. The myoglobin concentration noted in clinically normal Doberman Pinschers was similar to cardiac myoglobin concentrations in dogs with heart failure experimentally induced by rapid ventricular pacing.[30] These findings indicate that changes in myoglobin concentration may be important in the progression of heart failure and that it may be an important component of the DCM of Doberman Pinschers. However, the fact that experimentally induced heart failure resulted in a lowering of myoglobin may also suggest that the lowered myoglobin found in the clinically normal Doberman Pinschers may simply be yet another indicator of underlying cardiac dysfunction due to some other etiology. In the same study, mitochondrial ATPase activity was 45% lower in both clinically affected and normal Doberman Pinschers when compared with normal dogs. A similar decrease was also noted in experimental models of heart failure, suggesting again that this finding is most likely a result rather than a cause of heart failure.[30]

McCutcheon et al[31] examined myocardial metabolite and enzyme levels for the major metabolic pathways for energy production and calcium transfer in Doberman Pinschers with DCM. They found significant decreases of metabolites and enzymes associated with mitochondrial ATP production. The greatest decreases were found for the mitochondrial respiratory chain enzymes and myoglobin. The authors conceded that their findings do not indicate whether the decreased mitochondrial energy production is a primary or secondary defect. Comparison with experimentally induced models of heart failure will help resolve this question. Lower concentrations of enzymes and myoglobin in DCM of Doberman Pinschers may not be unique to that form of DCM but may be secondary compensatory changes of the failing heart.

The clinical and postmortem findings in the 12 affected POWD described in this report are consistent with the findings reported for other canine DCM. The heart : body weight ratios available for 3 of the pups were all above 1%, which is greater than that reported for normal dogs (0.084%).[32] The lack of apparent underlying systemic or structural causes for DCM in these dogs places this form of DCM in the category of primary or idiopathic DCM, and the apparent autosomal recessive pattern of inheritance is consistent with a familial disease.

The histologic features noted in the myocardium are subtle and lack changes associated with chronicity, ie, fibrosis or inflammation found in other forms of canine DCM. The changes in the myofibers and interstitium were diffusely distributed in the myocardium of affected POWD but were most pronounced in the left ventricular and septal myocardium. The cause of the expanded interstitium was edema, and the myofiber swelling and loss of cross-striations was attributable to cytoplasmic fluid accumulation (hydropic change) and an apparent increase in the numbers of mitochondria as confirmed by use of special stains to detect the deposition of lipid, glycogen, or mucopolysaccharides, which may have expanded the interstitium and sarcoplasm. Hydropic change is a nonspecific indicator of membrane dysfunction caused by a defect in energy production or structural membrane failure. Although myofibers were thinner than normal, the increased heart weights and the nuclear hyperchromasia and size variability are consistent with myofiber hypertrophy. Myofiber splitting/branching and disarray, noted in other forms of cardiomyopathy, were also noted in the myocardium of the affected POWD. There was no evidence of active myofiber necrosis in the 12 pups examined. Thus, myocardial decompensation probably is acute and rapidly fatal, precluding cellular degeneration that would be noted histologically.

There was no evidence for myocardial storage disease as a cause for POWD DCM. Eleven of the POWD pups lacked any evidence of cardiac inflammation; however, a single pup did have rare perivascular and endocardial inflammation. The significance of the inflammation noted in the single pup is unknown. The general lack of inflammation suggests that the underlying cause is most likely not infectious or immune mediated. However, because this is a preliminary description of a new DCM, the possibility of underlying infectious or immune-mediated causes should still be considered. There was no indication that this DCM was the result of primary vascular disease; all coronary vasculature examined histologically and at postmortem was normal. Skeletal muscle obtained from the extremities of affected pups was histologically normal, indicating that a primary DCM is present in the POWD breed. There was also no clinical evidence of noncardiac skeletal muscle involvement. The finding of Anitchkow cells in the interstitium of 1 pup is nonspecific. Anitchkow cells are mesenchymal cells located in the myocardial interstitium and are suspected to be activated myofibroblasts, considered indicative of myocardial damage.[33]

The clinical course of the POWD DCM was distinctive. The age of onset noted in the POWD (13 $\pm$ 7.3 weeks) is the youngest for any form of canine DCM, and the progression of disease (sudden death to 5 days) is significantly more rapid than has been reported in other dogs with DCM (0.5–24 months). All pups either died suddenly without previous clinical signs or had vague clinical signs related to left ventricular failure for 1–5 days prior to death, and treatment did not affect outcome in these pups. Pups evaluated prior to death had signs referrable to left ventricular failure and radiographic, electrocardiographic, and echocardiographic indices consistent with a diagnosis of DCM. Serum biochemical and urine analyses and CBCs were within normal ranges for the pups examined, and urinary metabolic screening for inborn errors of metabolism did not indicate inherited metabolic diseases such as mucopolysacchridosis and several amino acidurias (data not shown). Unfortunate-

ly, no additional biochemical evaluations for serum constituents more specific for cardiac disease, eg, creatine phosphokinase or plasma carnitine, were performed on these pups.

The true prevalence of DCM in the POWD breed cannot be determined at this time. The POWD are a relatively new breed in the United States, and they comprise a small population. All of the current US dogs came from foundation stock originating in Portugal, hence the gene pool is small. Several breeders in the USA and Portugal have anecdotally reported sudden death in young pups, but the causes of these deaths have not been investigated.

This study was limited by the lack of available fresh tissues and active cases for more complete analysis. Future investigations should be designed to expand information concerning biochemical, molecular, and histologic/ultrastructural changes and to confirm the mode of inheritance. POWD DCM also may serve as a useful canine model for DCM.

This newly described familial DCM of the Portuguese Water Dog breed appears to have an autosomal recessive mode of inheritance. It is distinguished clinically from other forms of canine DCM by the young age at onset (13 ± 7.3 weeks) and the rapid clinical course (days). The preliminary histologic findings suggest that this DCM is not the result of an infectious or immune-mediated etiology, but it is most likely caused by an underlying molecular (biochemical/structural) defect.

Acknowledgments

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Plasma and whole blood taurine in normal dogs of varying size fed commercially prepared food

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Summary

The objective of the present study was to examine the effect of signalment, body size and diet on plasma taurine and whole blood taurine concentrations. A total of 131 normal dogs consuming commercially prepared dog food had blood drawn 3–5 h post-prandially to be analysed for plasma amino acids and whole blood taurine. Body weight and morphometric measurements of each dog were taken. Plasma and whole blood taurine concentrations were 77 ± 2.1 nmol/ml (mean ± SEM) and 266 ± 5.1 nmol/ml (mean ± SEM), respectively. No effect of age, sex, body weight, body size, or diet was seen on plasma and whole blood taurine concentrations. Mean whole blood taurine concentrations were lower in dogs fed diets containing whole grain rice, rice bran or barley. The lowest whole blood concentrations were seen in dogs fed lamb or lamb meal and rice diets. Plasma methionine and cysteine concentrations were lower in dogs fed diets with animal meals or turkey, and whole grain rice, rice bran or barley. Fifteen of 131 dogs had plasma taurine concentrations lower than, or equal, to the previously reported lowest mean food-deprived plasma taurine concentration in normal dogs of 49 ± 5 nmol/ml (mean ± SEM) (ELLIOTT et al., 2000). These findings support the theory that taurine deficiency in dogs may be related to the consumption of certain dietary ingredients. Scientific and clinical evidence supports the hypothesis that dilated cardiomyopathy is associated with low blood taurine concentration in dogs; therefore, further work is indicated to determine the mechanism by which diet can affect taurine status in dogs.

Introduction

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Taurine deficiency in dogs with dilated cardiomyopathy: 12 cases (1997–2001)

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Quinton R. Rogers, PhD, DACVN; Robert C. Backus, DVM, PhD

Objective—To determine signalment, history, clinical signs, blood and plasma taurine concentrations, electrocardiographic and echocardiographic findings, treatment, and outcome of dogs with low blood or plasma taurine concentrations and dilated cardiomyopathy (DCM).

Design—Retrospective study.

Animals—12 client-owned dogs with low blood or plasma taurine concentrations and DCM.

Procedure—Medical records were reviewed, and clinical data were obtained.

Results—All 12 dogs were being fed a commercial dry diet containing lamb meal, rice, or both as primary ingredients. Cardiac function and plasma taurine concentration improved with treatment and taurine supplementation. Seven of the 12 dogs that were still alive at the time of the study were receiving no cardiac medications except taurine.

Conclusions and Clinical Relevance—Results suggest that consumption of certain commercial diets may be associated with low blood or plasma taurine concentrations and DCM in dogs. Taurine supplementation may result in prolonged survival times in these dogs, which is not typical for dogs with DCM. Samples should be submitted for measurement of blood and plasma taurine concentrations in dogs with DCM, and taurine supplementation is recommended while results of these analyses are pending. (*J Am Vet Med Assoc* 2003;223:1137–1141)

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Commentary

Diet-associated dilated cardiomyopathy in dogs: what do we know?

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Ryan Fries DVM
Darcy B. Adin DVM
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Diet-associated DCM first came to light in cats in the late 1980s[1] and in dogs in the mid-1990s.[2] The association between diet and DCM in dogs has generally not been much in the news since the early 2000s, but over the past few years, an increasing number of DCM cases involving dogs appear to have been related to diet. The extent of this issue is not clear, not all cases have been confirmed to be linked to diet, and a true association has not been proven to exist. However, when one of the authors (RF) recently surveyed veterinary cardiologists about cases of possible diet-associated DCM in dogs examined in the past 2 years, information for > 240 cases was obtained, with responses received from the United States, United Kingdom, Canada, Israel, and Austria (unpublished data). Dogs for which breed was specified consisted of mixed-breed dogs (n = 134), Golden Retrievers (23), Labrador Retrievers (9), German Shepherd Dogs (8), Cocker Spaniels (7), and between 1 and 5 dogs each of 25 other breeds. Further, possible diet-associated DCM represented 16% of all cases of DCM diagnosed by the respondents during this period.

The recent announcement from the US FDA[3] alerting pet owners and veterinarians about reports of DCM in dogs eating pet foods containing peas, lentils, other legume seeds, or potatoes as main ingredients has raised concerns among the pet-owning public. Therefore, we wanted to increase awareness of this issue among veterinarians, review what is currently known about the possible association between certain diets and DCM in dogs, and discuss what veterinarians can do to help identify underlying causes.

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Idiopathic dilated cardiomyopathy in Dalmatians: Nine cases (1990–1995)

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Objective—To describe the historical, clinical, and echocardiographic findings in Dalmatians with dilated cardiomyopathy (DCM).

Design—Retrospective case series.

Sample Population—9 Dalmatians with a diagnosis of DCM and congestive heart failure (CHF), 9 Doberman Pinschers with DCM and CHF, and 9 dogs of other breeds with DCM and CHF.

Procedure—Disease history; signalment; physical, radiographic, and echocardiographic examination findings; treatment; and outcome from medical records were analyzed.

Results—All Dalmatians were male, with a mean age of 6.8 years. Eight dogs had been fed a commercially available low-protein diet formulated for the prevention of urate uroliths. All dogs had clinical signs consistent with left-sided CHF and had marked left ventricular systolic dysfunction and severe left ventricular dilatation, although arrhythmias were not an important finding in this series of dogs. Median duration of survival was 10 months.

Clinical Implications—The DCM syndrome in Dalmatians has some qualities that are distinct from DCM in other breeds of dogs. (*J Am Vet Med Assoc* 1996; 209:1592–1596)

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Relationship Between Circulating and Dietary Taurine Concentrations in Dogs with Dilated Cardiomyopathy

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ABSTRACT

A retrospective study was conducted to determine dietary taurine concentrations in dogs with dilated cardiomyopathy (DCM) and to compare the clinical outcome of taurine-deficient and non–taurine-deficient dogs. Taurine concentrations were low in blood samples from 20 of 37 dogs with DCM. Median dietary taurine concentration was not significantly different between taurine-deficient and nondeficient dogs. There was no correlation between dietary and circulating taurine concentrations. The outcome of taurine-deficient dogs supplemented with taurine was not different from the outcome of nondeficient dogs. The role of taurine and its relationship to dietary intake in canine DCM remain unclear.

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The Journal of Nutrition
Nutrient Physiology, Metabolism, and Nutrient-Nutrient Interactions

Copper Deficiency Does Not Lead to Taurine Deficiency in Rats[1]

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Abstract

Copper deficiency has been reported to cause a decrease in urinary taurine excretion in rats. We determined whether Cu deficiency would decrease taurine status and the hepatic activities of cysteine dioxygenase (CDO) and/or cysteine sulfinic acid decarboxylase (CSAD) in rats. Ten weanling male rats were assigned to either a Cu-adequate (+Cu) or Cu-deficient (−Cu) group. All rats consumed a Cu-deficient purified diet and water ad-libitum for 16 wk. The water for the +Cu group contained 20 mg Cu/L as $CuSO_4$. At wk 16, the groups differed ($P < 0.05$) in the following variables (means ± SEM, −Cu vs. +Cu): body weight (BW), 375 ± 19 vs. 418 ± 2.9 g; food intake, 16.2 ± 0.7 vs. 18.5 ± 0.4 g/d; hematocrit, 0.294 ± 0.027 vs. 0.436 ± 0.027; hemoglobin, 95.2 ± 9 vs 134 ± 10 g/L; liver Cu, 8.7 ± 2.0 vs. 65.9 ± 2.5 nmol/g; plasma Cu, 0.38 ± 0.09 vs. 13.4 ± 0.61 μmol/L; plasma ceruloplasmin activity, 1.75 ± 1.0 vs. 67.9 ± 8.4 IU; relative heart weight, 0.56 ± 0.04 vs. 0.35 ± 0.02% BW; relative liver weight, 4.06 ± 0.23 vs. 3.37 ± 0.06% BW; and liver CSAD activity, 18.8 ± 1.37 vs. 13.5 ± 1.11 nmol · min^{-1} · mg $protein^{-1}$. The groups did not differ at wk 16 in: plasma taurine, 249 ± 14 vs. 298 ± 63 μmol/L; whole blood taurine, 386 ± 32 vs. 390 ± 25 μmol/L; urinary taurine excretion, 82.5 ± 15 vs. 52.0 ± 8.3 μmol/d; liver taurine, 2.6 ± 0.7 vs. 2.8 ± 0.4 μmol/g; liver total glutathione, 6.9 ± 0.48 vs. 6.3 ± 0.40 μmol/g; liver cyst(e)ine, 96 ± 7.1 vs. 99 ± 5.3 nmol/g and liver CDO activity, 2.19 ± 0.33 vs. 2.74 ± 0.21 nmol · min^{-1} · mg $protein^{-1}$. These findings support the conclusion that Cu deficiency does not affect body taurine status. J. Nutr. 136: 2502–2505, 2006.

Introduction

Taurine (2-aminoethanesulfonic acid) is a beta-amino sulfur amino acid, but it is neither an essential amino acid in most animals nor a building block of proteins. Taurine is known to be synthesized from the sulfur amino acids, methionine/cyst(e)ine (1) at a sufficient rate to meet biological needs in most animals. However, since taurine deficiency was found to be a cause of dilated cardiomyopathy (DCM)[4] in cats (2), taurine deficiency has been considered by many nutritionists and veterinarians as a possible causative factor for DCM in dogs.

Moise et al. (3) reported that taurine deficiency was linked to DCM in foxes, a canid, which suggests that taurine deficiency may occur in dogs under certain metabolic conditions, even though it has been shown that with many diets no dietary taurine is required for normal taurine status. Clinical signs of DCM associated with taurine deficiency in dogs have been reported by various cardiologists. Although the metabolic basis for the taurine deficiency has not been elucidated, it is thought to involve abnormal energetics via calcium channel disregulation in mitochondria (4). The majority of clinical signs of DCM in dogs were in large-breed dogs that had been fed commercial dog foods for long periods of time that were composed primarily of lamb meal and rice (5). This suggests a dietary link between certain dog foods and the development of DCM in dogs.

Because Gray and Daniel (6) reported that urinary taurine excretion was reduced in Cu-deficient rats and suggested that it may be the result of a decreased synthesis of taurine, we examined the Cu content of the dog foods reported to be associated with taurine deficiency. The lamb and rice diet, which most of the affected dogs were consuming, was not supplemented with Cu [3.1mg/1000 kcal (4184 kJ) ME], but was supplemented with Zn at several-fold (84mg/1000 kcal ME) the minimum requirement for the dog. This resulted in a relatively high Zn to Cu ratio of a magnitude known to induce metallothionein formation in some species (7) which, in turn, binds Cu and decreases Cu bioavailability (8). We hypothesized that the high Zn to Cu ratio present in the diet may have decreased the availability of Cu and thereby had an effect on taurine status via the activity of cysteine dioxygenase [CDO, Enzyme Commission(EC) 1.13.11.20] and/or cysteine sulfinic acid decarboxylase (CSAD, EC 4.1.1.29), key enzymes for the synthesis of taurine from cysteine.

To test this hypothesis, Cu deficiency was induced in male weanling rats and taurine status and the activities of the 2 enzymes involved in taurine synthesis were examined as a model to determine whether Cu deficiency in dogs may be involved in causing DCM in dogs.

[1] Supported by the Center for Companion Animal Health (CCAH), the School of Veterinary Medicine, University of California, Davis.

[4] Abbreviations used: BW, body weight; CDO, cystein dioxygenase; CSAD, cystein sulfinic acid decarboxylase; +Cu, copper-adequate; −Cu, copper-deficient; DCM, dilated cardiomyopathy.

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Materials and Method

Rats and diets. The husbandry and treatment of the rats were approved by the Animal Use and Care Administrative Advisory Committee at University of California, Davis and were in compliance with the NRC guidelines for laboratory animals (9). Ten male weanling rats were purchased (Harlan-Sprague-Dawley) and were divided into 2 groups. Both groups, Cu deficient group (−Cu) and Cu adequate group (+Cu), were fed the same Cu-deficient diet (**Table 1**), throughout the entire experimental period. The mineral composition of the Cu deficient diet was based on the AIN-76A diet (10) except that the diet contained no added Cu. The diet provided protein at 180 g/kg with no supplementation of methionine to avoid excess substrates for taurine biosynthesis. In addition to the diet, the +Cu group was given Nanopure water (Barnstead Nanopure II System, Barnstead International) containing 20 mg Cu/L as $CuSO_4$. To ensure the consumption of satisfactory amounts of Cu for +Cu group, the amount of Cu-supplemented water consumed for 3 d was recorded once every 4 wk, and the amount of Cu consumed was calculated to be adequate. The mean Cu consumption by the +Cu group was 0.155 mg/d, which exceeds the Cu requirements of growing rats. The −Cu group was given Nanopure water without any supplementation. All rats had free access to food and water throughout the experiment. The rats were housed in hanging stainless-steel cages with a 12-h light-dark cycle. The room temperature ranged between 14 and 29°C.

Sampling. To determine the Cu status of the rats, ~500 μL of blood was collected every 2 wk from the saphenous vein (11), using heparinized Microvette CB300 (Sarstedt) blood collection tubes. When the −Cu group showed hematological and biochemical signs of Cu deficiency (hematocrit <40, hemoglobin concentration <120g/L, and/or ceruloplasmin activity <10 IU), the rats were placed in metabolic cages to collect urine for taurine analysis (3 d for adaptation and 4 d for collection). At the end of the urine collection period, the rats were anesthetized with ethyl ether, and the blood, liver, and heart collected. Blood was taken from abdominal aorta using heparinized syringes (~20 μL of sodium heparin solution, 1000 USP kU/L, Baxter HealthCare). A portion of blood was centrifuged, at 15,800 × *g* for 15 min, immediately after collection to obtain plasma for determination of taurine concentration and ceruloplasmin activity. Liver samples for assays of CDO and CSAD activities and metabolite concentrations were frozen at −80°C until analyses. Other samples were stored at −20°C.

TABLE 1 Composition of copper-deficient diet

Ingredients	*g/kg*[1]
Casein, high protein[2]	180.00
Sucrose[3]	518.53
Corn starch[4]	159.27
Corn oil[5]	50.00
Fiber (Cellufil)[6]	50.00
Mineral mix (modified AIN-76)[7]	35.00
Vitamin mixture[8]	5.00
50% Choline chloride in water[9]	2.20
Total	1000.00

[1] As-fed basis.
[2] New Zealand Milk Products.
[3] Westco Products.
[4] National Starch and Chemical Co.
[5] ACH Food Companies.
[6] Amersham Life Science.
[7] No supplementation of copper; modified AIN-76 mineral mix (10) (g/kg mineral mix): Calcium phosphate-dibasic, 500.00; sodium chloride, 74.00; potassium citrate-monohydrate, 220.00; potassium sulfate, 52.00; magnesium oxide, 24.00; manganese sulfate, 5.14; ferric citrate, 6.00; zinc sulfate-septahydrate, 3.67; cupric carbonate, 0.00; potassium iodate, 0.01; sodium selenate, 0.007; chromium potassium sulfate, 0.55; sucrose-finely powdered, 114.623.
[8] Vitamin mixture for adult cats (29) which exceeds all of minimum vitamin requirements of growing rats.
[9] International Mineral and Chemical Corp.

Measurements. During the experiment, daily food intakes were recorded and body weights (BW) were measured every 3 d. Hematocrits and hemoglobin concentrations were measured every 2 wk. The weights of hearts and livers were measured immediately after collection. A portion of the collected blood was prepared by centrifugation in a model MB micro-capillary centrifuge (IEC) at 10,285 × *g* for 4 min before hematocrit measurements were taken. Hemoglobin concentration was measured as described by van Kampen and Zijlstra (12). Cu concentrations in the diets, plasma, and liver were measured by atomic absorption spectrometry (AAnalyst 800, Perkin Elmer Instrument) and samples were prepared as described by Clegg et al. (13). Taurine concentrations in whole blood, plasma, and urine were determined using an amino acid analyzer (Beckman 7300 Analyzer C7 Model, Beckman Instruments) (14). Plasma ceruloplasmin activity was measured as its oxidase activity using the modified *o*-dianisidine dihydrochloride method (15). Liver samples were transported on dry ice from the University of California to Cornell University. Then, CDO and CSAD activities in the livers and concentrations of taurine, total glutathione, and cyst(e)ine in the livers were measured. CDO activity was measured as described by Bagley et al. (16). CSAD activity was measured as described by Bella et al. (17). Total glutathione and cyst(e)ine were quantified by the HPLC method of Fariss and Reed (18) as modified by Stipanuk et al. (19). Protein concentration was determined by the method of Smith et al. (20).

All results are expressed as means ± SEM. Differences between groups at wk 16 were compared using 1-way ANOVA (SYSTAT 10.2, SYSTAT Software). For all analyses, differences were considered significant at $P < 0.05$. Probability values in the range of $0.05 \leq P < 0.1$ indicated a noteworthy trend.

Results

The diets were prepared 3 times during the experiment. The Cu concentrations in the 3 batches of the experimental diets were 1.16, 0.11, and 0.13 mg/kg diet (as-fed basis), respectively. All were lower than the minimum Cu requirement for growing rats (5.0 mg/kg diet) as listed by the NRC (21).

The −Cu group consumed 12% less food and had a 10% lower BW than the +Cu group ($P < 0.05$; **Table 2**). However, relative heart ($P < 0.01$) and liver ($P < 0.05$) weights were greater in the −Cu group than in the +Cu group (Table 2).

Several metabolic indicators of Cu deficiency differed between the groups at wk 16 ($P < 0.01$, Table 2). The hematocrit and hemoglobin concentrations of the −Cu group were 67 and 71%, respectively, of those of the +Cu group. Liver and plasma

TABLE 2 Anthropometric variables and indicators of copper and taurine status in rats fed −Cu or +Cu diets for 16 wk[1]

	−Cu	+Cu	*P*-value
Body weight, *g*	375 ± 19	418 ± 2.9	<0.05
Food intakes,[2] *g/d*	16.2 ± 0.7	18.5 ± 0.4	<0.05
Relative heart wt, *% BW*	0.56 ± 0.04	0.35 ± 0.02	<0.01
Liver weights, *% BW*	4.06 ± 0.23	3.37 ± 0.06	<0.05
Hematocrit	0.294 ± 0.027	0.436 ± 0.027	<0.01
Hemoglobin, *g/L*	95.2 ± 9	134 ± 10	<0.01
Plasma copper, *μmol/L*	0.38 ± 0.09	13.4 ± 0.61	<0.01
Liver copper, *nmol/g wet tissue*	8.7 ± 2.0	65.9 ± 2.5	<0.01
Plasma ceruloplasmin, *IU*[3]	1.75 ± 1.0	67.9 ± 8.4	<0.01
Plasma taurine, *μmol/L*	249 ± 14	298 ± 63	0.45
Whole blood taurine, *μmol/L*	386 ± 32	390 ± 25	0.92
Urinary taurine,[2] *μmol/L*	82.5 ± 15	52.0 ± 8.3	0.087

[1] Values are means ± SEM, $n = 5$.
[2] During wk 16.
[3] IU, International unit, $\mu mol \cdot min^{-1} \cdot L^{-1}$.

TABLE 3 Hepatic cysteine dioxygenase and cysteine sulfinic acid decarboxylase activities in rats fed −Cu and +Cu diets for 16 wk[1]

	CDO			CSAD		
	−Cu	+Cu	*P*-value	−Cu	+Cu	*P*-value
$\mu mol \cdot min^{-1} \cdot liver^{-1}$	5.07 ± 0.95	5.53 ± 0.42	0.60	41.1 ± 1.31	27.3 ± 2.62	0.0008
$\mu mol \cdot min^{-1} \cdot g\ liver^{-1}$	0.33 ± 0.04	0.39 ± 0.02	0.19	2.78 ± 0.21	1.90 ± 0.15	0.005
$nmol \cdot 100\ g\ BW^{-1}$	1.29 ± 0.25	1.34 ± 0.11	0.83	11.0 ± 0.66	6.56 ± 0.59	0.0006
$nmol \cdot min^{-1} \cdot mg\ protein^{-1}$	2.19 ± 0.33	2.74 ± 0.21	0.14	18.8 ± 1.37	13.5 ± 1.11	0.001

[1] Values are mean ± SEM, $n = 5$ except CDO, −Cu, $n = 4$ (due to an outlier).

Cu concentrations in −Cu group were only 13 and 3%, respectively, of those of the +Cu group. The plasma ceruloplasmin activity in the +Cu group was about 40 times that of the −Cu group.

Taurine concentrations in plasma and whole blood did not differ between the groups but urinary taurine excretion tended to be greater in the −Cu group than in the +Cu group ($P = 0.09$, Table 2). The groups did not differ (−Cu vs. +Cu) in liver taurine (2.6 ± 0.7 vs. 2.8 ± 0.4 μmol/g), cyst(e)ine (96 ± 7.1 vs. 99 ± 5.3 nmol/g), and total glutathione (GSH + GSSG) (6.9 ± 0.48 vs 6.3 ± 0.40 μmol/g) concentrations.

Hepatic CDO activity did not differ between the groups whether expressed relative to the total liver, g liver, liver protein, or body weight (**Table 3**). The CSAD activity was greater in the +Cu group, regardless of the base used for calculation than in the −Cu group ($P < 0.005$, Table 3).

Discussion

In this study we focused on the relatively high ratio of Zn to Cu in some lamb and rice diets as a possible factor causing taurine deficiency in dogs. After failing to induce Cu deficiency in 12 medium-to-large mixed breed adult dogs fed a commercial type diet with a Cu chelating agent, Syprine (trientine hydrochloride), for 1 y, we decided to examine a cheaper, more expedient model, the albino rat, to examine the effect of Cu deficiency on taurine status.

The lower BW and food intake in the −Cu group than in the +Cu group and the greater relative heart and liver weights in −Cu group than in the +Cu group (Table 2) are typical and consistent with other reports for Cu-deficient rats (6,22,23). All metabolic indicators of Cu deficiency were significantly lower in the −Cu group than in the +Cu group, confirming that the −Cu group was Cu-deficient after a period of 16 wk (6,23).

Taurine homeostasis is maintained predominantly by the regulation of renal taurine reabsorption so that excess dietary taurine is excreted in the urine (24). Therefore, it is generally assumed that the amount of taurine excreted in urine reflects the extent of excess taurine in the taurine pools of animals. The taurine status of the rats was determined by evaluating plasma and whole blood taurine concentrations and urinary taurine excretion (Table 2). The fact that none of these values were significantly different between the −Cu and +Cu group, and the finding that there was a trend for a higher urinary taurine excretion in the −Cu group, which is the opposite of that found by Gray and Daniel (6), negates our hypothesis that Cu deficiency causes taurine deficiency.

A lower food intake by the −Cu group provided less total substrate and might have been expected to result in less taurine synthesis. Food intakes relative to metabolic body weights of the rats during the last 3 d of the experiment, were 34.3 ± 1.02 g/kg $BW^{0.75}$ for the −Cu group and 41.4 ± 0.95 g/kg $BW^{0.75}$ for the +Cu group ($P < 0.01$). Perhaps the results would have been different if a less severe Cu deficiency had been induced or if the rats were fed on the diets for a longer period of time.

Cu deficiency had no effect on the taurine, cyst(e)ine, or total glutathione concentrations at the major site of taurine synthesis, the liver. These results indicate that Cu deficiency in rats does not affect the major products of cysteine metabolism in the liver. However, some reports indicate that Cu deficiency in rats increases hepatic GSH concentration (25,26). The cause for this inconsistency is unclear. Perhaps a more prolonged Cu deficiency in the earlier studies is responsible.

The only significant effect of Cu deficiency on sulfur amino acid metabolism was a higher CSAD activity in liver ($P < 0.01$). The activities of CDO and CSAD are critical to taurine synthesis because they are the key enzymes in the synthesis of taurine from its direct precursor, cysteine. The regulation of these key enzymes in the synthesis of taurine has been reported (27,28). Bagley and Stipanuk (28) demonstrated that, as the dietary protein concentration increases, CDO activity increases and CSAD activity decreases. That is, CDO and CSAD are regulated in a reciprocal manner in response to dietary protein or sulfur amino acid concentration in the diet. In the current study, the reciprocal regulations of activities in the 2 enzymes were not found because CDO did not change. However, the difference in CSAD activity in this study was consistent with previous finding that CSAD activity decreases with higher protein intake (27,28). The food intake/kg $BW^{0.75}$ of the rats during the last 3 d of the the experiment was higher in the +Cu group ($P < 0.01$) and the CSAD activity was lower in this group. Although the CDO activity did not differ between groups, it was 10% higher in the +Cu group ($P = 0.60$), possibly showing a trend for metabolic adaptation of the taurine synthesis system to maintain taurine homeostasis.

In conclusion, Cu deficiency did not affect taurine or other sulfur amino acid metabolites in plasma or in the liver of rats in this study. CSAD activity appeared to be controlled in a normal manner by the amount of dietary protein ingested. We conclude that Cu deficiency does not affect cysteine metabolism or taurine homeostasis in rats and that it is highly unlikely that DCM-induced taurine deficiency in large-breed dogs is the result of a dietary-induced Cu deficiency.

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Differences in Taurine Synthesis Rate among Dogs Relate to Differences in Their Maintenance Energy Requirement[1–3]

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Abstract

Diet-induced (taurine deficiency) dilated cardiomyopathy is reported more in large than small dogs possibly because taurine biosynthesis rate (TBR) is lower in large than small dogs. The TBR in 6 mongrels (37.9 ± 2.1 kg) and 6 beagles (12.8 ± 0.4 kg) was determined from the fractional dilution rate of urinary [1,2-$^2H_2$]-taurine, (d4-tau). All dogs were given a 15.6% protein, 0.60% sulfur amino acid (SAA) diet in amounts to maintain an ideal body condition score. After 3 mo, 14.6 mg/kg body weight of d4-tau was given orally and TBR determined from d4-tau to taurine ratio in urine collected each d for 6 d. Enrichments of d4-tau were determined by GC-MS. Thereafter, mongrels and beagles were paired by ranking of SAA intake per metabolic body weight per $kg^{0.75}$. Each pair received the same amount of diet/$kg^{0.75}$ for 2 wk, then TBR was again determined. Concentrations of taurine in plasma, blood, and urine and concentrations of plasma thiols were measured during each TBR determination. In Expt. 1, TBR and taurine concentrations in plasma and urine of mongrels were lower ($P < 0.05$) than those of beagles. In Expt. 2, TBR and taurine concentrations in blood and plasma of mongrels were lower ($P < 0.05$) than beagles. Together, the results support the hypothesis that large compared with small dogs have lower TBR when fed diets near-limiting in dietary SAA, but adequate to maintain ideal body condition. J. Nutr. 137: 1171–1175, 2007.

Introduction

Dilated cardiomyopathy (DCM)[7] is a disease of the myocardium with impaired systolic pumping function in the ventricles of the heart. Approximately 0.5% of dogs are diagnosed for DCM among all of the dogs admitted to veterinary teaching hospitals (1). Interestingly, it has been reported that large breed dogs are predisposed to developing DCM (2). The etiology for DCM has not been clearly elucidated; however, genetic predisposition, viral infection, immune-mediated disorders, toxin, arrhythmias, and nutritional deficiencies such as taurine deficiency or L-carnitine deficiency have been suggested as possible causes (3). Of the nutritional factors, taurine deficiency has gained attention because taurine deficiency in cats was shown to directly cause a DCM that was reversible by taurine supplementation (4).

Taurine (2-aminoethanesulfonic acid) is a beta, sulfur-containing, amino acid ubiquitously found in animals and reported in especially high concentrations in heart, brain, central nervous system, retina, olfactory bulb, and white blood cells (5). The physiological function of taurine in heart is not fully understood. Proposed mechanisms include osmoregulation, calcium regulation, and inactivation of free-radicals (6).

Taurine is synthesized from the sulfur amino acids, methionine and cyst(e)ine (7), by the activities of the enzymes, cysteine dioxygenase (EC 1.13.11.20) and cysteine sulfinic acid decarboxylase (EC 4.1.1.29) in animals, excluding most carnivores (8). Because of this, taurine is not considered as an essential nutrient in many species. However, it is known that generally, carnivores have a dietary requirement for taurine, and there is evidence that under certain dietary conditions dogs require dietary taurine. Sanderson et al. (9) found a significant decrease in plasma taurine concentration in healthy beagles fed a high-fat, protein-restricted (10% dry matter basis) diet that exceeded the NRC minimum protein requirement of maintenance in adult dogs (10). After feeding the diet for 48 mo, these investigators found 1 dog developed DCM. This indicated that prolonged provision of a protein-restricted diet, although above the minimum protein requirement, could result in taurine deficiency in dogs. More recently, Fascetti et al. (11) reported 12 cases of low blood taurine concentration and DCM in large-breed dogs given apparently nutritionally complete and balanced commercial diets. They suggested that body size may be a factor contributing to development of taurine deficiency in dogs.

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[3] Supplemental Tables 1 and 2 and Supplemental Figures 1 and 2 are available with the online posting of this paper at jn.nutrition.org.

[7] Abbreviations used: BCS, body condition score; BFM, body fat mass; BW, body weight; d4-tau, [1,2-$^2H_2$]-taurine; DCM, dilated cardiomyopathy; LBM, lean body mass; MBW, metabolic body weight; MLBM, metabolic lean body mass; RLW, relative liver weight; SAA, sulfur amino acid; TBR, taurine biosynthesis rate; TTR, tracer to tracee ratio.

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Our research group recently found that plasma taurine concentration and taurine biosynthesis rate (TBR) in Newfoundland dogs, a giant dog breed, are substantially lower than those in beagles when both breeds are fed the same diet (12). We hypothesize that the greater incidence of taurine-deficiency DCM reported in large relative to small dogs is the result of lower TBR in large dogs. In the present study, we compare the abilities of large and small dogs to synthesize taurine when intake of diet is controlled to maintain ideal body condition and when intake is controlled to provide similar dietary sulfur amino acid (SAA) intake on a metabolic body weight (MBW, $kg^{0.75}$) basis.

Materials and Methods

Animals and diet. Husbandry and treatment of the dogs were in compliance with the NRC Guide for Laboratory Animals (13), and were approved by the Animal Use and Care Administrative Advisory Committee at University of California, Davis. Six sexually intact male beagles (12.8 ± 0.4 kg, 5–7 y) and 6 male mongrels (37.9 ± 2.1 kg, 5 intact and 1 neutered, 6–8 y), owned by the University, were designated small dogs and large dogs, respectively. The dogs were individually housed simultaneously in semi-open runs in the same building, and they received an allotment of diet each day that was completely consumed by the following day. Body weights (BW) and body condition scores (BCS) were determined each week.

All dogs were given the same, nutritionally complete and balanced, extruded dry-type diet produced for the study (Royal Canin). Dietary protein was limited to 15.6% to provide adequate but not excessive SAA to maintain nitrogen balance and provide for taurine biosynthesis (**Table 1**). The dietary protein content exceeded recommended allowance for maintenance of adult dogs (10% for 16.7 kJ/g metabolizable energy in the diet, dry matter basis) (10,14). Sulfur amino acid bioavailability of the diet was estimated by cecectomized rooster assay (15).

Expt. 1. For 3 mo, the amount of diet given to each dog was adjusted each wk, as needed, to achieve and maintain ideal BCS (5 on a 9 point scale) (16). After 2 mo, baseline venous blood and urine samples were collected, body composition determined, and 14.6 mg/kg BW of 99 atom % deuterated taurine ([1,2-$^2H_2$]-taurine, d4-tau, CDN Isotopes) was given per os in a gelatin capsule wrapped in a marshmallow. Urine collection was repeated each morning before feeding for 5 d after administration of d4-tau. Concentrations of taurine in blood, plasma, and urine, and concentrations of total glutathione (reduced + oxidized), total cyst(e)ine (free plus bound to protein via a sulfhydryl bond), cysteinyl-glycine and homocysteine in plasma, and complete amino acid profiles (including cysteine and cystine not bound to protein) in plasma were determined as previously described (12). Urinary tracer (d4-tau) to tracee (taurine) ratio (TTR) for calculation of TBR of the dogs was determined by GC-MS.

TABLE 1 Composition and properties of the experimental diet[1]

Crude protein, %	15.6
Acid hydrolyzed fat, %	23.2
Crude fiber, %	1.9
Ash, %	8.3
Metabolizable energy,[2] *kJ/g*	18.0
Metabolizable energy from protein, %	12.7
Sulfur amino acid, %	0.60
Methionine	0.34
Cyst(e)ine	0.24
Taurine, *mg/kg*	280.0
Sulfur amino acid digestibility, %	77.9

[1] Ingredient list as provided by the diet manufacturer, Royal Canin: brewer's rice, rice bran, lamb-meal, poultry fat, lamb digest, and proprietary vitamin and mineral mixtures.
[2] Calculated using modified Atwater coefficients in the equation; metabolizable $energy_{kJ/g}$ = [(crude $protein_g$ × 3.5) + (ether $extract_g$ × 8.5) − (nitrogen free $extract_g$ × 3.5) + (crude $fiber_g$ × 0)] × 4.19 (15).

Expt. 2. Control of diet presentation to maintain ideal BCS was continued after Expt. 1 so that SAA intake per MBW could be calculated for each dog. The dogs were then ranked from least to highest SAA intake per MBW, and large and small dogs were paired by rank of SAA intake per MBW to make 6 experimental pairs. The mean SAA intake per MBW for each pair was determined, and the quantity of diet it represented was given to the pairs each d for 2 wk. After 1 wk, blood, plasma, and urine were sampled, body composition determined, d4-tau administration and urine collection repeated, and biochemical analyses conducted, as described in Expt. 1.

Sample collection, processing, and analysis. Blood (~5 mL) was collected from the cephalic vein by venipuncture into heparinized syringes (~20 μL of sodium heparin solution, 1000 USP kU/L, Baxter Health Care). Urine (≅5 mL) was collected by free-catch before feeding.

Taurine concentrations in blood, plasma, and urine were determined by the method of Kim et al. (17) using an amino acid analyzer (12). To normalize urinary taurine concentration, urinary creatinine concentrations were determined with a commercial kit (Cold Stable, Pointe Scientific).

The GC-MS analysis and calculation of TBR from enrichment of TTR in urine were conducted using a modification (12) of the method of Fay et al. (18). MS of the deuterated taurine derivative revealed a unique fragment of 241 m/z, which was assumed to be an M+3 rather than the expected M+4 fragment. Deuterium on carbon adjacent to the sulfonate group of the taurine label was assumed to exchange with available protium during the derivatization step. Use of the M+3 fragment was justified because its fractional abundance increased linearly with increasing enrichment of the M+4 tracer in standards.

TBR was calculated using equations,

$$TBR = \frac{D}{TTR(t_0)} \times (-K)$$

$$TTR = \left(\frac{P_{M+3}}{P_M}\right) sample - \left(\frac{P_{M+3}}{P_M}\right) nature \times \left(\frac{1}{1+A}\right),$$

where D is the dose in mg given, $TTR(t_0)$ is the TTR at time 0 as interpolated from TTR in d 1–5 urine samples, K is the rate constant, P_{M+3} and P_M are areas of peaks corresponding to ions of tracer and tracee, respectively, and A is natural abundance of the isotope used ($^2H = 0.00015$).

Body composition. Lean body mass (LBM) and body fat mass (BFM) was estimated by isotopic water dilution (19,20). For this, sterile filtered (0.2 μm/25 mm Anotop, Whatman), salinated (90 g/L NaCl), deuterated-water (99.9%, Sigma-Aldrich) was subcutaneously injected (0.4 g/kg), and after 4.5 h, cephalic venous blood (2 mL) was collected by venipuncture. Deuterium enrichment in serum water was measured as previously described (20).

Statistical analysis. Effect of body-size (large and small) and means of food intake control (that supporting ideal body condition [Expt. 1] and that supporting similar SAA intakes between large and small dog pairs [Expt. 2]) on food and SAA intakes, TBR, BW, LBM, BFM, and circulating amino acid and thiol concentrations were evaluated using mixed-model ANOVA (PROC MIXED, version 9.1, SAS Institute). Body-size and means of food intake control were assigned as fixed and random effects, respectively, and Tukey multiple comparisons adjustment were used in post-hoc analyses. Significance of correlations between food intake and taurine entry on taurine concentrations in blood, plasma, and urine were determined by regression analysis. Percentage data were transformed [2 × arcsin × $(observation)^{-1/2}$] prior to analyses. Differences were considered significant at $P \leq 0.05$ or a noteworthy trend at $P > 0.05$ and <0.10. Results are expressed as means ± SEM unless otherwise stated.

Results

Clearly, BW and food intake in large dogs were greater ($P < 0.01$) than those in small dogs in Expt. 1 and Expt. 2 (**Table 2**). However, mean SAA intake per MBW of large dogs was 23.2%

TABLE 2 Body composition and food intake of dogs given enough diet to maintain ideal body condition (Expt. 1) or similar amounts per kg MBW between small and large dog pairs (Expt. 2)[1]

	Expt. 1		Expt. 2	
	Small dogs	Large dogs	Small dogs	Large dogs
Body weight, *kg*	12.7 ± 0.3[a]	36.3 ± 1.9[b]	13.1 ± 0.4[a]	38.3 ± 2.7[b]
Lean body mass, *kg*	9.8 ± 0.5[a]	28.5 ± 1.3[b]	8.9 ± 0.4[a]	27.9 ± 2.1[b]
Body fat mass, *kg*	2.9 ± 0.3[a]	8.1 ± 0.7[b]	4.2 ± 0.3[a]	10.5 ± 0.5[c]
Body fat mass, *%*	23.2 ± 2.9[a]	21.9 ± 1.6[a]	32.0 ± 2.5[b]	27.5 ± 1.2[ab]
Food intake, *g/d*	208 ± 12[a]	347 ± 24[b]	257 ± 16[a]	570 ± 21[c]
SAA intake, $g \cdot kg^{-0.75} \cdot d^{-1}$	0.19 ± 0.01[ab]	0.14 ± 0.01[a]	0.22 ± 0.01[b]	0.22 ± 0.01[b]

[1] Observations are before d4-tau administration and represent mean ± SEM, $n = 6$. Values in rows with superscripts without a common letter differ, $P \leq 0.05$).

less ($P < 0.05$) than that of small dogs in Expt. 1 and exactly the same for large and small dogs in Expt. 2 because SAA intake was intentionally controlled for each pair of dogs in Expt. 2 to provide the same amount of the precursor for taurine synthesis (Table 2).

In Expt. 1, plasma ($P < 0.06$) and urine ($P < 0.07$) taurine concentrations tended to be lower in large than in small dogs (**Table 3**). Blood taurine and plasma glutathione, cyst(e)ine, cysteinyl-glycine and homocysteine in Expt. 1 did not differ between large and small dogs ($P > 0.05$). Plasma and blood taurine concentrations in Expt. 2 were 110 and 54% greater in small dogs, respectively, than in large dogs ($P < 0.05$). In contrast, concentrations of urine taurine and plasma glutathione and cyst(e)ine did not differ ($P > 0.05$) between small and large dogs in Expt. 2.

Due to limited sample volume, only 5 plasma samples could be submitted for complete amino acid profile analysis in large dogs for Expt. 1. In Expt. 1 but not Expt. 2, plasma concentrations of glycine ($P < 0.01$) and serine ($P < 0.02$) were greater in large than in small dogs (**Supplemental Table 1**). In Expt. 2 but not Expt. 1, plasma concentrations of tryptophan were less ($P < 0.05$) in large than small dogs. Hydroxyproline was less ($P < 0.04$) in small than in large dogs in Expt. 2. All other plasma amino acid concentrations were not significantly ($P > 0.05$) different between small and large dogs in either experiment.

TABLE 3 Taurine and thiol concentrations in dogs given enough diet to maintain ideal body condition (Expt. 1) or similar amounts per kg MBW between small and large dog pairs (Expt. 2)[1]

	Expt. 1		Expt. 2	
	Small dogs	Large dogs	Small dogs	Large dogs
Taurine concentration				
Plasma, *μmol/L*	69 ± 10[ab]	40 ± 6[a]	86 ± 11[b]	41 ± 15[b]
Blood, *μmol/L*	198 ± 18	157 ± 20	232 ± 30	151 ± 21
Urine, $\mu mol \cdot L^{-1} \cdot mg\ creatinine^{-1}$	13 ± 4.5	1.8 ± 0.9	10.0 ± 3.4	3.6 ± 3.3
Thiol concentration in plasma, *μmol/L*				
Glutathione	13 ± 1.3[a]	15 ± 1.2[ab]	16 ± 1.[b]	17 ± 1.0[b]
Cyst(e)ine	182 ± 23	200 ± 10	164 ± 10	170 ± 12
Cysteinyl-glycine	14 ± 1.0	20 ± 3.0	nd[2]	nd
Homocysteine	10 ± 0.9	10 ± 1.9	nd	nd

[1] Observations are before d4-tau administration and represent mean ± SEM, n = 6. Values in rows with superscripts without a common letter differ, $P \leq 0.05$.
[2] nd, not determined.

The TBR were normalized to BW, MBW, relative liver weight (RLW, $kg^{0.87}$), LBM, and metabolic LBM (MLBM, LMB $kg^{0.75}$) (**Table 4**). TBR was normalized to RLW for comparison between large and small dogs because the liver is the major organ of taurine biosynthesis in dogs (21). For Expt. 1, all normalized TBR were lower ($P < 0.05$) in large compared with small dogs, where the per MBW, LBM, MLBM, and RLW TBR were lower by 49, 37, 48, and 43%, respectively. In Expt. 2, TBR/LBM was lower ($P < 0.03$) and TBR/BW tended to be lower ($P = 0.06$) in large than in small dogs.

Taurine entry rate in dogss (taurine synthesized + ingested food each day) was determined for Expt. 1 and 2. The entry rates were then normalized by BW, MBW, RLW, LBM, and MLBM and regressed against the indicators of taurine status. Each of the normalized entry rates and taurine concentrations in blood and plasma were positively correlated ($P < 0.05$) in both experiments (**Supplemental Table 2 and Supplemental Fig. 1**). Relative to the blood and plasma correlations, correlations between urine taurine concentration and taurine entry rates were higher in Expt. 2 and lower or not significant ($0.05 < P < 0.1$) in Expt. 1.

With decreasing percentage of food intake relative to that expected based on BW (10,22), concentrations of taurine in Expt. 1 decreased ($P < 0.05$) in plasma, blood, and urine (Supplemental Table 2 and **Supplemental Fig. 2**). The same relations between food intake and indicators of taurine status were not significant ($P > 0.33$) in Expt. 2, where the range in food intake was substantially less (32–44 g/MBW) than that in Expt. 1 (17–35 g/MBW).

Discussion

The major difference between the 2 experiments of this study was the way in which food intake (i.e., SAA intake) was controlled. In Expt. 1, all dogs were given enough diet to maintain an ideal BCS for 3 mo including the period when TBR was determined. This feeding condition resulted in similar body fat percentages among the small and large dogs (Table 2) and body fat percentages consistent with previously reported ideals in dogs (16). Thus, in Expt. 1, TBR associated with maintenance energy intake of small and large dogs was determined. The most salient finding of Expt. 1 was that, although large dogs consumed 67% more diet than small dogs (Table 2), their TBR were similar to those of small dogs (Table 4), whereas there was a trend for lower plasma taurine concentrations ($P = 0.06$) than those of small dogs (Table 3). It is noteworthy in this context that mean plasma and blood taurine concentrations in the large, but not the small dogs, were indicative of marginal taurine status

TABLE 4 Taurine biosynthesis rate in dogs given enough diet to maintain ideal body condition (Expt. 1) or similar amounts per kg MBW between small and large dog pairs (Expt. 2)[1]

Taurine biosynthesis rate	Expt. 1		Expt. 2	
	Small dogs	Large dogs	Small dogs	Large dogs
Total, *mg/d*	749 ± 53	816 ± 218	752 ± 97	1228 ± 315
BW, $mg \cdot kg^{-1} \cdot d^{-1}$	59.1 ± 4.4[a]	22.3 ± 6.0[b]	58.4 ± 6.5[ac]	3′.6 ± 7.5[bc]
MBW, $mg \cdot kg^{-0.75} \cdot d^{-1}$	112 ± 8[a]	54.7 ± ′5[b]	111 ± 13[a]	78.8 ± 19[ab]
RLW, $mg \cdot kg^{-0.87} \cdot d^{-1}$	82.2 ± 6.1[a]	35.5 ± 9.6[b]	80.0 ± 8.9[a]	50.4 ± 12[a]
LBM, $mg \cdot kg^{-1} \cdot d^{-1}$	77.0 ± 5.0[a]	28.3 ± 7.3[b]	83.7 ± 8.0[a]	42.9 ± 9.9[b]
MLBM, $mg \cdot kg^{-0.75} \cdot d^{-1}$	136 ± 8[a]	65.6 ± ′7.1[b]	145 ± 15[a]	99.0 ± 23.4[a]

[1] Total and normalized taurine biosynthesis rates are expressed as mean ± SEM, $n = 6$. Values in rows with superscripts without a common letter differ, $P \leq 0.05$.

(11). The plasma taurine concentration observed in 1 large dog (15 μmol/L) was similar to concentrations reported in dogs with DCM that was corrected by taurine supplementation (11,12). These results support the hypothesis that large compared with small dogs are at greater risk for development of taurine deficiency when dietary SAA concentrations are marginal.

Urine taurine concentration was determined because it reflects acute changes in taurine status as a result of renal homeostatic modulation of taurine excretion (23). Variances in urine taurine concentrations within dog groups were great compared with variances observed in blood and plasma taurine concentrations. Nonetheless, there was a trend ($P = 0.07$) for urine taurine concentrations to be lower in large compared with small dogs in Expt. 1(Table 3). This finding is consistent with a trend of a lower taurine status in large compared with small dogs consuming the same diet.

The lower than expected TBR in large dogs appears to be at least partially a result of lower than expected SAA intake by large dogs. Although the large and small dogs were housed in the same environment during the experiments, large dogs consumed less diet (and therefore less SAA) on a MBW basis than small dogs to maintain ideal body condition (Table 2, Expt. 1). Energy intakes of small dogs [555 ± 29 kJ $\cdot$ kg$^{-0.75}$ $\cdot$ d^{-1}] were very close to intakes that would be predicted from body weight using a well established allometric relation [552 kJ $\cdot$ kg$^{-0.75}$ $\cdot$ d^{-1}, (10)]. In contrast, energy intakes of large dogs were substantively less than those that would be predicted [427 ± 37 kJ $\cdot$ kg$^{-0.75}$ $\cdot$ d^{-1}]. Variations in breed attributes other than body weight, such as conformation, hair coat, and physical activity, may account for deviations in scaling of maintenance energy intake (22,24). The observed positive correlations between taurine status indicators (blood, plasma, and urine taurine concentrations) and food intake (Supplemental Fig. 1 and Supplemental Table 2) indicates that food intake differences probably accounted for the observed size-effects on TBR and taurine status.

To the authors' knowledge, the scaling of taurine metabolism with body mass has not been reported. In Expt. 2, exactly the same amount of SAA per MBW was given to each pair of small and large dogs so that effect of metabolic body size on TBR could be evaluated when the same quantity of substrates of taurine metabolism is provided. It was presumed that taurine metabolism scales with MBW as is reported with metabolism of other nutrients (25,26). However, although food intake was controlled according to MBW in Expt. 2, correlations between taurine entry and indicators of taurine status were greatest with taurine entry rate normalization by BW and LBM (Supplemental Table 2). This may indicate taurine entry scales linearly rather than exponentially with body weight.

In Expt. 2, SAA intake relative to that in Expt. 1 was increased in both large and small dogs, but more so in large dogs (69 ± 15 vs. 24 ± 4%). The TBR in large dogs tended to be lower than those in small dogs after normalization to MLBM ($P = 0.32$) and RLW ($P = 0.20$) (Table 4). These normalizations were used because most taurine synthesis occurs in the lean mass, especially liver (23), and the percentage body fat in small compared with large dogs tended to be greater, in Expt. 2 ($P = 0.31$) relative to Expt. 1 ($P = 0.99$) (Table 2). Together, findings of the experiments indicate that the observed body-size effect on TBR was primarily a result of size-related difference in SAA intake relative to expected energy needs.

Plasma thiol concentrations did not differ between large and small dogs but plasma cysteinyl-glycine tended ($P = 0.10$) to be higher in large dogs. However, a trend ($P < 0.10$) of higher cysteinyl-glycine concentration was found in large compared with small dogs in Expt. 1. Lower intake of dietary SAA in large dogs relative to small dogs may result in lower γ-glutamyl transpeptidase (EC 2.3.2.2) and dipeptidase (EC 3.4.3.5) activities to hydrolyze plasma glutathione and cysteinyl-glycine (23). This should spare plasma glutathione and cysteinyl-glycine, maintaining homeostatic concentrations of these thiols.

Most of plasma amino acid concentrations (Supplemental Table 1) were similar to or greater than those in other reports with healthy dogs (27,28). The exceptions were proline, hydroxyproline and a few other dispensable amino acids. This indicates that the experimental diet and amount consumed were adequate for maintenance of protein and amino acid balance, with the exception of taurine (29). The low-normal plasma concentrations of free cyst(e)ine in dogs in this study are consistent with the experimental diet providing SAA sufficient for protein synthesis, but not sufficient for optimal taurine status in large dogs.

In summary when a low, but adequate, protein diet was given to dogs of varying body size to maintain ideal body condition, a trend of lower taurine concentrations in blood, plasma, and urine was found in large dogs, but not in small dogs. Some large dogs had taurine deficiency (plasma taurine ≤40 μmol/L) such that, if continued for the long-term, would be at risk for development of taurine-deficiency DCM. Our results support the hypothesis that the rate of taurine synthesis in large dogs is lower than that in small dogs when taurine precursor SAA are not in excess. In general, large relative to small dogs appear to be at greater risk for taurine deficiency because they ingest less diet for their MBW than small dogs. We conclude that the SAA allowance should be increased enough for large-breed dogs and dogs with low maintenance energy requirement to enable them to maintain an optimal taurine status.

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Congestive Cardiomyopathy in the Canine

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Congestive Cardiomyopathy in the Canine

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Introduction

Diseases of the myocardium can be classified either as primary or secondary. Primary cardiomyopathies include idiopathic congestive or hypertropic forms. Causes of secondary cardiomyopathies are primary, systemic diseases, the most common of which are infectious, metabolic, toxic, ischemic, and neoplastic diseases that cause some myocardial damage.

Idiopathic congestive cardiomyopathy of dogs was first recognized as a specific disease in 1970.[1] This disease is characterized by a progressive dilation of all cardiac chambers which results in decreased contractility and cardiac output. This leads to congestive heart failure and its compensatory mechanisms. As the atria continue to dilate, arrhythmias can be seen, the most common being fibrillation and premature ventricular contraction. These arrhythmias cause further reduction in cardiac output, thus increasing the degree of congestive heart failure.[2]

Congestive cardiomyopathy is also known to occur in other species as well as humans. Specific forms of the disease have been described in boxers and Doberman pinschers.[2,3]

Incidence

Idiopathic congestive cardiomyopathy is the most common cardiomyopathy in the dog. Generally, the disease is seen most often in large and giant breed dogs. The most common breeds are listed as Great Dane, Doberman pinscher, Saint Bernard, Irish setter, English bulldog, Newfoundland, standard poodle, Great Pyrenees, Afghan hound, Scottish deerhound, bull-mastiff, Bouvier des Flandres, greyhound, Labrador retriever, Chesapeake Bay retriever, and Gordon setter.[1]

The disease may strike dogs between the ages of four months and 11 years, but it most commonly occurs in the middle years of three through eight.[1,3,6] The incidence is much higher in males than females.

History

The historical complaints many times give a vague picture of illness. These dogs often present with anorexia, weight loss, weakness and general debility.[4] The signs can be descriptive of right, left or combined heart failure. They would include abdominal distention caused by ascites, hepatomegaly, or splenomegaly, or even loose stools as a result of venous stasis in the gut.[7] Owners may also describe respiratory signs such as coughing, hacking, and dyspnea.[1,6] Other possible complaints are exercise intolerance and syncope.

The onset is usually subacute, including a gradual deterioration over a one to three week period. Also possible is a more acute type onset over a two or three day period. Most likely the sudden onset occurs after a prolonged period of subclinical disease, and leads finally to atrial fibrillation which forces a rapid decompensation and resulting signs of heart failure.[2]

Physical Exam

The physical exam often includes weakness, depression and general malaise. Respiratory signs will include dyspnea, orthopnea, and a moist, productive cough.[2,8] Decreased capillary refill time and cyanotic mucous membranes are sometimes noted. The pulse is rapid (150–250 beats per minute) and irregular in rate and strength. During atrial fibrillation or ventricular premature contractions, there will be a pulse deficit. Ascites may be detected by abdominal distention and a fluid wave on bal-

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lottement.[2] Also seen are venous distention, engorgement of subcutaneous veins, and jugular pulses if tricuspid insufficiency has developed. On abdominal palpation hepatosplenomegaly is frequently present.

Auscultation

Over the lung fields coarse bubbling rales are heard, suggestive of pulmonary alveolar edema.[1] Often pleural fluid is recognized by muffled lung sounds below a fluid line.[8]

The heart sounds may be hard to evaluate due to the loud background respiratory noise and the rapid heart rate. An irregular tachycardia (up to 280 beats per minute) with detectable pulse deficit is often found. Dilation of the heart may cause a moderate systolic murmur over the mitral valve area or a diastolic gallop.[1,2] Characteristically with atrial fibrillation, the first heart sound intensity will vary from one beat to the next.[8]

Clinical Diagnostics

Blood serum parameters are usually not grossly abnormal, but severe congestive heart failure can cause some abnormal values. Prerenal azotemia can be caused by decreased renal perfusion. Hypoproteinemia and hyponatremia are the results of simple dilution of the fluid retained by the kidneys with decreased perfusion.[8] Hepatic congestion may result in liver enzyme leakage. Elevated SGOT and LDH values are probably due to liver congestion rather than cardiac muscle disease.[2] Pleural and abdominal fluid are generally evaluated as true or modified transudates.[2]

Hypothyroidism has been reported as being a related condition in idiopathic congestive cardiomyopathy.[2,8] Thyroid function tests may give interesting data, but the relative diagnostic significance, insofar as this disease is concerned, is as yet undetermined.[2]

Radiographically the major abnormality found is a moderately large to large cardiac shadow on chest films. Also, pulmonary venous distention two to three times normal size with rapidly diminishing size as the veins extend into the lung fields is a helpful diagnostic lesion.[8] Left atrial enlargement can become big enough to displace the left main stem bronchus dorsally.[8] On angiocardiography, researchers have found dye retention in the ventricles with no difference between end-systolic and end-diastolic volumes.[9]

Chest radiographs will often have evidence of pulmonary edema and pleural fluid. The abnormal findings are described as alveolar patterns or interstitial-alveolar patterns. If abdominal films are taken, hepatomegaly and the "ground glass" density of ascites are common findings.

The electrocardiograms of congestive cardiomyopathy dogs are generally helpful in diagnosis. By far the most common arrhythmia seen is atrial fibrillation. Atrial fibrillation is a supraventricular arrhythmia recognized by tachycardia (180–280 beats per minute), random R-R intervals, absence of P waves, and baseline fluctuations called F waves.[2,8] The QRS complex can be normal or increased in amplitude and/or duration with left ventricular enlargement. Also, in the absence of atrial fibrillation, atrial enlargement (P mitrale or P pulmonale) can be seen.[8] Generally, the mean electrical axis will be normal in these dogs.[2] In a smaller percentage of the cases (approximately 20%), and often late in the disease, ventricular premature contractions have been observed.[7,8] S-T segment depression and T wave changes have also been observed.[2]

These findings may be the result of myocardial degeneration, or hypoxia and microinfarctions due to decreased coronary circulation.[1] Also described in rare cases is evidence of conduction disturbances.[8]

Differential Diagnosis

Other causes of right heart failure and ascites must be ruled out when diagnosing congestive cardiomyopathy. Dirofilariasis is an important differential diagnosed by microfilariaemia, right axis deviation on the ECG, and specific changes in pulmonary artery configuration on chest radiographs. Sometimes an occult heartworm test is needed to confirm dirofilariasis. Pericardial effusion or restrictive pericarditis should be considered with muffled heart sounds, cardiac friction rub, or elevated central venous pressure. Other rule-outs would include congenital cardiac anomalies as cause for heart failure or abdominal neoplasia and hypoproteinemia for ascites.[1]

Therapy

Congestive cardiomyopathy has no specific cure, so therapy is aimed at clinical management for symptomatic improvement. Generally, the disease is managed as a congestive heart failure.[7]

There are four major goals of therapy to serve as guidelines: (1) attempt to strengthen

the heart muscle as a pump; (2) decrease the workload of the heart thereby sparing the pump; (3) prevent secondary damage to other organs as a result of heart failure; and (4) promote recovery of myocardial function.[1] Therapy will ultimately be a combination of treatments with each case being managed individually.[8] In the acutely symptomatic patient, it is important to avoid stress to the dog, which might result in further decompensation. If necessary, acepromazine or morphine may be administered to reduce anxiety.

To strengthen the heart muscle as a pump, digoxin is used. Digoxin will reduce the heart rate making the pump more efficient. Also, the contractile strength of the heart is increased.[7] The speed of digitalization is dependent on the severity of the condition. Rapid intravenous digitalization is reserved for life-threatening situations.[9] It should be remembered that large breed dogs require smaller doses of digoxin per pound than used for other dogs.

Positive signs of effective digitalization are diuresis and reduced heart rate.[8,10] The heart rate at full digitalization should be in the 80–120 beats per minute range. Also signs of toxicity, such as anorexia, vomiting, diarrhea, and cardiac arrhythmias, should be monitored.[8,10]

If the heart rate is effectively altered with digoxin, a beta-adrenergic blocker such as propranolol can be used. Propanolol will help slow the heart rate, suppress ventricular premature contractions, and help restore normal sinus rhythm to atrial contractions.[7] However, propanolol has a negative inotropic effect on the heart muscle, and thus should only be used with or following digoxin therapy.[8]

Decreasing the workload of the heart is an important objective of therapy, and this can be done in more than one way. Afterload can be decreased by vasodilators such as acepromazine. Preload can be reduced with diuretics.[1] Diuretics can also help reduce pulmonary edema and thus increase blood oxygenation.[1] Furosemide given intravenously is used in critical patients.[9]

In preventing secondary damage to other organs, perfusion and oxygenation are the keys. Digoxin and diuretics help considerably towards this goal; however, if the dog is cyanotic or severely dsypneic, oxygen therapy is indicated.[9]

To promote recovery of myocardial function, long-term management must be considered.

Dietary management with low salt or low sodium content feeds is advised to reduce the resulting fluid retention.[10] These diets can be home-prepared or commercially obtained.[10] Exercise restrictions also are necessary in long-term managment to keep the cardiac work load down and to avoid catecholamine and sympathetic affects on a now-irritable myocardium.

Pathology

The most significant gross pathological findings are in the heart. Cardiac lesions include a large rounded heart, thin-walled, dilated chambers, ruptured chordae tendineae, endocardial jet lesions, dilated atrioventricular annular rings, and disseminated foci of myocardial necrosis.[2,4,8,11]

The rest of the gross pathology found is generally related to a failing heart muscle. These findings include hepatic congestion, pulmonary congestion, ascites, hydrothorax, and infarcts in multiple organs.[3,11]

On histological sections of cardiac muscle, the lesions found are subendocardial necrosis and scattered myocardial necrosis and fibrosis.[11] Also seen in cardiac muscle are irregularly-sized muscle fibers.[3] Small to medium sized myocardial arteries have intimal and medial hyperplasia. Ultrastructural changes in the myocardial cells include sarcoplasmic vacuoles, lipofuscin granules, proliferated elements of sarcoplasmic reticulum and mitochondrial alterations.[3,11] None of these ultrastructural changes are considered pathognomonic for congestive cardiomyopathy; however, many of these nonspecific changes of myocardial necrosis are seen in similar cardiac diseases in cats and humans.[11,12]

Prognosis

Long-term survival of these dogs is unlikely, with most authors suggesting 6–12 months maximum survival time.[1,7,8] It has been observed that the prognosis is generally worse in Doberman pinschers. Considering the grave prognosis, emphasis should be placed on correct diagnosis and therapeutic management as long as the dog can be kept comfortable. At that point in the progression of the disease, where the animal is judged to be suffering from decompensation unresponsive to treatment, the humane option may be euthanasia.

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Taurine and Carnitine in Canine Cardiomyopathy

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Dilated cardiomyopathy (DCM) is one of the most common acquired cardiovascular diseases in dogs [1–4]. Although few studies of the prevalence of DCM in the overall population of dogs have been reported, estimates range from 0.5% to 1.1% [5,6]. Only degenerative valvular disease and, in some regions of the world, heartworm infection are more common causes of cardiac morbidity and mortality in dogs. DCM is seen most commonly in large and giant breeds of dogs, although its frequency seems to be increasing in medium-sized breeds, such as the English and American cocker spaniels [4–8]. It has been reported rarely in small and miniature breeds of dogs [9].

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Effects of dietary fat and L-carnitine on plasma and whole blood taurine concentrations and cardiac function in healthy dogs fed protein-restricted diets

Sherry L. Sanderson, DVM, PhD; Kathy L. Gross, PhD; Phillip N. Ogburn, DVM, PhD; Clay Calvert, DVM; Gil Jacobs, DVM; Stephen R. Lowry, PhD; Kathy A. Bird; Lori A. Koehler; Laurie L. Swanson

Objective—To evaluate plasma taurine concentrations (PTC), whole blood taurine concentrations (WBTC), and echocardiographic findings in dogs fed 1 of 3 protein-restricted diets that varied in fat and L-carnitine content.

Animals—17 healthy Beagles.

Design—Baseline PTC and WBTC were determined, and echocardiography was performed in all dogs consuming a maintenance diet. Dogs were then fed 1 of 3 protein-restricted diets for 48 months: a low-fat (LF) diet, a high-fat and L-carnitine supplemented (HF + C) diet, or a high-fat (HF) diet. All diets contained methionine and cystine concentrations at or above recommended Association of American Feed Control Officials (AAFCO) minimum requirements. Echocardiographic findings, PTC, and WBTC were evaluated every 6 months.

Results—The PTC and WBTC were not significantly different among the 3 groups after 12 months. All groups had significant decreases in WBTC from baseline concentrations, and the HF group also had a significant decrease in PTC. One dog with PT and WBT deficiency developed dilated cardiomyopathy (DCM). Taurine supplementation resulted in significant improvement in cardiac function. Another dog with decreased WBTC developed changes compatible with early DCM.

Conclusions and Clinical Relevance—Results revealed that dogs fed protein-restricted diets can develop decreased taurine concentrations; therefore, protein-restricted diets should be supplemented with taurine. Dietary methionine and cystine concentrations at or above AAFCO recommended minimum requirements did not prevent decreased taurine concentrations. The possibility exists that AAFCO recommended minimum requirements are not adequate for dogs consuming protein-restricted diets. Our results also revealed that, similar to cats, dogs can develop DCM secondary to taurine deficiency, and taurine supplementation can result in substantial improvement in cardiac function. (*Am J Vet Res* 2001;62:1616–1623)

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Taurine status in normal dogs fed a commercial diet associated with taurine deficiency and dilated cardiomyopathy

By C. L. Tôrres, R. C. Backus, A. J. Fascetti and Q. R. Rogers

Summary

Taurine (Tau) deficiencies have been associated with the feeding of commercial lamb-meal and rice diets to dogs. We hypothesized that the poor digestibility of some lamb-meals may limit sulphur amino acids availability for Tau synthesis and/or increase of Tau degradation in the gut. Growing dogs were fed either a lamb-meal-based (Diet A) or poultry by-product-based (Diet B) commercial diet. Plasma, whole blood and urinary Tau were measured for 22 weeks. Plasma and whole blood Tau concentrations were similar between the groups throughout the study. Urinary excretion of Tau in dogs fed diet A was 3.2 times greater than that from dogs fed Diet B, suggesting greater renal reabsorption and the need for conservation of Tau in the Diet A group. Food restriction affected Tau status as indicted by a positive correlation of food intake and urinary Tau. Dogs fed Diet A were given antibiotics to inhibit bacterial activity in the gut. Increases in breath hydrogen, indicative of increased bacterial activity, correlated negatively with urinary Tau. Urinary Tau increased by 54% when methionine (Met) was supplemented to Diet A, supporting the suggestion of a low bioavailability of sulphur amino acids and/or an increased fecal loss of Tau in dogs consuming Diet A.

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Determination of the prevalence of whole blood taurine in Irish wolfhound dogs with and without echocardiographic evidence of dilated cardiomyopathy☆

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KEYWORDS
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Abstract ***Objectives:*** Taurine plays an important role in maintaining myocardial function. Irish wolfhound dogs (IW) are at risk for dilated cardiomyopathy (DCM), but a relationship between whole blood taurine (WBT) deficiency and DCM has not been established. Our aim was to determine prevalence of WBT deficiency in IW with and without DCM and assess its association with diet.
Animals: 115 privately owned IW.
Methods: Whole blood taurine was measured in IW that received cardiovascular examination. Dietary history was recorded; crude protein and energy intake were estimated.
Results: Forty-nine (42.6%) had DCM; 66 (57.4%) had no DCM. Dogs with DCM were older ([median; inter-quartile range or IQR] 5.3; 4.3, 6.2 years) than dogs without heart disease (3; 2, 4 years; $P < 0.001$). There was no significant relationship between WBT concentration and age ($P = 0.64$). Whole blood taurine was severely reduced (<130 nmol/mL) in 8 dogs (4 with and 4 without DCM) and moderately reduced (130–179.9 nmol/mL) in 32 dogs (12 with DCM and 20 without DCM). Follow

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up of dogs without DCM revealed that a higher proportion of dogs with any degree of WBT deficiency developed DCM later compared to dogs with normal WBT ($P < 0.001$).

Conclusions: Whole blood taurine deficiency occurred in IW with and without DCM. Based on taurine measurement on a single occasion, there was no clear relationship between low WBT and presence of DCM in this population. Regardless of WBT, DCM affected predominantly older dogs, suggesting a relatively late onset disease in the IW.

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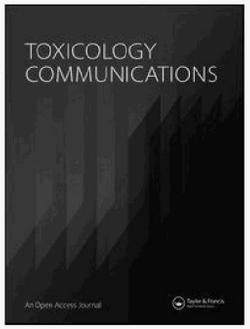

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Comparison of mycotoxin concentrations in grain versus grain-free dry and wet commercial dog foods

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Comparison of mycotoxin concentrations in grain versus grain-free dry and wet commercial dog foods

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ABSTRACT

Mycotoxins are secondary fungal metabolites that cause both acute and chronic disease in humans and animals. Grains are a common substrate for molds and the production of mycotoxins. This study compared mycotoxin concentrations between grain and grain-free commercial dog foods. In total, 60 samples of dry and wet dog foods produced by five major manufacturers within the US were purchased from pet food retailers in southern California. A standard mycotoxin panel was performed by a reference laboratory in Seattle using industry standard methodology for pet foods. Results of the study demonstrated measurable mycotoxin concentrations in dry dog foods containing grains but not in grain-free dry dog foods, or in wet foods either containing grains or grain-free. This study suggests that the risk of mycotoxin exposure is higher in dry dog foods containing grains. To mitigate this risk, dog food manufacturers could incorporate grains that are categorized as US No. 1 by the USDA and therefore less susceptible to mycotoxin formation.

KEYWORDS

Mycotoxin; dog food; grain; grain-free; fumonisin

Introduction

Grains, particularly corn and wheat, have been used as sources of carbohydrates in pet food formulations for decades [1]. Recently, grain co-products from corn, such as corn gluten meal, or bran derived from whole grains like barley and oats, are also commonly added to pet foods as indigestible fiber sources [1]. In recent years grain-free diets for companion animals have been gaining popularity among pet owners [2, 3] who often choose grain-free diets because of perceived health benefits. Sales of grain-free pet foods increased by 28% in US pet stores during a one-year period from September 2012 to September 2013. In 2015, 45% of all new pet food items introduced were grain-free [2, 3]. Despite this increasing popularity of grain-free diets, there are very few scientific studies determining what, if any, benefits these diets may provide.

One of these perceived health benefits of grain-free diets is the possibility to reduce grain consumption by companion animals, theoretically reducing the risk of potential exposure to mycotoxins [4]. Mycotoxins are secondary metabolites produced by filamentous fungi that can contaminate grains, often due to improper grain storage. The most common contaminants of feed include aflatoxins, fumonisins, ochratoxin A, zearalenone, and the trichothecenes deoxynivalenol, T-2 toxin, and HT-2 toxin. These mycotoxins have a variety of harmful cytotoxic mechanisms [5].

Raw grains, feed ingredients, and finished feed are governed by specific regulatory guidelines [6, 7] but mycotoxin contamination is particularly difficult to avoid because mycotoxins are relatively robust to heat and chemical inactivation processes in downstream processing steps [7, 8]. A study conducted in Poland found multiple mycotoxins in dry veterinary diets for dogs [9]. Among the various mycotoxins detected in the veterinary diets zearalenone was detected in 69% of samples, deoxynivalenol (DON) in 52%, fumonisin B1 in 33%, and nivalenol in 26% [9]. The clinical effects of mycotoxins vary based on type, concentration, and frequency of exposure. Some mycotoxins cause morbidity and mortality both acutely due to high dose exposures and chronically after prolonged low-dose exposures. Effects can include acute toxicosis such as acute hepatic injury presenting as anorexia, depression, gastrointestinal hemorrhage, jaundice or seizures [10, 11]. Chronic diseases such as liver and kidney fibrosis, infections resulting from immunosuppression,

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and cancer have been associated with low-dose, chronic mycotoxin exposure [10, 11]. In one clinical study, a combination of mycotoxins including aflatoxin B1, aflatoxin B2, fumonisin B1, fumonisin B2, ochratoxin A, and zearalenone induced immunotoxicity on canine peripheral blood mononuclear cells [5]. Therefore, the potential for mycotoxin contamination in pet food poses a serious health threat [12].

Regulations regarding permissible concentrations of mycotoxins in animal feeds focus mainly on farm animals used for food production. While much of what is known about mycotoxins in animals is based on toxicological data demonstrating adverse effects in farm and laboratory animals exposed to naturally occurring concentrations of mycotoxins, there is perhaps even more concern for companion animals who are often maintained and fed for longer periods of time on a homogeneous, grain-containing diet and thus more likely to have chronic exposures to pet foods contaminated with either single mycotoxins, or multiple mycotoxins in various combinations [4]. Maximum concentrations permitted in pet foods are generally extrapolated from a generalized "other animal" category, meaning non-food animal guidelines rather than pet-specific regulations [4]. However, these concentrations do not necessarily indicate "safe levels" for mycotoxin exposure in companion animals [13] since very few studies have been conducted in pets. Moreover, none of these studies have investigated the long-term chronic exposures that likely occur if pets are fed a contaminated feed over a typical lifespan [4, 13]. Due to this uncertainty, one of the perceived health benefits of grain-free diets might be due to the elimination of low-dose chronic exposures to mycotoxins, as grains in pet food are presumed to be the main source of mycotoxin contamination [4]. However, the true prevalence of mycotoxins in either grain-containing or grain-free pet food has not been systematically examined.

While there have been only a few reports, previous studies have detected mycotoxins in dog foods, especially dry foods. Dry dog foods contain 3–11% moisture, while wet dog foods contain 60–87% moisture [14]. DON contamination was common in studies conducted in Austria [15] and Italy [16]. In both of these studies, measurable concentrations of DON were detected in all dry food samples. A broad range of DON concentrations in dry food were found in the Austrian study and 27% of wet food samples also contained detectable concentrations of DON [15]. A second study conducted in Austria found similar patterns of DON, fumonisins, and zearalenone [4]. A study conducted in Brazil also reported low-levels of multiple mycotoxins in dry dog foods [8]. In all four of these studies mycotoxins produced by *Fusarium* species of fungi were most common, often contaminating the same dog food with three different types of mycotoxins [8].

In the current study, we sampled wet and dry commercial dog foods produced by five different manufacturers with and without grains and measured the concentrations of 11 mycotoxins in these samples.

Methods

Samples were obtained from five different brands in an attempt to broadly sample commercially available dog food from different supply chains. All pet foods sampled were manufactured in the U.S. following US guidelines for the manufacturing of dog food. Formulations from the same brand were paired such that the only significant difference in the ingredients list was the presence or absence of grain. For example, adult maintenance formulations were chosen by the same product name clearly labeled as either containing grains, or as grain-free, ensuring brand consistency across all paired samples. Six dry food (three containing grains and three grain-free) and six wet food samples (three containing grains and three grain-free) were obtained for each manufacturer except for one manufacturer that does not formulate any dry foods. Because the number of samples was constrained by cost, we ignored brand designation in all analyses, clustering the samples only as dry versus wet food and grain-containing or grain-free food.

A total of 60 dog food samples were analyzed for 11 different mycotoxins using stable isotope dilution LC-MS/MS methodology at IEH Laboratories (Seattle, WA) [17, 18]. Analytical detection limits ranged from 1.0 ppb to 0.10 ppm depending on the mycotoxin (Table 1).

Table 1. Detection limits for each mycotoxin analyzed.

Mycotoxin	Reporting Limit
Aflatoxin B1	1.0 ppb
Aflatoxin B2	1.0 ppb
Aflatoxin G1	1.0 ppb
Aflatoxin G2	1.0 ppb
Deoxynivalenol	0.10 ppm
Fumonisin B1	0.10 ppm
Fumonisin B2	0.10 ppm
HT-2 Toxin	0.10 ppm
Ochratoxin A	2.0 ppb
T-2 Toxin	0.10 ppm
Zearalenone	20 ppb

Results

Only dry dog foods containing grains had detectable mycotoxin contamination, and only mycotoxins that are products of the *Fusarium* genus were detected (Table 2). Of the 12 dry dog foods containing grains that were analyzed, nine of the twelve had at least one detectable *Fusarium* mycotoxin (Table 3). For DON and fumonsin B1, 9/12 dry grain foods were above detection limits while 8/12 samples were positive for fumonsin B2 and 4/12 samples tested positive for zearalenone (Table 3). These results are consistent with findings from studies conducted in Austria [4, 15], Italy [16], and Brazil [8]. None of the 60 samples tested had concentrations above the detection limits for aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, HT-2 toxin, ochratoxin A, or T-2 toxin. When considered by brand, at least one of the four *Fusarium* mycotoxins was found in each of the four brands of dry grain foods (Table 4). For two brands (Brand 4 and Brand 5), at least one of the three samples tested were positive for all four *Fusarium* mycotoxins (Table 4).

The US Food and Drug Administration (FDA) has published guidance concentrations for pet foods, but not regulatory limits, for aflatoxin, fumonisin, and DON [6]. The guidance concentration is 10 ppm for total fumonisins (fumonisin B1 + fumonisin B2 + fumonisin B3). The concentrations detected in this study were below the 10 ppm guidance value (Figures 1–4).

Table 2. Number of samples with values above the detection threshold for deoxynivalenol, fumonisin B1, fumonisin B2, and zearalenone respectively, according to grain and food type for all samples.

	Dry	Wet
Grain	9, 9, 8, 4 ($n = 12$)	0, 0, 0, 0 ($n = 18$)
Grain-free	0, 0, 0, 0 ($n = 12$)	0, 0, 0, 0 ($n = 18$)

For the only category with positive values (Dry Grain; shown as shaded) the data are shown in more detail by brand in Table 4.

Discussion

In this study, we identify low-level *Fusarium*-derived mycotoxin contamination in grain-containing dry dog food but did not detect any mycotoxin contamination in either grain-free dry dog food or wet dog food. In addition, none of the analyzed samples contained aflatoxins in detectable concentrations, which may reflect how regulatory and control strategies have been effective in reducing the incidence of aflatoxins in dry commercial dog foods. The presence of *Fusarium* mycotoxins highlights the need to establish similar control strategies targeting these mycotoxins, especially for the manufacture of dry dog foods. We found *Fusarium*-derived mycotoxin concentrations well below amounts considered to be acutely toxic to dogs, but these data support the possibility that feeding grain-containing pet food may result in chronic exposure to a variety of mycotoxins. The effects of chronic low-level mycotoxin exposure in dogs remain unknown but merit further study [4].

Dry dog foods contain higher amounts of grains than wet dog foods, potentially explaining the higher levels of mycotoxins in grain-containing foods. Grains in these dog foods are the most likely source of mycotoxin contamination, although we cannot be certain of the source because we only analyzed end products in this study. When grains are incorporated into dog food formulations it is important that high quality grain is used. Grain quality is correlated with

Table 3. Concentration ranges and number of positive samples for mycotoxins detected in dry dog food.

Dry Dog Food	Deoxynivalenol (0.10 ppm)	Fumonisin B1 (0.10 ppm)	Fumonisin B2 (0.10 ppm)	Zearalenone (20 ppb)
Grain ($n = 12$)	$n = 9$	$n = 9$	$n = 8$	$n = 4$
Concentration Range	0.12–0.32 ppm	0.32–3.2 ppm	0.21–1.6 ppm	24–65 ppb
Grain-free ($n = 12$)	0	0	0	0

Analytical detection limits are shown in parentheses for each mycotoxin.

Table 4. Number of samples with values above the detection threshold for deoxynivalenol, fumonisin B1, fumonisin B2, and zearalenone respectively, according to brand for dry grain samples.

	Dry, Grain
Brand 1	3, 0, 0, 0 ($n = 3$)
Brand 2	$n = 0$
Brand 3	3, 3, 2, 0 ($n = 3$)
Brand 4	2, 3, 3, 3 ($n = 3$)
Brand 5	1, 3, 3, 1 ($n = 3$)

For Brand 2, no dry grain product is sold. For each of the four other brands three samples were tested. N/A = not applicable.

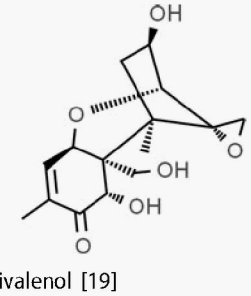

Figure 1. Deoxynivalenol [19]

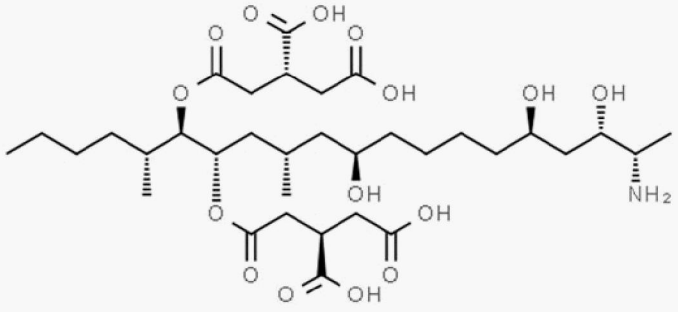

Figure 2. Fumonisin B1 [20]

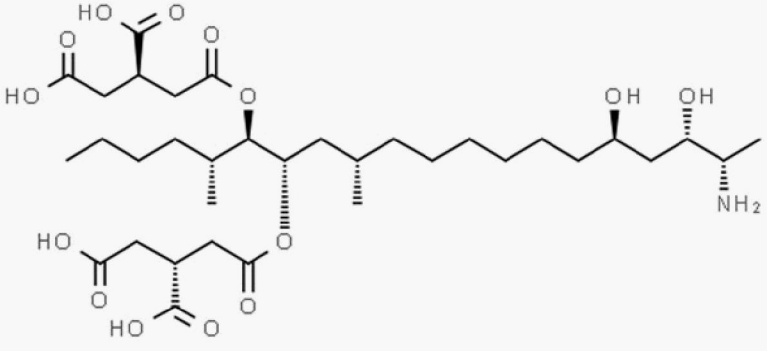

Figure 3. Fumonisin B2 [21]

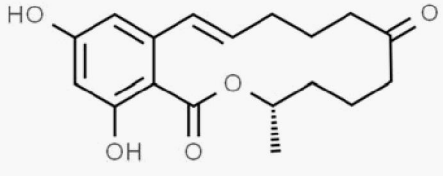

Figure 4. Zearalenone [22]

mycotoxin contamination as lower grade grains often contain broken and fragmented grains which are much more susceptible to mold growth and subsequent mycotoxin production [23]. Grains are numerically graded based on factors such as test weight, proportion of damaged or broken kernels, presence of foreign odors, or heat-damage [24]. Any of these factors can contribute to mold growth and mycotoxin production. However, pet food manufacturers may choose grains unfit for human consumption as a cost-cutting strategy [25]. Using only grains graded as US No. 1 by the USDA could be a control strategy to minimize mycotoxin contamination from ingredients incorporated into pet food. Currently, there is no requirement to reveal the grade of grain incorporated into pet food, but noting the grade of grains used on the ingredients list could help consumers choose pet foods with more confidence.

We did not test any cat foods in this study. Cats are obligatory carnivores and grains are less frequently incorporated into dietary formulations. It has been proposed that finding measurable mycotoxins in cat foods is indicative of high grain content [25]. Further studies could assess the frequency of mycotoxins found in cat foods and correlate findings with the presence of grains.

While the results of this study might suggest that grain incorporation into dog food formulations has risks, we do not conclude that it is inappropriate to use them in dog foods. Grain-free dog foods need to be carefully formulated to meet nutritional requirements. A recent study demonstrated evidence of partially reversible cardiomyopathy in some dogs fed grain-free diets. While the exact associations with grain-free diets remains unclear, the data suggested that the condition could be reversed after a diet change [26]. Additionally, more work needs to be done to assess the effects of mycotoxins in combinations and in low, chronic concentrations in dogs, perhaps studying them in multi-year long-term research studies. Also, there is a need to continue to explore strategies to minimize the concentrations of all mycotoxins in the manufacturing of dog food. Perhaps requiring grain grades on ingredient lists could increase understanding about the potential sources of mycotoxins, inform consumer choice, and provide insights to other strategies to further minimize contamination.

Disclosure statement

JT has a financial interest as a shareholder with Just Food For Dogs.

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From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Freeman, Lisa
Sent: 10/22/2018 12:58:18 PM
Subject: Re: JAVMA

Thank you very much for the heads up, Lisa.

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Date: October 21, 2018 at 5:38:50 PM CDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: JAVMA

Hi Jen
I just wanted to give you a heads up that Darcy, Josh, Ryan, John Rush, and I had a Commentary accepted regarding the diet/DCM issue. It most summarizes the 2 separate categories – taurine and non-taurine dependent - and emphasizes that it may not just be grain-free diets but also boutique and exotic ingredient. Josh, Ryan, and Darcy include some preliminary data from their studies and we discuss possible nutritional causes of cardiac pathology. I also included a section on the importance of getting diet history on all patients. We refer people to your recent commentary in JAVMA as well.

I thought you'd want to know because we do, of course, encourage people to report any cases they see.
Thanks
Lisa

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Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 11/18/2018 8:25:14 PM
Subject: FW: JAVMA Manuscript (18-08-0453)
Attachments: 18-08-0453_COM.pdf

Hi Jen
Please see attached. I got permission fro[B6]to share this with you for internal use only. The planned publication date is Dec 1.
Kind regards,
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
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From: Julie McLearen <JMcLearen@avma.org>
Sent: Friday, November 16, 2018 5:25 PM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: FW: JAVMA Manuscript (18-08-0453)

Hi Dr. Freeman,

The final PDF is attached.

Kind Regards,
Julie

Julie L. McLearen
Senior Production Coordinator | Publications
American Veterinary Medical Association

www.avma.org

Commentary

Diet-associated dilated cardiomyopathy in dogs: what do we know?

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Joshua A. Stern DVM, PhD
Ryan Fries DVM
Darcy B. Adin DVM
John E. Rush DVM, MS

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Address correspondence to Dr. Freeman (lisa.freeman@tufts.edu).

Diet-associated DCM first came to light in cats in the late 1980s[1] and in dogs in the mid-1990s.[2] The association between diet and DCM in dogs has generally not been much in the news since the early 2000s, but over the past few years, an increasing number of DCM cases involving dogs appear to have been related to diet. The extent of this issue is not clear, not all cases have been confirmed to be linked to diet, and a true association has not been proven to exist. However, when one of the authors (RF) recently surveyed veterinary cardiologists about cases of possible diet-associated DCM in dogs examined in the past 2 years, information for > 240 cases was obtained, with responses received from the United States, United Kingdom, Canada, Israel, and Austria (unpublished data). Dogs for which breed was specified consisted of mixed-breed dogs (n = 134), Golden Retrievers (23), Labrador Retrievers (9), German Shepherd Dogs (8), Cocker Spaniels (7), and between 1 and 5 dogs each of 25 other breeds. Further, possible diet-associated DCM represented 16% of all cases of DCM diagnosed by the respondents during this period.

The recent announcement from the US FDA[3] alerting pet owners and veterinarians about reports of DCM in dogs eating pet foods containing peas, lentils, other legume seeds, or potatoes as main ingredients has raised concerns among the pet-owning public. Therefore, we wanted to increase awareness of this issue among veterinarians, review what is currently known about the possible association between certain diets and DCM in dogs, and discuss what veterinarians can do to help identify underlying causes.

DCM and Diet in Dogs and Cats

Dilated cardiomyopathy used to be one of the most common cardiac diseases in cats. In 1987, however, Pion et al[1] published a landmark paper reporting that DCM in cats was associated with taurine deficiency and could be reversed by providing supplemental taurine. On the basis of that report and substantial subsequent research, the requirement for taurine in cat foods was increased, and taurine deficiency–related DCM is now uncommon in cats. However, it can still be seen in cats eating home-prepared diets or commercial diets prepared with inadequate nutritional expertise or quality control.

In 1995, veterinary cardiologists investigating the role of taurine deficiency in dogs with DCM suggested that certain breeds (eg, Golden Retrievers and American Cocker Spaniels) may be predisposed to taurine deficiency,[2] and a study in Cocker Spaniels subsequently showed that supplementation with taurine and L-carnitine could partially or completely reverse the disease.[4] Additional dog breeds potentially predisposed to taurine deficiency–associated DCM were identified, including Newfoundlands, English Setters, Saint Bernards, and Irish Wolfhounds.[5–10] Later, certain types of diets, including lamb and rice, low-protein, and high-fiber diets were associated with taurine deficiency in some dogs.[5,7,9,11–14] Research suggested that other ingredients (eg, beet pulp) may also increase the risk of taurine deficiency,[15] although the exact role of these ingredients was still unclear. In addition, the apparent breed predispositions suggested that genetic factors, breed-specific metabolic abnormalities, or low metabolic rates may also have been playing a role.[8,9,16]

ABBREVIATIONS

BEG	Boutique, exotic-ingredient, and grain-free
CHF	Congestive heart failure
DCM	Dilated cardiomyopathy

Current Concerns About Diet and DCM in Dogs

Beginning in the early 2000s, the number of dogs with taurine deficiency and DCM subjectively appeared to decrease. Recently, however, we have heard from veterinary cardiologists who had an impression that they were diagnosing DCM in Golden Retrievers at higher rates than expected and in dogs of breeds

typically not thought to be prone to this condition. Subjectively, it also appeared that these dogs were frequently eating BEG diets containing foodstuffs such as kangaroo, duck, buffalo, salmon, lamb, bison, venison, lentils, peas, fava beans, tapioca, barley, or chickpeas as major ingredients. Some of the affected dogs had low plasma or whole blood taurine concentrations and improved with taurine supplementation and a diet change. On the other hand, some dogs that did not have low plasma or whole blood taurine concentrations also improved with a diet change and taurine supplementation. Cardiologists and other veterinarians have been reporting cases to the US FDA, which is investigating the issue.[3]

Currently, it seems that in addition to those dogs with DCM completely unrelated to diet (eg, breed-specific DCM), there may be 2 groups of dogs with diet-associated DCM: dogs with DCM specifically related to taurine deficiency and dogs with DCM associated with separate, but yet unknown, dietary factors. Identifying the potential dietary factors contributing to DCM in these latter 2 groups may be challenging. From our discussions with veterinary cardiologists, it appears that many dogs in both groups have been eating BEG diets; however, the true percentages are not known. The previously mentioned survey identified 23 types of BEG diets being fed to dogs with DCM, including home-prepared diets, and not all diets were grain-free diets. Importantly, BEG diets have increased in popularity in recent years, and many dogs with DCM unrelated to diet and many dogs without DCM are likely eating these diets.

Multiple factors play a role in the increased popularity of BEG diets.[17] Regardless, the apparent link between BEG diets and DCM may be due to the grain-free nature of these diets (ie, use of ingredients such as lentils, chickpeas, or potatoes to replace grains), other common ingredients in BEG diets (eg, exotic meats, flaxseed, fruits, or probiotics), possible nutritional imbalances, or inadvertent inclusion of toxic dietary components. Or, the apparent association may be spurious.

The complexity of pet food manufacturing is often underestimated. Pet foods must contain all required nutrients in the right amounts and right proportions. Nutrient standards (minimums and, for some nutrients, maximums) are established by the Association of American Feed Control Officials. However, the effects of processing (or not processing) the ingredients must also be considered, along with nutrient bioavailability and the effects of all other ingredients in the food. Unfortunately, this may not always be done. In addition, extensive testing is needed on an ongoing basis to ensure rigorous quality control. Inclusion of exotic ingredients, such as kangaroo, alligator, fava beans, and lentils, adds another level of complexity to ensuring the diet is nutritious and healthy. Exotic ingredients have different nutritional profiles and different digestibility than typical ingredients and have the potential to affect the metabolism of other nutrients. For example, the bioavailability of taurine is different when included in a lamb-based diet, compared with a chicken-based diet, and can be affected by the amount and types of fiber in the diet.[14,15]

Diet-associated DCM in dogs with taurine deficiency

Golden Retrievers have been reported, as a breed, to be susceptible to development of taurine deficiency–associated DCM,[2,8] leading some to suggest a breed-wide genetic propensity for diet-associated DCM. One of the authors (JAS) recently concluded a study evaluating 24 Golden Retrievers with echocardiographically confirmed DCM and low plasma or whole blood taurine concentrations that were followed up for 12 to 24 months after a diet change and the addition of supplemental taurine to their diet (unpublished data). Although the results are still preliminary, all but 1 dog for which follow-up data were available had substantial echocardiographic improvement. In addition, in all 9 dogs that initially had CHF, the heart failure resolved, and diuretic administration was substantially reduced or safely discontinued. All 24 of these Golden Retrievers were eating BEG diets at the time DCM was diagnosed.

Although taurine deficiency appears to be more common in Golden Retrievers than in dogs of other breeds, plasma and whole blood taurine concentrations should be measured in every dog with DCM because some dogs of other breeds with DCM have been found to have taurine deficiency. Even dogs of breeds that have previously been found to be genetically predisposed to developing DCM, such as Doberman Pinschers and Boxers, should be tested because taurine concentrations have been found to be low in some of these dogs also. In addition, taurine deficiency should be considered as a possibility not just in dogs eating BEG, very-low-protein, or high-fiber diets, but also in dogs eating vegetarian, vegan, or home-prepared diets.

The reasons for taurine deficiency in dogs are not completely understood but could be related to reduced synthesis of taurine resulting from an absolute dietary deficiency of the taurine precursors methionine and cystine; reduced bioavailability of taurine, methionine, or cystine in the diet; abnormal enterohepatic recycling of bile acids because of fiber content of the diet; increased urinary loss of taurine; or altered metabolism of taurine in the intestine as a result of interactions between certain dietary components and intestinal microbes.[9,12–16] In addition to the possibility of breed-related metabolic differences, there may be genetic factors that play a role in susceptibility to taurine deficiency, as appeared to be the case in cats with taurine deficiency.[18]

Diet-associated DCM in dogs without taurine deficiency

Preliminary results of a study[a] performed by one of the authors (DBA) found that dogs with DCM that had been eating grain-free diets had more advanced cardiomyopathic changes than did dogs with DCM that had been eating grain-based diets. Unreported results of the study indicated that a subset of dogs

clinically and echocardiographically improved after a diet change. Notably, however, some dogs improved after a diet change from one grain-free diet to another, and this finding, along with the differences identified between dogs fed various BEG diets, suggested that DCM was not necessarily tied to the grain-free status of the diet. Taurine supplementation was prescribed for many of these dogs despite the lack of apparent deficiency, and it is unclear what role taurine may have played in their recovery.

Although DCM in some dogs without any apparent taurine deficiency appears to be reversible with a change in diet, with or without taurine supplementation, no cause has thus far been identified for non-taurine deficiency–associated DCM. Possible causes that are being investigated include absolute deficiencies of other nutrients, altered bioavailability of certain nutrients because of nutrient-nutrient interactions, and the inadvertent inclusion of toxic ingredients.

For example, BEG diets could possibly be more likely to have deficiencies of nutrients other than taurine, such as choline, copper, L-carnitine, magnesium, thiamine, or vitamin E and selenium, that have been associated with cardiomyopathies.[19] Although pet foods are required to be nutritionally complete and balanced (unless they have a label statement that they are for intermittent or supplemental use only), that does not always provide a guarantee,[20] and deficiencies could occur if diets do not contain appropriate amounts of all dietary nutrients. Further, a deficiency may occur even if a diet contains the required minimum amount of a nutrient because of reduced bioavailability or interaction with other ingredients in the diet. This may be a concern for diets based on exotic ingredients, whose nutritional properties may not be as well studied.

Researchers are also exploring whether diet-associated DCM in dogs without taurine deficiency may be related to inclusion of a cardiotoxic ingredient in the diet. This could be an adulterated ingredient, as with ingredients containing melamine–cyanuric acid that affected pet foods in 2007, resulting in extensive recalls[21]; a heavy metal; a chemical sprayed on 1 of the ingredients; or even a natural chemical compound in 1 of the ingredients that has toxic effects when fed in large amounts.

Of course, the cause may be even more complicated, such as an interaction between gut microbiota and a dietary factor (eg, trimethylamine *N*-oxide).[22] It is encouraging that some recovery of cardiac function has been observed in some dogs following a change in diet, with or without taurine supplementation. However, research is needed to identify the underlying cause.

Diet History

For many years, veterinary nutritionists have emphasized the importance of nutritional assessment.[23,24] Nutritional assessment includes 4 key components: body weight, body condition score, muscle condition score, and diet history. Body weight and body condition score are likely already a part of most clinicians' standard physical examination, and muscle condition scoring would be a valuable addition. Cardiac cachexia (muscle loss) occurs early in patients with CHF and should be detected at its mildest stages, when interventions are more likely to be successful.[25] Muscle condition scoring charts and training videos are available.[26,27]

The fourth component of nutritional assessment—diet history—may not be routinely collected but is equally important. A diet history, for example, can help identify issues that could be contributing to an underlying disease. For patients with recent-onset CHF, for example, the diet history may reveal that the owner changed to a new diet with a higher sodium content. Other diet-associated issues that can be identified from the diet history include anemia or thiamine deficiency caused by a nutritionally unbalanced home-prepared diet or diarrhea due to a contaminated raw meat diet. Veterinary cardiologists examining dogs with DCM were able to make an association with BEG diets because they were obtaining a diet history, and obtaining a diet history may help researchers identify patterns (eg, products made by the same manufacturer or by manufacturers using ingredients from the same supplier) that could eventually lead to determining the underlying cause.

A diet history can also identify an individual patient's food preferences, such as whether canned or dry food is preferred or whether specific flavors are preferred, that can be helpful for feeding when the patient is hospitalized. And, a diet history is useful in determining whether the patient's usual diet is appropriate after discharge or needs to be changed. For example, dietary modification will be required for dogs with cardiac disease that are eating high-sodium dog food or treats.

The diet history should include the main foods being fed. However, this is more than just "dry dog food" or "brand X dog food." It is critical to solicit information on brand, the exact product, and even the flavor, as these factors can make a big difference in the ingredients and nutrient profile. We recommend telling owners that their description of a product should be detailed enough that we could go to the store and buy the exact product they are feeding. If owners are feeding a home-prepared diet, the exact recipe should be provided.

Of course, pet food is often just the tip of the iceberg. The diet history should also include all treats; table food; rawhides, bully sticks, and other chews; dietary supplements; and foods used to administer medications. These other components of the diet can contribute large amounts of sodium and other nutrients to a patient's overall intake or unbalance the overall diet. In addition, these other components may contribute to adverse effects. For example, a Fanconi-like syndrome associated with jerky treats has been reported[28] but may not have been identified if complete diet histories had not been obtained for affected dogs. In addition, although diet-associated DCM is most likely related to pet food, it may possibly be a result of another dietary

component (eg, treats, chews, or supplements) commonly fed to dogs eating these diets.

Use of a standard form, such as the generic form recommended by the World Small Animal Veterinary Association,[26] or a cardiology-specific form (**Supplementary Appendix S1**, available at avmajournals.avma.org/doi/suppl/10.2460/javma.253.11.1390) will facilitate obtaining a complete diet history. We recommend all clinicians collect a diet history for every dog and cat patient at every appointment. Because many owners are unable to recall specific diet details at the time of their appointment, we recommend having owners complete the diet history form at home prior to the appointment so that they can provide exact details on all components of the diet.

Recommendations

If DCM is diagnosed in a dog that is eating a BEG, vegetarian, vegan, or home-prepared diet, we recommend measuring plasma and whole blood taurine concentrations.[b] It is still unclear whether plasma or whole blood taurine concentration more accurately reflects myocardial concentration in dogs, so measurement of both plasma and whole blood taurine concentrations is recommended. However, if cost is an issue, measurement of whole blood taurine concentration should be prioritized because it is thought to be a better indicator of long-term taurine status. Importantly, reference ranges for taurine concentrations in dogs should be interpreted cautiously. Dilated cardiomyopathy has been diagnosed in some dogs, particularly Golden Retrievers, with whole blood taurine concentrations between 200 and 250 nmol/L, which would generally be considered within reference limits, although at the low end of the reference range. At least some of these patients, however, have responded well to a diet change and taurine supplementation. Therefore, reference ranges for plasma and whole blood taurine concentrations may need to be breed specific. Research in Golden Retrievers with taurine deficiency–associated DCM is ongoing, but a whole blood taurine concentration of at least 250 nmol/L is recommended for this breed.

We also recommend that all other dogs in the household that are eating the same diet be screened for DCM. Further, we recommend that owners of dogs with possible diet-associated DCM be instructed to save samples of all dietary components they are currently feeding, including not only the main food itself but also all treats, chews, and supplements. Ideally, this would include not just samples of the dietary components but also product bags or labels. With complete diet information in hand, the veterinarian or owner should report the case to the FDA, which can be done either online or by telephone[29] because this will help the agency identify possible underlying causes as quickly as possible. A recently published article[30] provides an excellent summary of information for veterinarians on reporting suspected animal food issues. If the dog is a Golden Retriever, the veterinarian or owner may also consider reporting the case to the Josh Stern Cardiac Genetics Laboratory,[31] which is currently evaluating possible genetic factors that may increase susceptibility to taurine deficiency.

For dogs in which possible diet-associated DCM is diagnosed, we recommend the owner change the diet to one made by a well-established manufacturer that contains standard ingredients (eg, chicken, beef, rice, corn, and wheat). In the authors' (LMF and JER) hospital, we recommend several specific products with a low sodium content that only contain standard ingredients.[32] We also emphasize that changing to a raw or home-prepared diet may not be sufficient to improve cardiac abnormalities and may increase the risk for other nutritional deficiencies or infectious diseases. For dogs that require a home-prepared diet or that have other medical conditions that require special dietary considerations, consultation with a board-certified veterinary nutritionist is recommended.

We also provide supplemental taurine for all dogs with possible diet-associated DCM. In dogs with a taurine deficiency, taurine supplementation is critical. In dogs with taurine concentrations within reference limits, it is unclear whether taurine supplementation is needed, and some patients have recovered with only a diet change. However, taurine supplementation may still have some benefits owing to other effects of taurine (eg, antioxidant and positive inotropic effects). Taurine supplements from manufacturers with a history of good quality control should be used. A 2009 study[33] identified certain brands with good quality control. In addition, ConsumerLab is expected to release a report in late 2018 on independent quality control testing of taurine supplements.

Although the optimal taurine dosage for dogs with taurine deficiency is not fully understood, we recommended 250 mg, PO, every 12 hours for dogs weighing < 10 kg (22 lb); 500 mg, PO, every 12 hours for dogs weighing 10 to 25 kg (55 lb); and 1,000 mg, PO, every 12 hours for dogs weighing > 25 kg.

Follow-up echocardiography should be performed in 3 to 6 months. In our experience, some improvements are typically evident in this time span. However, in certain dogs, it may take even longer for improvements to be apparent echocardiographically.

Finally, although an association between BEG diets and DCM in cats has not been recognized, we recommend collecting diet histories on all cats as well and especially in cats with DCM. If cats with DCM are eating a BEG, vegetarian, vegan, or home-prepared diet, we recommend following the same protocol as described for dogs.

Summary

Pet food marketing has outpaced the science, and owners are not always making healthy, science-based decisions even though they want to do the best for their pets. The recent cases of possible diet-associated DCM are obviously concerning and warrant vigilance within the veterinary and research communities. Importantly, although there appears to be an association between DCM and feeding BEG, vegetarian, vegan, or home-prepared diets in dogs, a cause-and-effect rela-

tionship has not been proven, and other factors may be equally or more important. Assessing diet history in all patients can help to identify diet-related cardiac diseases as early as possible and can help identify the cause and, potentially, best treatment for diet-associated DCM in dogs.

Acknowledgments

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Footnotes

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 11/19/2018 3:39:08 PM
Subject: RE: checking in

Thank you again, Lisa. I hope you have a nice Thanksgiving holiday.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Friday, November 16, 2018 4:24 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: checking in

Hi Jen
Let me get the final copy from JAVMA and I'll send that to you asap
Thanks and have a great weekend
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, November 15, 2018 10:58 AM
To: Darcy Adin <dbadin@ncsu.edu>; Freeman, Lisa <lisa.freeman@tufts.edu>
Cc: adind@ufl.edu
Subject: RE: checking in

Great! I sent a calendar appointment. Please forward as necessary.
Would you be willing to forward me a copy of the DCM article for JAVMA? I'd like to share it with our communication team. They may get some inquiries after it's release, and it would help them prepare.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Darcy Adin <dbadin@ncsu.edu>
Sent: Thursday, November 15, 2018 8:01 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; adind@ufl.edu

Subject: Re: checking in

Hi Jennifer,
Based on Lisa's times, I could do the B5.
Thanks!
Darcy

On Nov 15, 2018, at 7:55 AM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

Hi Jen
B5
Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, November 15, 2018 7:44 AM
To: Darcy Adin <dbadin@ncsu.edu>
Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; adind@ufl.edu
Subject: RE: checking in

Good morning Darcy and Lisa,
Yes, let's plan for a meeting after Thanksgiving. When in early B5 would work well for you?
Thanks,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

<image001.png>

From: Darcy Adin <dbadin@ncsu.edu>
Sent: Wednesday, November 07, 2018 3:20 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Freeman, Lisa <lisa.freeman@tufts.edu>; adind@ufl.edu
Subject: checking in

Hi Jennifer,

I hope you are doing well! I wanted to check in with you to let you know that I have changed affiliations and am now working at the University of Florida (my new email is adind@ufl.edu, copied above).

Dr. Freeman and I wanted to check to see if your group be willing to have a follow up call regarding the dietary induced DCM issue?

Thanks!

Darcy

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Adjunct Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From:	Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To:	Carey, Lauren; Jones, Jennifer L; DeLancey, Siobhan; Hartogensis, Martine; Burkholder, William; Rotstein, David; Palmer, Lee Anne; Peloquin, Sarah
CC:	Ceric, Olgica; Reimschuessel, Renate
Sent:	12/10/2018 7:03:16 PM
Subject:	RE: FYI-DCM Article-FW: article

S.T. wrote about the JAVMA paper: http://truthaboutpetfood.com/diet-associated-heart-disease-in-dogs-what-we-know/

From: Carey, Lauren
Sent: Monday, December 10, 2018 11:38 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: FYI-DCM Article-FW: article

Did they mention any diets? Just curious how much this matches our reported products.

From: Jones, Jennifer L
Sent: Friday, December 07, 2018 8:07 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: FYI-DCM Article-FW: article

From Dr. Adin.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: ADIN,DARCY BRITTAIN <adind@ufl.edu>
Sent: Friday, December 07, 2018 7:49 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: article

Hi Jen,

Just thought I'd share out diet DCM paper from NCSU with you. It is available for sharing but won't be in the journal til 2019.

It was great to talk this week and hear all the progress you've made!

Take care
Darcy

Darcy B. Adin, DVM, Diplomate ACVIM (Cardiology)
Clinical Associate Professor, Cardiology
University of Florida
College of Veterinary Medicine
PO Box 100136
2015 SW 16th Ave
Gainesville, FL 32608
(352) 294-8606

From: ADIN,DARCY BRITTAIN <adind@ufl.edu>
To: Jones, Jennifer L
Sent: 12/7/2018 9:53:54 PM
Subject: Re: article

you too!

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Friday, December 7, 2018 8:05 AM
To: ADIN,DARCY BRITTAIN
Subject: RE: article

Thank you, Darcy. I'll share with our team here. I hope you have a happy holiday.
Take care,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: ADIN,DARCY BRITTAIN <adind@ufl.edu>
Sent: Friday, December 07, 2018 7:49 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: article

Hi Jen,

Just thought I'd share out diet DCM paper from NCSU with you. It is available for sharing but won't be in the journal til 2019.

It was great to talk this week and hear all the progress you've made!

Take care
Darcy

Darcy B. Adin, DVM, Diplomate ACVIM (Cardiology)
Clinical Associate Professor, Cardiology
University of Florida
College of Veterinary Medicine
PO Box 100136
2015 SW 16th Ave
Gainesville, FL 32608
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FDA In Brief

METADATA
Title: FDA investigates cases of canine heart disease potentially linked to diet

Description: FDA investigates dilated cardiomyopathy in dogs that ate certain pet foods labeled as "grain-free."

Short Title: FDA investigates canine heart disease cases potentially linked to diet

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For Immediate Release: July 12, 2018
Media Inquiries: Juli Putnam, 240-402-0537, juli.putnam@fda.hhs.gov

FDA In Brief: FDA investigates cases of canine heart disease potentially linked to diet

"We are concerned about reports of canine heart disease, known as dilated cardiomyopathy (DCM), in dogs that ate certain pet foods containing peas, lentils, other legumes or potatoes as their main ingredients. These reports are highly unusual as they are occurring in breeds not typically genetically prone to the disease," said Martine Hartogensis, D.V.M., deputy director of the FDA's Center for Veterinary Medicine's Office of Surveillance and Compliance. "The FDA is investigating the potential link between DCM and these foods. We encourage pet owners and veterinarians to report DCM cases in dogs who are not predisposed to the disease."

The U.S. Food and Drug Administration's Center for Veterinary Medicine and the Veterinary Laboratory Investigation and Response Network, a collaboration of government and veterinary diagnostic laboratories, are investigating the potential association between reports of canine dilated cardiomyopathy (DCM) in dogs and certain pet foods containing peas, lentils, other legume seeds or potatoes as main ingredients. Canine DCM is a disease of a dog's heart muscle and often results in congestive heart failure. In cases that are not linked to genetics, heart function may improve with appropriate veterinary treatment and dietary modification if caught early.

A genetic predisposition for DCM is typically seen in large and giant breed dogs, such as Great Danes, Newfoundlands, Irish Wolfhounds, Saint Bernards and Doberman Pinschers. The disease is less common in small and medium breed dogs, except American and English Cocker Spaniels. However, recently reported atypical cases have included Golden and Labrador Retrievers, a Whippet, a Shih Tzu, a Bulldog, and Miniature Schnauzers as well as mixed breeds. Early reports from the veterinary cardiology community indicate that the impacted dogs consistently ate foods containing peas, lentils, other legume seeds or potatoes as main ingredients as their primary source of nutrition for time periods ranging from months to years. That's why the FDA is conducting an investigation into this potential link. In the meantime, the FDA continues to recommend that changes in diet, especially for dogs with DCM, should be made in consultation with a licensed veterinary professional.

Cases of DCM in dogs suspected of having a link to diet can be reported to the FDA's electronic Safety Reporting Portal. For additional instructions, see "How to Report a Complaint about Pet Food."

As part of its investigation, the FDA has been in contact with the pet food manufacturers and the veterinary community to discuss these reports and will provide updates as more information becomes available.

###

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

From: McDermott, Patrick </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3D75459A1C2A40B8B73B8B1484C8B850-PMCDERMO>
To: Reimschuessel, Renate
Sent: 7/11/2018 8:13:21 PM
Subject: FW: For CVM Review: CVM Update for Canine DCM & GF Diets

Not for sharing, but FYI.
Pat

From: Norris, Anne
Sent: Wednesday, July 11, 2018 3:54 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; McDermott, Patrick <Patrick.McDermott@fda.hhs.gov>
Subject: RE: For CVM Review: CVM Update for Canine DCM & GF Diets

Hi Martine,

B5

Going to compare notes with Juli in case there are **B5** but don't see any reason why we couldn't get these out tomorrow.

Note that in the **B5**
B5 Please let me know if you have any concerns.

I'll let you know when we have scheduled a time to publish.

Thanks!
Anne

From:	Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To:	Solomon, Steven M; Forfa, Tracey; Moxley, Shera; Flynn, William T; Murphy, Jeanette; Hartogensis, Martine; Allen, Mary; Edwards, David; Conway, Charlotte; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Burkholder, William; Benton, Denise; Goddard, Kristina; Dewitt, Susan J; Alvey, Laura - CVM; Stamper, Carmela; Smith-Collier, Chandra E; DeLancey, Siobhan
Sent:	2/19/2019 3:07:09 PM
Subject:	Now live: DCM Investigation Update
Attachments:	DCM Plan_Feb2019.docx

Good morning,

The long-awaited investigative update about the potential link between certain diets and canine DCM is now live. Outreach may now begin (plan is attached). Social media and an email to our CVM subscribers will go out around 11:00 am EST.

Links:
CVM Update: https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm630991.htm
Investigation home page: http://www.fda.gov/AnimalVeterinary/NewsEvents/ucm630993.htm
Vet-LIRN page: https://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm630738.htm
Web Q&A: https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm616279.htm

Thanks so much to everyone for their hard work and patience! And thank you on behalf of the people who will be emailing and calling who might be too preoccupied to express their gratitude.

Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
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Anne.Norris@fda.hhs.gov

CVM Update

FDA Provides Update on Investigation into Potential Connection Between Certain Diets and Cases of Canine Heart Disease

February 19, 2018

The U.S. Food and Drug Administration today is providing an update on its investigation into reports of dilated cardiomyopathy (DCM) in dogs eating certain pet foods. The update covers reports of DCM received by FDA through November 30, 2018.

This update does not include reports received in December and January due to the lapse in appropriations from December 22, 2018, to January 25, 2019. Because the Anti-Deficiency Act does not except activities that are solely related to protecting "animal health," FDA was not able to continue its investigation during that time.

The FDA first alerted the public about this investigation in July 2018. Since then, the FDA's Center for Veterinary Medicine (CVM) has taken a multi-pronged approach to the investigation, collaborating with a variety of components of the animal health sector to collect and evaluate information about the DCM cases and the diets pets ate prior to becoming ill.

Based on the information gathered as part of our investigation to date, our advice to pet owners remains consistent. The agency has not identified specific recommendations about diet changes for dogs who are not displaying DCM symptoms, but encourages pet owners to consult directly with their veterinarians for their animal's dietary advice. FDA-CVM investigative activities include:

- Analyzing cases statistically to search for correlations between diagnosed DCM cases and what those dogs did or did not eat.
- Working with the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), a collaboration of government and veterinary diagnostic laboratories to test blood, serum and tissues from affected animals.
- Collaborating with Chesapeake Veterinary Cardiology Associates (CVCA) to collect case summaries and blood/serum/tissue of dogs diagnosed with DCM to see if there are unique factors that separate diet-associated DCM from genetic. The FDA is also reviewing echocardiograms of dogs who are not showing symptoms of DCM to evaluate the significance of early changes in heart function.
- Consulting with board certified veterinarians in animal nutrition to identify nutritional factors such as nutrient bioavailability and ingredient digestibility that may contribute to the development of heart disease.
- Examining ingredient sourcing/processing and product formulation with pet food manufacturers.

Between January 1, 2014, and November 30, 2018, the FDA received 300 reports of DCM (294 canine reports, 6 feline reports); 276 of these (273 canine, 3 feline) were reported after the July public notification about FDA's investigation. Some of these reports involved more than one affected animal from the same household. While there are dog breeds (typically large and giant breeds, plus Cocker Spaniels) that are known to have a genetic predisposition to dilated cardiomyopathy, the reports to the FDA continue to span a wide range of breeds, many that do not have a known genetic predisposition.

The FDA has received reports of cats with DCM, but due to the low number of reports (10 since January 2014), dogs are the primary focus of the agency's investigation. For details about the number of reports, visit the DCM Investigation webpage.

In cases in which dogs ate a single primary diet (i.e., didn't eat multiple food products, excluding treats), 90 percent reported feeding a grain-free food. Approximately 10 percent reported feeding a food containing grains and some of these diets were vegan or vegetarian. A large proportion of the reported diets in DCM cases – both grain-free and grain-containing – contained peas and/or lentils in various forms (whole, flour, protein, etc.) as a main ingredient (listed within the first 10 ingredients, before vitamins and minerals). The products included commercially available kibble, canned and raw foods, as well as home-cooked diets.

The agency appreciates the support from pet owners and veterinarians who have submitted data through case reports that included extensive diet histories, medical records, diagnostic samples of blood, serum, and/or tissue, and echocardiograms. Due to the high volume of reports, the agency cannot respond to each report individually, but each report is valuable and becomes part of the FDA's investigation.

The FDA continues to encourage pet owners and veterinary professionals to report both symptomatic and asymptomatic cases of dogs suspected to have DCM connected to diet by using the electronic Safety Reporting Portal or calling their state's FDA Consumer Complaint Coordinators. Please see the link below about "How to Report a Pet Food Complaint" for additional instructions. The FDA will continue to provide updates on the progress of this investigation and will alert the public about significant developments.

Additional Information

- FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy
- Questions & Answers: FDA Center for Veterinary Medicine's Investigation into a Possible Connection Between Diet and Canine Heart Disease
- Vet-LIRN Investigative Update (December 2018)
- How to Report a Pet Food Complaint
- Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

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Author: Norris, Anne
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Scope: DCM Investigation webpage

Author: Norris, Anne
Date: 12/18/2018 1:09:00 PM
Initial: NA
Range: link to investigation web page
Scope: FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy

FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy

Updated February 19, 2019

In July 2018, the FDA announced that it had begun investigating reports of canine dilated cardiomyopathy (DCM) in dogs eating certain pet foods containing a high proportion of peas, lentils, other legume seeds (pulses), and/or potatoes in various forms (whole, flour, protein, etc.) as main ingredients (listed within the first 10 ingredients in the ingredient list, before vitamins and minerals). Many of these case reports included breeds of dogs not previously known to have a genetic predisposition to the disease. The FDA's Center for Veterinary Medicine (CVM) and the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), a collaboration of government and veterinary diagnostic laboratories, continue to investigate this potential association. Based on the data collected and analyzed thus far, the agency believes that the potential association between diet and DCM in dogs is a complex scientific issue that may involve multiple factors.

We understand the concern that pet owners have about these reports: the illnesses can be severe, even fatal, and many cases report eating "grain-free" labeled pet food. The FDA is using multiple science-based investigative tools as it strives to learn more about the evolution of this outbreak of DCM and its potential link to certain diets or ingredients.

This update does not include reports received in December and January due to the lapse in appropriations from December 22, 2018, to January 25, 2019. Because the Anti-Deficiency Act does not except activities that are solely related to protecting "animal health," FDA was not able to continue its investigation during that time.

Cases Reported to FDA

For the purposes of this investigation, the FDA defines a "case" as an illness reported to FDA involving a dog or cat that includes a diagnosis of DCM. Many of the reports submitted to the FDA included very supportive clinical information, including echocardiogram results, cardiology/veterinary records, and detailed diet histories. The numbers below only include reports in which a veterinarian made a formal diagnosis of DCM. We did not include, in these numbers, the many general cardiac reports submitted to the FDA that did not have a DCM diagnosis. This case information is still valuable, as it may show heart changes that occur before a dog develops full-blown DCM. (Please see the Vet-LIRN DCM Investigative Update for more technical information on the reported cases, including those without a formal diagnosis of DCM).

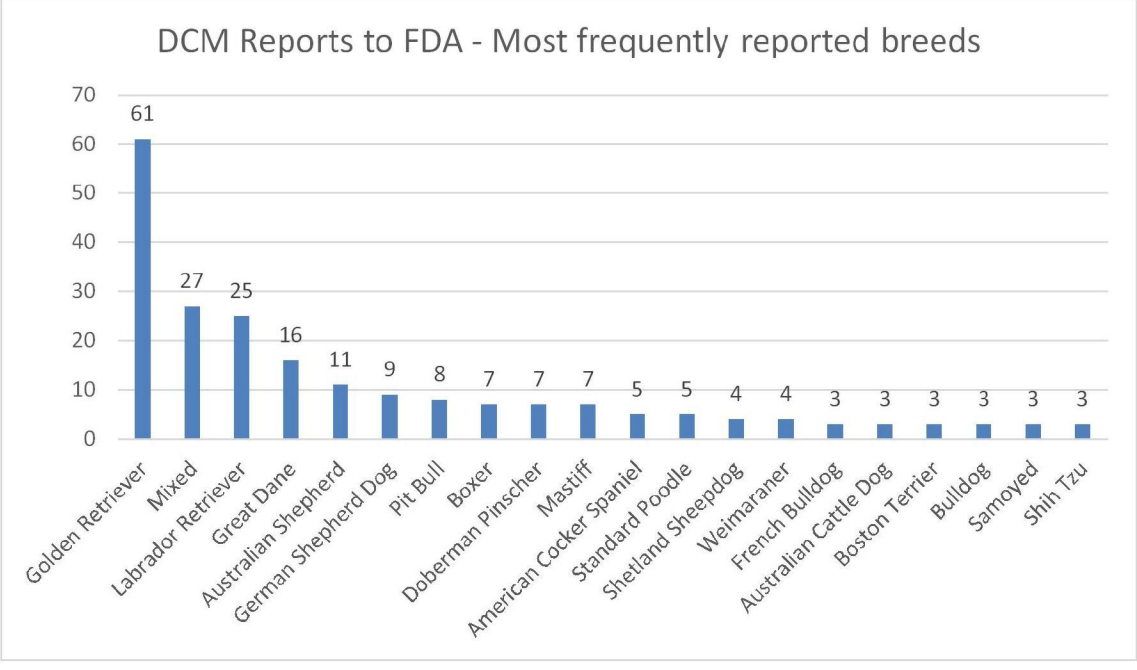
Between January 1, 2014 and November 30, 2018, the FDA received 300 reports of DCM (294 canine reports, 6 feline reports). Approximately 276 of these were reported after the July public notification about FDA's investigation (273 canine reports, 3 feline reports). Some of these reports involved more than one affected animal from the same household. The breakdown of reported illnesses below reflects the number of individual animals affected.

Animal numbers in DCM Reports received between January 1, 2014 and November 30, 2018

	Number of reactions	Number of deaths
Dogs	325	74
Cats*	10	2

*Cats are generally more likely to develop hypertrophic cardiomyopathy (a heart disease)

Dilated cardiomyopathy is recognized as a genetic condition in dogs, typically in large or giant breeds, such as the Doberman Pinscher, Great Dane, or the Irish Wolfhound. It is also seen in Cocker Spaniels. It is believed to be less common in small and medium breed dogs. We suspect that cases are underreported because animals are typically treated symptomatically, and testing and treatment can be complex and costly to owners. Because the occurrence of different diseases in dogs and cats is not routinely tracked and there is no widespread surveillance system like the Centers for Disease Control has for human health, we do not have a measure of the occurrence of disease apart from what is reported to the FDA.



Additional breeds with more than one report include Afghan Hound, Beagle, Dalmatian, English Springer Spaniel, Flat-coated Retriever, Hound (unspecified), Maltese, Miniature Schnauzer, Pomeranian, Portuguese Water Dog, Pug, Retriever (unspecified), Rhodesian Ridgeback, Rottweiler, Saluki, Vizsla, and Yorkshire Terrier.

Genetic forms of DCM tend to affect male large and giant breed dogs starting in middle to older age. DCM cases reported to FDA CVM have involved a wide range of dog breeds, ages and weights. There have been a greater proportion of males than females, consistent with what is seen in genetic forms. The significance of this is unknown, but it may be that some cases are genetic in origin or a combination of diet and genetic tendencies.

Table 1: Mean Age and Weight - DCM Cases in Dogs Reported to FDA-CVM

Dogs	Mean	Range
Age (years)	6.5	0.42 -16
Weight (lbs.)	68	8 – 212

Table 2: Mean Age and Weight - DCM Cases in Cats Reported to FDA-CVM

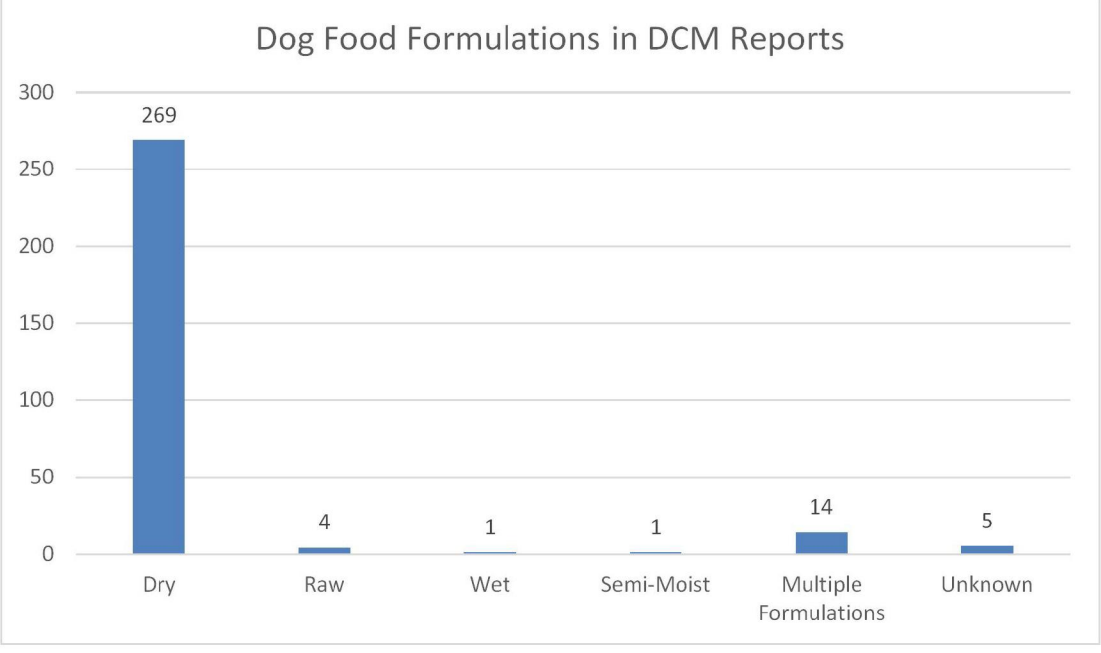
Cats	Mean	Range
Age (years)	5.5	0.4- 12
Weight (lbs)	11	7 -13

Table 3: Sex of DCM cases reported to FDA-CVM by species (%)

Sex (% of cases)	Male	Female
Dogs	59	41
Cats	60	40

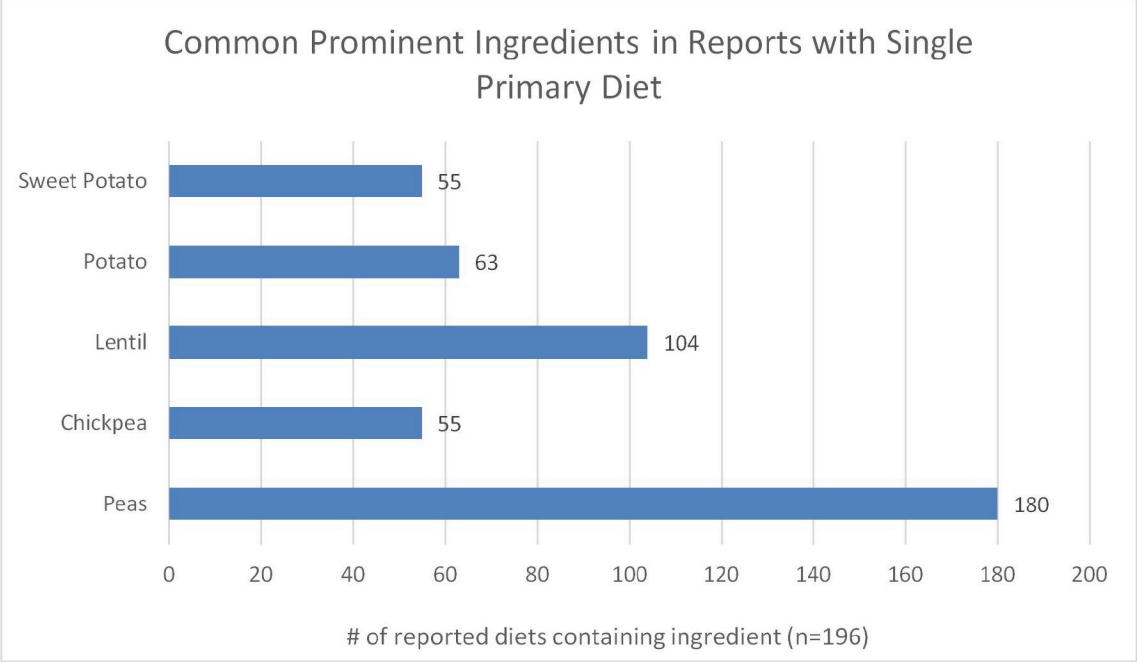
Diet Information from Reported Cases

Review of the canine reports shows that the majority of reports were for dry dog food formulations, but raw food, semi-moist food, and wet food were also represented.



Based on analysis of the 196 DCM reports to FDA in which dogs were fed only a single, primary diet (i.e., didn't eat multiple food products, excluding treats), approximately 90 percent of the foods were reported to be labeled "grain-free" (or labeled as zero-grain) and approximately 10 percent ate diets

containing grains, some of which were vegan or vegetarian. A large proportion of the reported diets in DCM cases contained peas and/or lentils.



Animal protein sources in the reported diets varied widely. Of the 191 reports with a single primary diet that contained animal protein (rather than being vegan/vegetarian), 31 percent contained more than one animal protein source. The majority of diets containing animal protein included fish, eggs, lamb or chicken. No one animal protein source was predominant.

Product Testing

Before the July 2018 DCM Update, FDA/Vet-LIRN had tested multiple products for minerals and metals (Ca, Mg, P, Fe, Co, Cu, Zn, Se, I) and amino acids including taurine, cysteine, and methionine. That product testing did not reveal any abnormalities.

Since the July 2018 DCM Update, Vet-LIRN tested both grain-free labeled and grain-containing products for the following:

- protein, fat, moisture
- crude fiber, total dietary fiber, soluble fiber, insoluble fiber
- total starch, resistant starch
- cystine, methionine, and taurine

The average percent protein, fat, total taurine, total cystine, total methionine, total methionine-cystine, and resistant starch content on a dry matter basis (in other words, after removing all moisture content) were similar for both grain-free labeled and grain-containing products. For more details, please see the Vet-LIRN DCM Update.

Taurine & Amino Acids

Nutritional research indicates that taurine is generally not considered an essential amino acid for dogs because they can synthesize taurine from cysteine and methionine. Nearly all of the grain-free products had methionine-cystine values above the minimum nutritional requirement of 0.65 percent for adult maintenance food for dogs published in the AAFCO Official Publication (OP).

The FDA is still gathering information in order to better understand if (and how) taurine metabolism (both absorption and excretion) may have a role in these reports of canine dilated cardiomyopathy.

Diagnostic Testing – Vet-LIRN

Vet-LIRN has interviewed 85 owners of affected dogs and cats to document the pets' complete dietary history and to explore any other factors that could have potentially contributed to development of DCM, such as environmental factors like heavy metal exposure or poisonous plant ingestion.

In addition, Vet-LIRN has contracted with a network lab to collect blood (whole blood and plasma), urine, feces, and DNA from dogs without a known breed predisposition to DCM (as a point of comparison) and to send to Vet-LIRN for testing.

Vet-LIRN has reviewed results of 15 gross necropsies from dogs with suspected heart disease, including ten necropsies that Vet-LIRN coordinated from cases reported through the FDA Safety Reporting Portal. The gross necropsies were performed by either veterinarians or veterinary pathologists, and Vet-LIRN is currently processing the tissues for histopathology. A board certified veterinary pathologist will review the histopathology slides.

Golden Retrievers

Past publications and research suggest that Golden Retrievers may be genetically predisposed to taurine deficiency, which is well-documented as potentially leading to DCM.

Veterinary cardiologist Dr. Joshua Stern from the University of California at Davis has been studying the rise in cases of DCM in Golden Retrievers, including a potential dietary link. Many cases of DCM in Golden Retrievers are taurine-deficient. Pet owners who suspect their Golden Retrievers may be affected may wish to consult their veterinarian to discuss checking taurine levels or conducting an echocardiogram.

Collaboration

When unprecedented events such as these occur, the FDA often consults with stakeholders across the animal health community to help fill any knowledge gaps that may help inform its investigation. These collaborations can help provide pieces to complete the puzzle and allow us to gain a better understanding of what happened.

Veterinary Community

FDA veterinarians have been working with the veterinary community to exchange information about existing cases and the type of clinical information that is most helpful to the investigation. We are also consulting with a cadre of board-certified veterinary cardiologists and nutritionists to learn more about the presentation of these cases and how they respond to treatment.

Chesapeake Veterinary Cardiology Associates (CVCA), a multi-location veterinary cardiology practice based predominantly in the Mid-Atlantic states, has provided comprehensive records for some DCM cases (including medical records, owner interviews, and diagnostic samples from pets with DCM diagnosed with an echocardiogram by a board-certified cardiologist) to the Vet-LIRN network for further

testing. These case records include imaging studies of the animal's hearts, comprehensive dietary histories, diagnostic and treatment records, as well as outcomes of the cases.

FDA veterinarians have been working with Drs. Lisa Freeman of Tufts University, Joshua Stern of UC Davis and Darcy Adin of the University of Florida to learn more about their research findings and the cases they've encountered. The three were contributing authors to a paper published in Journal of American Veterinary Medical Association in December 2018, "Diet-associated dilated cardiomyopathy in dogs: what do we know?"

Pet Owners

As animal lovers and pet owners, FDA employees understand that the sudden onset of a life-threatening disease in a previously healthy pet can be devastating. The FDA is incredibly grateful to those pet owners who have agreed to be interviewed and given permission for their veterinarians to share medical records and diagnostic samples, including blood, serum and tissue. The agency is especially appreciative when pet owners make the difficult decision to provide tissues for analysis when a beloved pet passes away. The FDA believes that the information gained will help the FDA to understand the specific changes that are happening in the cardiovascular system and how they may relate to diet.

Industry

Another puzzling aspect of the recent spike in DCM cases is that they have occurred just in the last few years. The FDA is working with the pet food industry to better understand whether changes in ingredients, ingredient sourcing, processing or formulation may have contributed to the development of DCM.

What you can do

The FDA is open to additional opportunities for collaboration and welcomes the submission of any information that may aid in our investigation. Detailed instructions for submitting case information can be found on "How to Report a Pet Food Complaint."

Pet Owners

If a dog is showing possible signs of DCM or other heart conditions, including decreased energy, cough, difficulty breathing and episodes of collapse, you should contact your veterinarian as soon as possible. If the symptoms are severe and your veterinarian is not available, you may need to seek emergency veterinary care. Your veterinarian may ask you for a thorough dietary history, including all the foods (including treats) the dog has eaten.

Veterinarians

CVM encourages veterinary professionals to report well-documented cases of DCM in dogs suspected of having a link to diet by using the electronic Safety Reporting Portal or calling their state's FDA Consumer Complaint Coordinators. The more information you are able to provide, particularly about feeding history, medical records, and diagnostic testing, the better. Detailed instructions can be found on "How to Report a Pet Food Complaint." Technical veterinary information that may aid veterinarians can be found in our Vet-LIRN Update - February 2019.

Industry

The FDA looks to industry organizations and pet food manufacturers to continue their own investigations to help shed light on potential issues with formulas or ingredients.

What's Next

The FDA is continuing to investigate and gather more information in an effort to identify the specific dietary link to development of DCM and will provide updates to the public as information develops.

Additional Information:

- FDA Provides Update on Investigation into Potential Connection Between Diet and Cases of Canine Heart Disease (February 2019)
- Vet-LIRN DCM Investigative Update (February 2019)
- FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease (July 2018)
- Journal of American Veterinary Medical Association - Diet-associated dilated cardiomyopathy in dogs: what do we know? (December 2018)

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Range: Hyperlink to Vet-LIRN update
Scope: Vet-LIRN DCM Investigative Update (February 2019)

Vet-LIRN Update on Investigation into Dilated Cardiomyopathy – February 2019

This update describes FDA and Vet-LIRN's investigative efforts through November 2018 at a level of technical detail geared toward veterinarians. For more general information, please visit FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy.

In July 2018, the FDA alerted the public about an investigation into reports of canine dilated cardiomyopathy (DCM) in dogs eating certain pet food. DCM itself is not considered rare in dogs, but these reports are unusual because many of the reported cases occurred in breeds of dogs not typically genetically predisposed to the disease and were reported to have been fed diets containing legumes like peas or lentils, other legume ingredients (pulses) or potatoes as main ingredients. Many of these products are labeled as "grain-free" or "zero-grain."

Since then, the FDA's Center for Veterinary Medicine (CVM) has taken a multi-pronged approach to the investigation. CVM veterinarians, nutritionists, pathologists and epidemiologists are collaborating with several sectors of the animal health world to collect and evaluate information about the DCM cases and the diets pets ate prior to becoming ill. A key partner in the investigation is the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), a collaboration of government and veterinary diagnostic laboratories.

Food Testing

Minerals and Elements

Prior to FDA's July 2018 notice about the investigation, Vet-LIRN collected and tested case-related food samples and purchased store-bought products labelled "grain free" for:

- Calcium
- Phosphorous
- Magnesium
- Cobalt
- Copper
- Zinc
- Selenium
- Iodine

The products tested within normal nutrient concentrations recommended in the Association of American Feed Control Officials (AAFCO) Dog and Cat Food Nutrient Profiles published in the AAFCO Official Publication (OP).

Nutritional Screening and Amino Acid Content

Because some products labelled "grain free" and containing legumes and/or potato products were potentially associated with DCM, Vet-LIRN collected case-related food samples and purchased store-bought products labelled "grain free". These products were tested, as well as grain-containing products not associated with development of DCM, to investigate any nutritional differences that could explain

the development of DCM. As of November 30, 2018, Vet-LIRN has tested grain-free products and grain-containing products for the following:

- protein, fat, moisture
- crude fiber, total dietary fiber, soluble fiber, insoluble fiber
- total starch, resistant starch
- cystine, methionine, and taurine

The average percent protein, fat, total taurine, total cystine, total methionine, total methionine-cystine, and resistant starch content on a dry matter basis were similar for both grain-free and grain-containing products (Table 1).

Table 1. Average values for grain-free and grain-containing products shown on a dry matter basis

Measurement	Average Grain-Containing	Average Grain-Free
Protein	28.8 %	29.6 %
Fat	15.2 %	16.6 %
Total Taurine	0.13 %	0.14 %
Total Cystine	0.3 %	0.29 %
Total Methionine	0.59 %	0.55 %
Total Methionine-Cystine	0.89 %	0.84 %
Total Dietary Fiber	8.6 %	12.1 %
Crude Fiber	2.5 %	4.6 %
Insoluble Fiber	7.2 %	11.7 %
Soluble Fiber	1.46	<1.41
Starch	37.4 %	26 %
Resistant Starch	<2.15 %	<2.15 %
Choline Chloride	3289 ppm	2731 ppm
Choline	2453 ppm	1979 ppm

All but one of the grain-free products had methionine-cystine values above the minimum nutrient concentration recommended in the AAFCO OP of 0.65% for adult maintenance foods for dogs. The grain-free foods had greater total dietary fiber, crude fiber, and insoluble fiber, and less starch and choline on average than the grain-containing products. One grain-free product contained choline levels below the minimum concentration recommended for adult maintenance food for dogs, as published in the AAFCO OP.

The FDA is still trying to better understand if (and how) taurine, cystine, and methionine metabolism (both absorption and excretion) may have a role in DCM in the context of the foods being fed.

Case Information

Between January 1, 2014 and November 30, 2018, the FDA received reports of 325 dogs and 10 cats diagnosed with DCM. The FDA additionally received many reports of non-DCM cardiac disease in dogs and cats during this timeframe. In an effort to better understand the reported cardiac diseases, FDA investigated many of the DCM cases, as well as some of these non-DCM cardiac cases by reviewing medical records and performing dietary and environmental exposure interviews. Additionally, FDA is working to determine whether there is a disease continuum that includes cardiac changes that could indicate developing DCM or if there are other cardiac changes of importance.

FDA's review of medical records for reports is ongoing and the following data are a summary for only a subset of collected medical records for both DCM and non-DCM cardiac cases. Of 168 dogs and 6 cats whose medical records were reviewed, 104 dogs and 2 cats were DCM cases with heart changes characteristic of DCM on cardiac ultrasound – including decreased ventricular systolic function and dilation. Approximately 67% of dogs (n=71) of those with confirmed DCM had progressed to congestive heart failure. Of the pets with confirmed DCM, approximately 18% (n=19) also had evidence of degenerative valvular disease and 11% (n=12) had atrial fibrillation. Approximately 42% (n=45) of dogs with DCM had a history of allergies or sensitivities to an environmental allergen and/or food that was manifested as dermatitis, otitis, or gastrointestinal disease. Approximately 9% (n=9) and 8% (n=8) of dogs with DCM had a history of hypothyroidism and one or more tick-borne diseases (e.g. Lyme, Anaplasmosis), respectively.

According to the medical records reviewed for the non-DCM cardiac disease cases, other cardiac changes were present on echocardiogram, including degenerative valvular disease, tricuspid and mitral valve regurgitation, and borderline to decreased left ventricular systolic function. For animals without DCM, there may be a spectrum of cardiac changes visualized on echocardiogram (e.g. borderline decreased left systolic function in the absence of left ventricular dilation) if the animal is progressing toward or recovering from DCM. While not DCM, these cases are important to report to FDA, so we may better understand if they could be related to development of DCM or associated with certain diets.

Taurine levels and cardiac disease status:

Eighty-three dogs and 2 cats (including both DCM and non-DCM cases) had both a taurine measurement and an echocardiogram (Table 2). A full summary of the taurine status and echocardiogram findings for the pets with a taurine measurement and echocardiogram is included in Table 2. Approximately 64% of dogs with DCM had a taurine measurement. Of the pets diagnosed with DCM, approximately 38% had at least one low blood taurine value (Table 4). Golden Retrievers represented approximately one third of all dogs with low taurine and DCM and approximately half of all dogs with low blood taurine regardless of type of cardiac findings. Table 3 shows the reported breed frequency for each category by breed of dog. Table 4 shows the taurine results for all dogs and cats with DCM.

Table 2. Number of pets with various taurine levels (either whole blood and/or plasma) and echocardiogram changes based on medical record review for dogs with a taurine test.

Status	Count
Low taurine with DCM	39 (37 dogs, 2 cats)

Normal taurine with DCM*	18 dogs
High taurine with DCM	11 dogs
Low taurine with non-DCM heart changes	10 dogs
Low taurine with normal heart	6 dogs
Normal taurine with non-DCM heart changes	1 dog
Normal taurine and normal heart	2 dogs

*One dog with DCM had a low plasma taurine and normal whole blood. This dog was considered Normal Taurine with DCM.

Table 3. Pet breeds grouped by taurine (Tau) status and echocardiogram changes for dogs with a Tau test.

Breed	Low Tau DCM	Normal Tau DCM	High Tau DCM	Low Tau non-DCM	Normal Tau non-DCM	Low Tau Normal heart	Normal Tau Normal heart
Boxer Mix	1		1				
Doberman Pinscher		3					
German Shepherd		1	1				
Goldendoodle	1	1		1			
Golden Retriever	14	1	1	8	1	6	2
Great Dane	1	2	2				
Labrador Retriever	3	2	1				
Miniature Schnauzer		1	1				
Bluetick Coonhound	2						
Cat	2						
Cocker Spaniel	2						
Blueheeler Mix	1						
Doberman Mix	1						
French Bulldog	1						
Golden Retriever Mix	1						
Maltese	1						
Pitbull	1						
Pitbull Mix	1						
Samoyed	1						
Sheepadoodle	1						
Standard Poodle	1						
Viszla Mix	1						
White Shepherd	1						
Australian Shepherd Mix		1					
Boston Terrier		1					
Labrador Retriever Mix		1					
Shetland Sheepdog		1					

Shih Tzu		1					
Wheaten Terrier		1					
American Staffordshire Terrier			1				
Catahoula Leopard Dog			1				
Pug			1				
Yorkshire Terrier			1				
Flat Coated Retriever				1			
Sum	38	17	11	10	1	6	2

Table 4. Taurine results for dogs and cats with confirmed DCM.

Taurine Status* and Sample Type	**Count**
Low Taurine, Whole blood only	21 dogs
Low Taurine, Plasma only	10 dogs, 2 cats
Low Taurine, Whole blood and Plasma	5 dogs
Low Taurine, Plasma with Normal Whole blood	1 dog
Low Taurine, unknown sample type	1 dog
Normal, Whole blood only	12 dogs
Normal, Plasma only	2 dogs
Normal, Whole blood and Plasma	2 dogs
Normal, unknown sample type	1 dog
High Taurine, Whole blood only	8 dogs
High Taurine, Plasma only	1 dog
High Taurine, Whole blood and Plasma	1 dog
High Taurine, Whole blood with Normal Plasma	1 dog

*The taurine status is based on reference ranges used by the laboratory that performed the test.

Course of disease:

According to recheck echocardiograms in the medical records, some pets with DCM improved after veterinary treatment, diet change, and taurine supplementation, while others improved with

appropriate veterinary care and diet change alone. Vet-LIRN has requested 30 additional repeat echocardiograms to better understand DCM heart changes over time. This repeat echocardiogram data are currently being collected and will be compared to the initial echocardiogram parameters to better understand the effects of diet change and/or taurine supplementation on the heart.

One example detailed in Table 4 describes a case in which a dog without taurine deficiency, according to the reference laboratory's reference range, improved with cardiac care and diet change alone. We provide the detailed echocardiogram data to show which parameters changed during recovery and at what rates.

The case involved a 3-year-old male, castrated, Beagle Mix, initially presented with a cough of six weeks duration that was treated with 30 days of doxycycline. The dog had been eating a limited ingredient grain-free diet containing a novel protein source and six legume-based ingredients. The whole blood and plasma taurine levels were above normal reference values. After DCM was diagnosed, the dog was diagnosed with a possible food allergy. This case shows the resolution of DCM at 2 years post presentation after treatment with cardiac prescriptions and diet change only. Taurine was not supplemented. A summary is below (Table 5).

Table 5. Echocardiogram changes in a 3-year-old Beagle mix over time and with a diet change

Echocardiogram Parameter	**Day 0** **Original Diet**	**1 week** **Similar to original diet**	**Approx. 5 months** **Chicken & Rice**	**Approx. 1 year** **Chicken & Rice**	**Approx. 1.5 years** **Chicken & Rice**	**Approx. 2 years** **Chicken & Rice**
LA/Ao	1.28	1.81	1.24	1.31		1.17
IVSd (mm)	9.3	8.6	11.1	7.6	9.2	9.4
LVIDd (mm)	51.4	55.4	51.6	45.8	44.7	45
LVPWd (mm)	8.7	7.9	8.8	9.3	9.5	10.3
IVSs (mm)	10	10.3	14	11.3	12.2	14.6
LVIDs (mm)	41.6	44.6	39.1	33.3	27.9	27.9
LVPWs (mm)	9.3	7.9	11.8	12	11.7	13.8
FS %	18.99	19.4	24.31	27.25	37.48	37.88
EF (Teich) %	41.78	35.78	34.03	33.5	57.13	
Mitral Valve	Mild thickening, Mild mitral regurgitation	Unchanged	Unchanged	Mild thickening, Trace mitral regurgitation	Mild thickening	Normal
Tricuspid Valve	Trace to Mild	Unchanged	Unchanged	Normal	Normal	Normal

	tricuspid regurgitation					
Pulmonary hypertension	Mild	Mild	Mild	Normal	Normal	Normal
Right heart	Enlargement	Unchanged	Unchanged	Unchanged	Unchanged	Normal
AV Vmax (m/s)	1.56	1.49	1.85	1.78	2.14	2.24

MR: mitral regurgitation, TR: tricuspid regurgitation, Severity Index: +/- trace, +1 mild, +2 moderate, +3 marked, +4 severe

Necropsy

As of November 30, 2018, Vet-LIRN has reviewed results of 15 gross necropsies from dogs with suspected heart disease, including 10 necropsies that Vet-LIRN coordinated from cases reported through the FDA Safety Reporting Portal. The dogs either died naturally or were euthanized and did not necessarily have a pre-mortem diagnosis of DCM. Of the 10 necropsies that Vet-LIRN coordinated, there have been 9 canine heart gross examinations, with one heart pending evaluation. During the gross evaluation, we measured dimensions including chamber lumen diameter, chamber wall thickness, and valve circumference. We collected other tissues for histopathology, including liver, kidney, gastrocnemius muscle, and spleen for 9 of the 10 requested necropsies. The histopathology results and data analysis are pending. The necropsy results will enable Vet-LIRN to evaluate the cases for any common histopathological lesions that could suggest a cause for illness and to confirm the antemortem diagnosis.

Prospective Diagnostic Sample Testing

Vet-LIRN has been collaborating with Chesapeake Veterinary Cardiology Associates (CVCA) to collect medical records, an owner interview, and diagnostic samples from pets with DCM diagnosed by a board-certified veterinary cardiologist by echocardiogram. These cases are included in the overall number of DCM cases, but were selected for further study because their ongoing program of care with the practice will be comprehensively documented and provided in full to Vet-LIRN.

Upon confirmation of a DCM diagnosis, CVCA will collect blood (whole blood and plasma), urine, feces, DNA swabs, and food, if the pet is not receiving any supplements (e.g. taurine, cystine, or methionine) and is still eating a diet labeled “grain-free.” Vet-LIRN will test the blood and urine for taurine, cystine, methionine, and other amino acids. Vet-LIRN is archiving feces and DNA from these cases for possible future testing.

CVCA will collect repeat urine, blood, and feces at 1 to 2 months and 6 months after the initial diagnosis and document any treatment or dietary changes, if any, that were recommended by the cardiologist. The repeat urine and blood samples will be tested for amino acid content and the feces archived. At the 6-month recheck, CVCA will also conduct a repeat echocardiogram to assess any changes to the heart. As of November 11, 2018, CVCA and Vet-LIRN have collected initial samples from 14 dogs. CVCA is currently collecting the 1 to 2-month samples. Two dogs have died and will not complete the sample collection. Vet-LIRN is currently evaluating the heart histopathology from those two dogs.

Vet-LIRN is also collecting food associated with each CVCA case and will test each diet for:

- protein, fat, moisture
- crude fiber, total dietary fiber, soluble fiber, insoluble fiber
- total starch, resistant starch
- free and total cystine, methionine, and taurine

Separate from the ongoing collaboration with CVCA, Vet-LIRN has contracted with a network lab to collect blood (whole blood and plasma), urine, feces, and DNA from healthy dogs without a known breed predisposition to DCM for comparison. The dog must also be consuming a grain-containing primary diet that meets the following criteria:

- not be labelled "grain-free"
- consuming the diet for at least 1 year before the samples are collected
- animal proteins are from either cattle, swine, poultry, and/or fish
- no more than 2 legume, pulse, or potato (including sweet potato) ingredients that must appear after the animal and grain ingredients
- the diet formulation was verified to be nutritionally adequate by animal feeding tests using AAFCO procedures

The blood and urine samples will be tested similarly to those collected in the cases from CVCA collaboration and compared to the values from the dogs diagnosed with DCM.

How You Can Help

FDA encourages veterinary professionals to report well-documented cases of DCM in dogs whose illness is suspected of having a link to diet. You can submit information by using the electronic Safety Reporting Portal or calling your state's FDA Consumer Complaint Coordinators. The more information you are able to provide, particularly about feeding history, medical records, and diagnostic testing, the better. Detailed instructions can be found on How to Report a Pet Food Complaint.

Additional Information

- FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy
- FDA Provides Update on Investigation into Potential Connection Between Diet and Cases of Canine Heart Disease (February 2019)
- FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease (July 2018)
- Journal of American Veterinary Medical Association - Diet-associated dilated cardiomyopathy in dogs: what do we know? (December 2018)

Document properties

Author: Norris, Anne
Template: Normal.dotm
Page count: 4
Paragraph count: 371
Line count: 720
Word count: 2665
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Character count (spaces included): 16735

Document Comments
Total Comments: 4

Author: Norris, Anne
Date: 2/1/2019 1:35:00 PM
Initial: NA
Range: Hyperlink to general web update
Scope: FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy

Author: Norris, Anne
Date: 2/1/2019 1:35:00 PM
Initial: NA
Range: Hyperlink to main investigation page
Scope: FDA Investigation into Potential Link between Certain Diets and Canine Dilated Cardiomyopathy

Author: Norris, Anne
Date: 2/1/2019 1:35:00 PM
Initial: NA
Range: Hyperlink to CVM Update for February update
Scope: FDA Provides Update on Investigation into Potential Connection Between Diet and Cases of Canine Heart Disease (February 2019)

Author: Norris, Anne
Date: 2/1/2019 1:35:00 PM
Initial: NA
Range: Are we allowed to link to this?
Scope: Journal of American Veterinary Medical Association - Diet-associated dilated cardiomyopathy in dogs: what do we know? (December 2018)

From:	Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To:	Solomon, Steven M; Flynn, William T; Forfa, Tracey; Schell, Timothy; Jones, Jennifer L; Palmer, Lee Anne; Burkholder, William; Carey, Lauren; DeLancey, Siobhan; Hartogensis, Martine; Murphy, Jeanette; Dewitt, Susan J; Cepeda, Sandra; Steinberg, Nadine; Rotstein, David; Moxley, Shera
Sent:	5/29/2019 8:38:59 PM
Subject:	RE: Checkpoint on DCM
Attachments:	COMMSPLAN_DCM_Summer_2019.docx

To help facilitate discussion, attached is the draft communications plan for the next DCM public update. Lee Anne, Lauren, and Jen will share some data points/high-level takeaways via WebEx tomorrow.

-----Original Appointment-----
From: Solomon, Steven M
Sent: Monday, May 20, 2019 10:36 AM
To: Solomon, Steven M; Flynn, William T; Forfa, Tracey; Norris, Anne; Schell, Timothy; Jones, Jennifer L; Palmer, Lee Anne; Burkholder, William; Carey, Lauren
Cc: DeLancey, Siobhan; Hartogensis, Martine; Murphy, Jeanette; Dewitt, Susan J; Cepeda, Sandra; Steinberg, Nadine; Rotstein, David
Subject: Checkpoint on DCM
When: Thursday, May 30, 2019 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: CVM 7500 Conf E473 and WebEx

Purpose: Discuss currently available DCM data, pending updates, and key messaging in forthcoming communications.

Meeting materials forthcoming.

Apologies for the lunchtime meeting, but schedules were tight.

Join Webex meeting
Meeting number (access code): B6
Meeting password: B6

Join by phone
+1-210-795-0506 US Toll
+1-877-465-7975 US Toll Free
Global call-in numbers | Toll-free calling restrictions

Can't join the meeting?

If you are a host, go here to view host information.

From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: Jones, Jennifer L; Rotstein, David
Sent: 6/12/2019 6:58:31 PM
Subject: RE: DCM write-up for June Web Update

One correction—I double checked and it should be "There are B5 evaluation."

FYI, these are the pending necropsy cases:

B5, B6

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Peloquin, Sarah
Sent: Wednesday, June 12, 2019 2:41 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Sorry for the delay—I added my changes in blue:

B5

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Jones, Jennifer L
Sent: Wednesday, June 12, 2019 2:10 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Excellent, thanks, Dave. I'll wait for Sarah P to reply to make sure our numbers are correct as of 5/31/2019.

Jennifer Jones, DVM

Veterinary Medical Officer
Tel: 240-402-5421

From: Rotstein, David
Sent: Wednesday, June 12, 2019 10:19 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Works for me!

Thank you!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6

From: Jones, Jennifer L
Sent: Wednesday, June 12, 2019 10:18 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

This looks great, Dave. I'm just going to change the date to B5 Does that still work?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Rotstein, David
Sent: Wednesday, June 12, 2019 10:05 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Jen,
Please see below.

I didn't put hard numbers in there given that B5. I can add those if you think it would be helpful.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6

From: Jones, Jennifer L
Sent: Wednesday, June 12, 2019 7:21 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: DCM write-up for June Web Update
Importance: High

Good morning team,
Could you please write-up a summary of the findings we would like to make public for DCM necropsies? This will be part of the technical Vet-LIRN update. The information will build on this paragraph:

B5

Can you get this to me by noon Thursday? I told comm's I'd have the update complete by COB Thursday.
Thank you :)
Jen

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708

new tel: 240-402-5421
fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Norris, Anne
CC: Peloquin, Sarah
Sent: 6/13/2019 1:31:11 PM
Subject: RE: Vet-LIRN Update on DCM

Good morning Anne,
I finished with the Vet-LIRN updates, and they're ready for your team.
Please let me know if you want to meet ahead of tomorrow's meeting to discuss the content.
Thanks again,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Jones, Jennifer L
Sent: Wednesday, June 05, 2019 9:38 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thank you :)

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sure, no problem at all. Thank you and enjo **B6**

From: Jones, Jennifer L
Sent: Wednesday, June 5, 2019 9:33 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. I'll take a look and work on the updates. **B6**
Can I get it to you by COB Thursday?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:23 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Vet-LIRN Update on DCM

Hi Jen,

Wanted to circle back after Dr. Solomon's DCM briefing. You did a great job! I think he has a much better appreciation for where things stand now.

I mocked up a new document for the June DCM Vet-LIRN Update using the last Vet LIRN-Update as the basis and thought you could edit/add/subtract as you wish.

Draft – Vet-LIRN DCM Update for June 2019

Happy to discuss/help however I can, please let me know! If at all possible, I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

Thanks!
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
B6
Anne.Norris@fda.hhs.gov

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Norris, Anne
CC: Peloquin, Sarah
Sent: 6/13/2019 2:03:15 PM
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. B5
time.
We don't need to meet unless B5 In that case, I'm free today until 3.
Otherwise, we can just chat tomorrow with the group.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Norris, Anne
Sent: Thursday, June 13, 2019 9:49 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, you're the best! Just one stat I need for the comms that I don't see in there - B5
B5

I'll give this a read through, but I think it's in great shape for tomorrow. If you'd like to talk it through before then, happy to do that.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 9:31 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Good morning Anne,
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Thanks again,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Jones, Jennifer L
Sent: Wednesday, June 05, 2019 9:38 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thank you :)

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sure, no problem at all. B6

From: Jones, Jennifer L
Sent: Wednesday, June 5, 2019 9:33 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. I'll take a look and work on the updates B6
Can I get it to you by COB Thursday?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Vet-LIRN Update on DCM

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Happy to discuss/help however I can, please let me know! If at all possible, I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

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Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
B6
Anne.Norris@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Jones, Jennifer L
CC: Peloquin, Sarah
Sent: 6/13/2019 2:41:29 PM
Subject: RE: Vet-LIRN Update on DCM

Thanks! Sounds good. Tracey just asked me to reschedule tomorrow's meeting for early next week. I'll still send around the comms docs links for people to start reviewing in the interim.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 10:03 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne **B5**
time.
We don't need to meet unless **B5** In that case, I'm free today until 3.
Otherwise, we can just chat tomorrow with the group.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Norris, Anne
Sent: Thursday, June 13, 2019 9:49 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, you're the best! Just one stat I need for the comms that I don't see in there **B5**
B5

I'll give this a read through, but I think it's in great shape for tomorrow. If you'd like to talk it through before then, happy to do that.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 9:31 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Good morning Anne,
I finished with the Vet-LIRN updates, and they're ready for your team.
Please let me know if you want to meet ahead of tomorrow's meeting to discuss the content.
Thanks again,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Jones, Jennifer L
Sent: Wednesday, June 05, 2019 9:38 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thank you :)

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Norris, Anne
Sent: Wednesday, June 05, 2019 9:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sure, no problem at all. **B6**

From: Jones, Jennifer L
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To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. I'll take a look and work on the updates. **B6**
Can I get it to you by COB Thursday?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

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I mocked up a new document for the June DCM Vet-LIRN Update using the last Vet LIRN-Update as the basis and thought you could edit/add/subtract as you wish.

Draft – Vet-LIRN DCM Update for June 2019

Happy to discuss/help however I can, please let me know! If at all possible, I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

Thanks!

Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
B6
Anne.Norris@fda.hhs.gov

From: Peloquin, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8607F880DF2B494AA639E6D9A3874132-SARAH.PELOQ>
To: Jones, Jennifer L
Sent: 6/13/2019 3:31:42 PM
Subject: RE: DCM write-up for June Web Update

The rest of the numbers shouldn't change, but--

As of April 30, 2019: There is B5

B5, B6

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Peloquin, Sarah
Sent: Wednesday, June 12, 2019 2:59 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

One correction—I double checked and it should be "There are B5 evaluation."

B5, B6

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Peloquin, Sarah
Sent: Wednesday, June 12, 2019 2:41 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Sorry for the delay—I added my changes in blue:

B5

B5

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Jones, Jennifer L
Sent: Wednesday, June 12, 2019 2:10 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Excellent, thanks, Dave. I'll wait for Sarah P to reply to make sure our numbers are correct as of 5/31/2019.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Rotstein, David
Sent: Wednesday, June 12, 2019 10:19 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Works for me!

Thank you!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6

From: Jones, Jennifer L
Sent: Wednesday, June 12, 2019 10:18 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

This looks great, Dave. I'm just going to change the d B5 Does that still work?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Rotstein, David
Sent: Wednesday, June 12, 2019 10:05 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: DCM write-up for June Web Update

Jen,
Please see below.

I didn't put hard numbers in there given B5 s. I can add those if you think it would be helpful.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6

From: Jones, Jennifer L
Sent: Wednesday, June 12, 2019 7:21 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: DCM write-up for June Web Update
Importance: High

Good morning team,
Could you please write-up a summary of the findings we would like to make public for DCM necropsies? This will be part of the technical Vet-LIRN update. The information will build on this paragraph:

B5

Can you get this to me by noon Thursday? I told comm's I'd have the update complete by COB Thursday.
Thank you :)
Jen

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Norris, Anne
CC: Peloquin, Sarah
Sent: 6/13/2019 3:37:04 PM
Subject: RE: Vet-LIRN Update on DCM

Done :)

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Norris, Anne
Sent: Thursday, June 13, 2019 11:17 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Shoot, sorry I spoke too soon. B5

B5

Sorry about that, I wish I could pull the numbers myself without having to bother you again!

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Subject: RE: Vet-LIRN Update on DCM

Thanks! Sounds good. Tracey just asked me to reschedule tomorrow's meeting for early next week. I'll still send around the comms docs links for people to start reviewing in the interim.

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 10:03 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, Anne. B5
time.
We don't need to meet unless B5 In that case, I'm free today until 3.
Otherwise, we can just chat tomorrow with the group.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Norris, Anne
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Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Thanks, you're the best! Just one stat I need for the comms that I don't see in there B5

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Please let me know if you want to meet ahead of tomorrow's meeting to discuss the content.
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U.S. FOOD & DRUG ADMINISTRATION

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Thank you :)

Jennifer Jones, DVM
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U.S. FOOD & DRUG ADMINISTRATION

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Sure, no problem at all. B6

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Sent: Wednesday, June 5, 2019 9:33 AM
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B6

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Draft – Vet-LIRN DCM Update for June 2019

Happy to discuss/help however I can, please let me know! If at all possible, I think we'd like to have drafts ready to share with the group by the middle of next week. Is that workable for you?

Thanks!
Anne

Anne Norris
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U.S. Food & Drug Administration
O: 240-402-0132
B6
Anne.Norris@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Jones, Jennifer L
Sent: 6/13/2019 4:43:51 PM
Subject: RE: Vet-LIRN Update on DCM

TY!

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 12:34 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Yes, correct.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Norris, Anne
Sent: Thursday, June 13, 2019 12:22 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Vet-LIRN Update on DCM

Sorry, and B5

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Anne Norris
Strategic Initiatives

Office of the Director
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U.S. Food & Drug Administration
O: 240-402-0132
B6
Anne.Norris@fda.hhs.gov

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Peloquin, Sarah
Sent: 6/14/2019 12:40:46 PM
Subject: RE: link to VL DCM update for June 2019

Excellent! I changed them :)
Thank you.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Peloquin, Sarah
Sent: Friday, June 14, 2019 8:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: link to VL DCM update for June 2019

And again, I'm sure this will be caught, but the title says 2018 in the description at the bottom.

Full Title: Vet-LIRN Update on Investigation into Dilated Cardiomyopathy – June 2018
Short Title: Vet-LIRN Update on Investigation into Dilated Cardiomyopathy – June 2018

Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Peloquin, Sarah
Sent: Friday, June 14, 2019 8:31 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: link to VL DCM update for June 2019

I know someone will probably catch this, but the last sentence in this paragraph (under "Course of disease") has a grammatical error.

B5

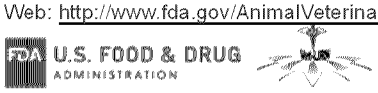
Sarah Peloquin, DVM
Veterinary Medical Officer
tel: 240-402-1218

From: Jones, Jennifer L
Sent: Thursday, June 13, 2019 10:55 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>

Subject: link to VL DCM update for June 2019

B5

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm



From:	Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To:	Hartogensis, Martine; Schell, Timothy; Murphy, Jeanette; Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Peloquin, Sarah; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Hodges, April; Nelson, Eric; McCoig, Amber; Conway, Charlotte; Edwards, David; Forfa, Tracey; Steinberg, Nadine
Sent:	6/13/2019 10:22:07 PM
Subject:	FOR CLEARANCE: DCM Comms - Review requested by 12pm on Monday, 6/17
Importance:	High

Hi all,

Using the SharePoint links below, could you please review the comms for the DCM investigative update by **noon on Monday, 6/17**? Our group call is at 4:00pm on Monday and that'll be an opportunity to discuss any outstanding questions/discrepancies while we have a quorum. This is a big group and not everyone needs to clear these, so if you didn't review the documents the last time we issued an update, you probably don't need to do it this time either. That said, feel free to take a look and weigh in if you have suggestions.

Please note that Lee Anne and Lauren are still slaving over some of the **B5** **B5** Would be great to discuss that on Monday as well.

B5

Thanks!
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
B6
Anne.Norris@fda.hhs.gov

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Hartogensis, Martine; Schell, Timothy; Murphy, Jeanette; Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Peloquin, Sarah; Rotstein, David; Burkholder, William; DeLancey, Siobhan; Hodges, April; Nelson, Eric; McCoig, Amber; Conway, Charlotte; Edwards, David; Forfa, Tracey; Steinberg, Nadine
Sent: 6/17/2019 1:26:42 PM
Subject: RE: FOR CLEARANCE: DCM Comms - Review requested by 12pm on Monday, 6/17

Friendly reminder to all who plan to review the comms to please B5 to do so by this afternoon.

Thanks!

From: Norris, Anne
Sent: Thursday, June 13, 2019 6:22 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Schell, Timothy <Timothy.Schell@fda.hhs.gov>; Jeanette Murphy (Jenny.Murphy@fda.hhs.gov) <Jenny.Murphy@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Siobhan DeLancey - FDA (Siobhan.Delancey@fda.hhs.gov) <Siobhan.Delancey@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; McCoig, Amber <Amber.McCoig@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Steinberg, Nadine <Nadine.Steinberg@fda.hhs.gov>
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U.S. Food & Drug Administration

O: 240-402-0132
B6
Anne.Norris@fda.hhs.gov

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To:	Palmer, Lee Anne; Jones, Jennifer L; Hartogensis, Martine; Murphy, Jeanette; Norris, Anne
CC:	Forfa, Tracey
Sent:	6/20/2019 3:57:31 PM
Subject:	RE: DCM roll-out timing question?

Jenny,

My slides may not be appropriate-they're **B5**

Dave

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: June 20, 2019 at 11:54:06 AM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM roll-out timing question?

Hi – here are the ones I made for Dave Edwards, but they're outdated. I would want to give you updated #'s – and those will be in the public update. Let me know what might be most useful to you.

From: Jones, Jennifer L
Sent: Thursday, June 20, 2019 11:47 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM roll-out timing question?

Here are a few slides we shared with Dave Edwards for the AFIA meeting.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Thursday, June 20, 2019 11:38 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DCM roll-out timing question?

B5

Lee Anne, Jen and Dave may be able to help you with some slides.

Martine

From: Palmer, Lee Anne
Sent: Thursday, June 20, 2019 10:45 AM
To: Murphy, Jeanette <Jenny.Murphy@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: DCM roll-out timing question?

B5

From: Murphy, Jeanette
Sent: Thursday, June 20, 2019 10:37 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: DCM roll-out timing question?

Greetings Ladies

B5

Jenny

From:	Freeman, Lisa <Lisa.Freeman@tufts.edu>
To:	Jones, Jennifer L
CC:	Norris, Anne
Sent:	6/27/2019 3:19:56 PM
Subject:	Re: FDA DCM Update Links-Live 6/27/2019
Attachments:	image005.png; image006.png

Hi Jen. I heard rumors of something coming so thanks for letting me know. Did you hear from **B6** about our preliminary data presented at ACVIM? Let me know if you'd like to discuss
Thanks. Lisa

Sent from my iPhone

On Jun 27, 2019, at 11:14 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning,
I wanted to let you know that FDA Consumer update about DCM when live this morning. Here are the links:
CVM Update

Web Update – DCM Investigation

Web QA (Updated)

Vet-LIRN Update

DCM Complaint Spreadsheet – 1/1/14 - 4/30/19

If you have any questions about the content, please direct them to: AskCVM@fda.hhs.gov

Thank you and take care,
Jen

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm
<image005.png> <image006.png>

From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Freeman, Lisa
CC: Norris, Anne
Sent: 7/5/2019 10:49:33 AM
Subject: RE: FDA DCM Update Links-Live 6/27/2019

Hi Lisa,
No, I did not hear about any preliminary data from B6 I'd love to read anything you're willing to share.
Thanks again,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Thursday, June 27, 2019 11:20 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: Re: FDA DCM Update Links-Live 6/27/2019

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Thank you and take care,
Jen

Jennifer L. A. Jones, DVM
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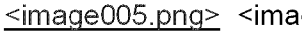
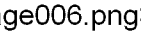
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm




From: Joshua A Stern <jstern@ucdavis.edu>
To: Jones, Jennifer L
CC: Norris, Anne
Sent: 6/27/2019 3:56:33 PM
Subject: Re: FDA DCM Update Links-Live 6/27/2019
Attachments: image005.png; image006.png

Thanks so much!

Joshua A. Stern, DVM, PhD, DACVIM
614.390.1516; jstern@ucdavis.edu
Sent from my iPhone

On Jun 27, 2019, at 8:11 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning,
I wanted to let you know that FDA Consumer update about DCM when live this morning. Here are the links:
CVM Update

Web Update – DCM Investigation

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Vet-LIRN Update

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Thank you and take care,
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Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm
<image005.png> <image006.png>

From: ADIN,DARCY BRITTAIN <adind@ufl.edu>
To: Jones, Jennifer L
Sent: 6/27/2019 4:47:40 PM
Subject: RE: FDA DCM Update Links-Live 6/27/2019

Thank you for the update! Sounds like you are making good progress!
Take care
Darcy

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Thursday, June 27, 2019 11:11 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>
Subject: FDA DCM Update Links-Live 6/27/2019

Good morning,
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Thank you and take care,
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fax: 301-210-4685
e-mail: *jennifer.jones@fda.hhs.gov*
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 6/13/2018 10:56:39 AM
Subject: RE: Notice

Thank you for the head's up Lisa!

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

-----Original Message-----
From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Tuesday, June 12, 2018 5:38 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Notice

Hi Jennifer. I heard a rumor that a notice was coming out B5 I hope that B5
Thanks. Lisa

Sent from my iPhone

From:	Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To:	Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
CC:	DeLancey, Siobhan; Hartogensis, Martine
Sent:	7/2/2018 7:56:51 PM
Subject:	FW: Redacted complaint file for the DCM webposting
Importance:	High
Attachments:	DCM Reports to FDA CVM_Redacted.pdf

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help B5

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point…

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Norris, Anne; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 7:58:22 PM
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

My understanding was that B5 reported.

Dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (BB)

From: Norris, Anne
Sent: Monday, July 02, 2018 3:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: FW: Redacted complaint file for the DCM webposting
Importance: High

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help B5

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From:	Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To:	Norris, Anne; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
CC:	DeLancey, Siobhan; Hartogensis, Martine
Sent:	7/2/2018 8:01:56 PM
Subject:	RE: Redacted complaint file for the DCM webposting

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 **(BB)**

From: Norris, Anne
Sent: Monday, July 02, 2018 3:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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Lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Rotstein, David; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:04:39 PM
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Dave. B5

B5

From: Rotstein, David
Sent: Monday, July 02, 2018 3:58 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

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7519 Standish Place
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To: Norris, Anne; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:07:12 PM
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

B5

Others may have differing thoughts.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (BB)

From: Norris, Anne
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To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Dave. **B5**

B5

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Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

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B6 BB)

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B5

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U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Rotstein, David; Norris, Anne; Jones, Jennifer L; Palmer, Lee Anne
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:30:55 PM
Subject: RE: Redacted complaint file for the DCM webposting

Hi Anne,

I'm in today, just with intermittent network connectivity at the moment. B5 B5 so I'm not any help even though I'm here. Lee Anne will be back on Thursday and should be able to help then, but I'm not sure if that decision was on her end or not.

Thanks,
Lauren

From: Rotstein, David
Sent: Monday, July 02, 2018 4:07 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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Subject: RE: Redacted complaint file for the DCM webposting

Anne,

B5

Others may have differing thoughts.

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CVM OSC/DC/CERT
7519 Standish Place
B6 BB)
U.S. FOOD & DRUG ADMINISTRATION

From: Norris, Anne
Sent: Monday, July 02, 2018 4:05 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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Thanks, Dave. B5

B5

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Dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 (BB)

From: Norris, Anne
Sent: Monday, July 02, 2018 3:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: FW: Redacted complaint file for the DCM webposting
Importance: High

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B5

Thanks,

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To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

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Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Carey, Lauren; Rotstein, David; Jones, Jennifer L; Palmer, Lee Anne
CC: DeLancey, Siobhan; Hartogensis, Martine
Sent: 7/2/2018 8:49:14 PM
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Lauren and Dave! We'll keep the comms moving in clearance, but will update them as needed with any further info from Lee Anne upon her return.

Anne

From: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Date: July 2, 2018 at 4:30:57 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Anne,

I'm in today, just with intermittent network connectivity at the moment. B5 B5 so I'm not any help even though I'm here. Lee Anne will be back on Thursday and should be able to help then, but I'm not sure if that decision was on her end or not.

Thanks,
Lauren

From: Rotstein, David
Sent: Monday, July 02, 2018 4:07 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

B5

Others may have differing thoughts.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT

7519 Standish Place
B6 (BB)

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From: Norris, Anne
Sent: Monday, July 02, 2018 4:05 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Thanks, Dave B5

B5

From: Rotstein, David
Sent: Monday, July 02, 2018 3:58 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Anne,

My understanding was that B5

Dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
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the sender immediately at david.rotstein@fda.hhs.gov.

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Sent: Monday, July 02, 2018 3:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: FW: Redacted complaint file for the DCM webposting
Importance: High

Hi Jen and Dave,

Looks like Lee Anne and Lauren are both out, so I'm hoping you can help. B5

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From:	Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To:	Norris, Anne; Carey, Lauren; Jones, Jennifer L; Palmer, Lee Anne
CC:	DeLancey, Siobhan; Hartogensis, Martine
Sent:	7/2/2018 8:53:12 PM
Subject:	RE: Redacted complaint file for the DCM webposting

The list was provided to me, but not sure who provided it to me.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
B6 BB)

From: Norris, Anne
Sent: Monday, July 02, 2018 4:49 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
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Others may have differing thoughts.

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David Rotstein, DVM, MPVM, Dipl. ACVP
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B5

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Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From:	Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To:	Norris, Anne; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
CC:	DeLancey, Siobhan
Sent:	7/2/2018 9:27:52 PM
Subject:	RE: Redacted complaint file for the DCM webposting

I am confused. **B5**

B5

Martine

From: Norris, Anne
Sent: Monday, July 02, 2018 3:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: FW: Redacted complaint file for the DCM webposting
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B5

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Anne

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Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
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OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Hartogensis, Martine; Norris, Anne; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne
CC: DeLancey, Siobhan
Sent: 7/2/2018 9:59:03 PM
Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

I just double checked our database and these are all complaints that came directly to FDA through our reporting portals, B5

Thanks,
Lauren

From: Hartogensis, Martine
Sent: Monday, July 02, 2018 5:28 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

I am confused. B5

B5

Martine

From: Norris, Anne
Sent: Monday, July 02, 2018 3:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: FW: Redacted complaint file for the DCM webposting
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B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

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Center for Veterinary Medicine
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Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov

From:	Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To:	Hartogensis, Martine; McDermott, Patrick; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Burkholder, William; Edwards, David; Conway, Charlotte
CC:	DeLancey, Siobhan
Sent:	7/12/2018 1:13:44 PM
Subject:	DCM Comms going live today at 2:00 pm
Attachments:	CVMU_DCM_GrainFree_FINAL.docx; FDA In Brief_DCM_grainfree_FINAL.docx

Hi all,

The DCM comms will be going live at 2:00 pm today! Attached are the final versions. I'll shoot you links when they're live. Thanks so much for everyone's cooperation. Hopefully getting the message out will help us get more/better reports to aid in the investigation.

Anne

Anne Norris

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
M: B6
Anne.Norris@fda.hhs.gov

From:	Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To:	Hartogensis, Martine; McDermott, Patrick; Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Burkholder, William; Edwards, David; Conway, Charlotte
CC:	DeLancey, Siobhan
Sent:	7/12/2018 6:07:27 PM
Subject:	RE: DCM Comms going live today at 2:00 pm

The CVM Update and FDA In Brief are now live!

From: Norris, Anne
Sent: Thursday, July 12, 2018 9:14 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; McDermott, Patrick <Patrick.McDermott@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
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Anne

Anne Norris

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
M: B6
Anne.Norris@fda.hhs.gov

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Hartogensis, Martine; Putnam, Juli; Carey, Lauren; Palmer, Lee Anne; DeLancey, Siobhan; Norris, Anne; Forfa, Tracey; Rotstein, David
Sent: 7/13/2018 5:42:02 PM
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

I have approximately B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Friday, July 13, 2018 9:47 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Looks good! B5

Martine

From: Putnam, Juli
Sent: Friday, July 13, 2018 9:45 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thanks, I've incorporated Martine's portion below. Just to confirm, B5

B5

Proposed response:

B5

From: Carey, Lauren

Sent: Friday, July 13, 2018 9:37 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

I think Martine's example is good. B5

B5

From: Hartogensis, Martine
Sent: Friday, July 13, 2018 9:33 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi Juli,

You could also say something like:

B5

Looping in Jen as well…

Martine

From: Putnam, Juli
Sent: Friday, July 13, 2018 9:29 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thank you, Lauren! How's this? I'm adding Dave to take a look as well.

B5

Proposed response:

B5

From: Carey, Lauren
Sent: Friday, July 13, 2018 9:18 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
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Hi,

B5

Thanks,
Lauren

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Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thanks, everyone. B5

B5 See the draft proposed response below for your review.

B5

Proposed response:

B5

From: Hartogensis, Martine
Sent: Thursday, July 12, 2018 6:21 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thanks Lee Anne! B6

From: Palmer, Lee Anne
Sent: Thursday, July 12, 2018 6:20 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: July 12, 2018 at 6:16:01 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi about **B5** dog reports to date . Can't see whole steam - will send them read all

---

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: July 12, 2018 at 5:28:58 PM EDT
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Cc: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Yes, me too.

As of right now, I believe we have about **B5** reports that have been sent to us.

Lee Anne or Lauren, can you confirm?

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Date: July 12, 2018 at 4:54:18 PM EDT
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

That works for me!

Siobhan DeLancey, RVT, MPH
O: 240-402-9973
M: **B6**

From: Putnam, Juli
Sent: Thursday, July 12, 2018 4:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

All good points. So can I consider this version CVM-cleared?

B5

From: DeLancey, Siobhan
Sent: Thursday, July 12, 2018 4:47 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

B5

Siobhan DeLancey, RVT, MPH
O: 240-402-9973
M: B6

From: Putnam, Juli
Sent: Thursday, July 12, 2018 4:44 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP
Importance: High

Hi again - just following on this. Bloomberg is pinging me again. They want the list of brands/products. Can we provide this? OCC has cleared it.

B5

B5

From: Putnam, Juli
Sent: Thursday, July 12, 2018 3:49 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan (Siobhan.Delancey@fda.hhs.gov) <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP
Importance: High

Hi all - I know Dr. Solomon is out this week so including you all in the interest of time. Please let me know if you have edits to the responses and if we can answer the last one. Thanks!
Best,
Juli

Reporter: Aziza Kasumov
Outlet: Bloomberg
Deadline: asap
Background: I'm Aziza, a reporter for Bloomberg News working on a story about your statement from today about the potential link between certain dog foods and canine heart disease. I have a few more questions about the report, can you answer these for me? We're on tight deadline, so the sooner, the better.

Questions and proposed responses:

B5

CVM, please advise.

From:	Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To:	Palmer, Lee Anne; Carey, Lauren; Rotstein, David; Jones, Jennifer L; Peloquin, Sarah; Reimschuessel, Renate; Hartogensis, Martine; Burkholder, William; DeLancey, Siobhan
Sent:	2/21/2019 5:11:55 PM
Subject:	RE: DCM paper - Darcy Adin, 2019 Vet Cardiology
Attachments:	sky488.pdf

I've lost track of whether we circulated this paper internally, but sharing because it caught the eye of Phyllis Entis from Food Safety News. She hasn't written about it (at least not yet). One of the authors is Greg Aldrich.

From: Norris, Anne
Sent: Tuesday, February 19, 2019 9:09 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: DCM paper - Darcy Adin, 2019 Vet Cardiology

Thanks!

From: Palmer, Lee Anne
Sent: Tuesday, February 19, 2019 9:05 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: DCM paper - Darcy Adin, 2019 Vet Cardiology

Hi – please forgive me if we have this already, but I think this just came out.

I haven't read it yet.

Thanks, lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

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Special topic: The association between pulse ingredients and canine dilated cardiomyopathy: addressing the knowledge gaps before establishing causation[1]

Wilfredo D. Mansilla,[†] Christopher P.F. Marinangeli,[‡] Kari J. Ekenstedt,[‖] Jennifer A. Larsen,[§] Greg Aldrich,[¶] Daniel A. Columbus,[††] Lynn Weber,[‡‡] Sarah K. Abood,[‖‖] and Anna K. Shoveller[†,2]

[†]Department of Animal Biosciences, University of Guelph, Guelph, ON N1G 2W1, Canada; and [‡]Pulse Canada, Winnipeg, Manitoba, Canada, R3C 0A5; [‖]Department of Basic Medical Sciences, College of Veterinary Medicine, Purdue University, West Lafayette, IN 47907; [§]Department of Molecular Biosciences, School of Veterinary Medicine, University of California, Davis, CA 95616; [¶]Department of Grain Science and Industry, Kansas State University, Manhattan, KS 66506; [††]Prairie Swine Centre, Saskatoon, SK S7H 5N9, Canada; [‡‡]Department of Veterinary Biomedical Sciences, University of Saskatchewan, 52 Campus Drive, Saskatoon, SK S7N 5B4, Canada; [‖‖]Department of Clinical Studies, University of Guelph, Guelph, ON N1G 2W1, Canada

ABSTRACT: In July 2018, the Food and Drug Administration warned about a possible relationship between dilated cardiomyopathy (**DCM**) in dogs and the consumption of dog food formulated with potatoes and pulse ingredients. This issue may impede utilization of pulse ingredients in dog food or consideration of alternative proteins. Pulse ingredients have been used in the pet food industry for over 2 decades and represent a valuable source of protein to compliment animal-based ingredients. Moreover, individual ingredients used in commercial foods do not represent the final nutrient concentration of the complete diet. Thus, nutritionists formulating dog food must balance complementary ingredients to fulfill the animal's nutrient needs in the final diet. There are multiple factors that should be considered, including differences in nutrient digestibility and overall bioavailability, the fermentability and quantity of fiber, and interactions among food constituents that can increase the risk of DCM development. Taurine is a dispensable amino acid that has been linked to DCM in dogs. As such, adequate supply of taurine and/or precursors for taurine synthesis plays an important role in preventing DCM. However, requirements of amino acids in dogs are not well investigated and are presented in total dietary content basis which does not account for bioavailability or digestibility. Similarly, any nutrient (e.g., soluble and fermentable fiber) or physiological condition (e.g., size of the dog, sex, and age) that increases the requirement for taurine will also augment the possibility for DCM development. Dog food formulators should have a deep knowledge of processing methodologies and nutrient interactions beyond meeting the Association of American Feed Control Officials nutrient profiles and should not carelessly follow unsubstantiated market trends. Vegetable ingredients, including pulses, are nutritious and can be used in combination with complementary ingredients to meet the nutritional needs of the dog.

Key words: dilated cardiomyopathy, dogs, feed formulation, grain-free, nutrition, pulse ingredients

[1]Funding for this project was provided by Pulse Canada. C.P.F.M. works for Pulse Canada and is a former employee of Kellogg Canada. W.D.M., A.K.S., K.J.E., G.A., J.A.L., D.A.C., L.W., and S.K.A. have no conflicts of interest. All authors contributed to the content of this paper. We would like to acknowledge the contribution of James Templeman, Sarah Dodd, and Emma Thornton.

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INTRODUCTION

In July 2018, the Food and Drug Administration (**FDA**) issued a statement relating dilated cardiomyopathy (**DCM**) in dogs to the consumption of foods that have potatoes and/or pulse ingredients, such as peas and lentils or their coproducts, as main ingredients (FDA, 2018). The FDA's statement, as well as media attention, has raised concern in some pet owners, veterinarians, nutritionists, and the pet food manufacturing and retail industry. The underlying cause for concern with pet food and DCM is that there is a link between nutrition that was previously tied to DCM and insufficient circulating taurine (Fascetti et al., 2003; Backus et al., 2006). The result was an increased need for dietary taurine or its precursor methionine due to higher fermentation of taurine and greater fecal excretion with dietary fermentable fiber (Kim et al., 1996a, 1996b). Whether this has any link to dietary pulses or the greater inclusion of pulses in grain-free dog food has yet to be directly demonstrated and mechanistic research is warranted.

Pulses are a subset of legumes, harvested as a dry crop, with low concentrations of lipid. They include peas, lentils, chickpeas, and dry beans (Marinangeli et al. 2017) which have been used as ingredients in dog food for their protein and fiber for more than 2 decades (Butterwick et al., 1994; Rice and Ihle, 1994). As a source of protein, the amino acid (AA) profile in peas, lentils, chickpeas, and beans is generally high in lysine and low in methionine (NRC, 2006) and serves as a complementary protein to both animal and plant-derived ingredients. As an example, soybean meal is derived from defatted soybeans and has an AA profile similar to pulses. In a 24-wk study that evaluated graded concentrations of soybean meal up to 17% (as-fed basis) in dog foods, soybean meal inclusion did not affect the nutrient status of dogs as indicated by serum biochemistry analysis (Menniti et al., 2014). However, Yamka et al. (2003) demonstrated that using soybean meal at more than 15% inclusion on a dry matter basis decreased crude protein digestibility. Based on the authors assessment of current formulas in the market, there is a high likelihood that legume seed use in some foods may be greater than 40%. This inclusion exceeds concentration of legumes previously investigated in dogs. When used to complement the nutritional profile of other ingredients, pulses can be used as nutrient-rich vehicles to meet the nutritional requirements of dogs and other companion animals. Given that companion animals most often consume static diets for long periods of time, overuse of any ingredient could facilitate higher risk of certain nutrient deficiencies if nutrient balance is not considered in the formulation. Thus, the formulation of static diets that use significant concentrations of a single ingredient, relative to other ingredients in the formulation, requires an in-depth knowledge of nutrient interactions, animal physiology, and effects of processing, beyond that of simply meeting minimum nutrient profiles stipulated in the Official Publication of The Association of American Feed Control Officials (AAFCO, 2018).

The present commentary discusses the following: 1) The limited data being used to support linkages between DCM and pulse ingredients; 2) The nutritional factors and physiological mechanisms that should be explored to establish causation between nutritional deficiencies and incidence of DCM; 3) The factors that nutritionists should consider when formulating complete diets destined for long-term consumption; and 4) The disadvantages of formulating protein and minimal AA recommendations rather than a balanced indispensable AA profile.

The Development of Canine DCM, Historical Linkages to Taurine Deficiency, and Pulses

Dilated cardiomyopathy is a disease of the myocardium that results in both mechanical dysfunction (enlarged heart cavities and congestion) and/or electrical dysfunction (arrhythmias and sudden death) (Sisson et al., 2000; Maron et al., 2006; Dutton and López-Alvarez, 2018). Development of DCM is slow and few clinical signs manifest over time. As DCM progresses, signs include lethargy, anorexia, shallow breathing, sudden fainting, and potential death. In some cases, animals may die from irregular heart rhythm without previous signs of the disease. In dogs, DCM can be

caused by various factors. Genetic predisposition is thought to play the most important role in the development of DCM in several dog breeds, mostly large and giant breeds. Genetic mutations associated with DCM have been discovered in American lines of Doberman and Boxer dogs (Meurs et al., 2012; Meurs et al., 2013). However, the Doberman variant's association was not upheld in a European population of Dobermans (Owczarek-Lipska et al., 2013). Similarly, a United Kingdom population of Boxers did not uphold their published DCM-associated variant (Cattanach et al., 2015). It is becoming increasingly clear that the genetic basis for DCM in dogs is not monogenic, but complex and polygenic. Breeds with the highest prevalence of DCM include Dobermans, Boxers, Great Danes, Newfoundlands, Irish Wolfhounds, English Cocker Spaniels, and Portuguese Water Dogs (Monnet et al., 1995; Borgarelli et al., 2006; Werner et al., 2008; Martin et al., 2009), and the genetic basis of DCM in each of these breeds has been investigated (Dutton and López-Alvarez, 2018). In addition, Golden Retrievers and American Cocker Spaniels appear to have breed predispositions to taurine deficiency (Kramer et al., 1995; Bélanger et al., 2005). When dogs are not genetically predisposed for developing DCM, diet and physiology are other factors that may be associated with the disease.

The first link between taurine deficiency and DCM was demonstrated in cats in 1987. Cats diagnosed with DCM recovered after taurine supplementation (Pion et al., 1987). Similarly, an inverse association between dietary taurine and the incidence of DCM in a population of foxes was documented by Moise et al. (1991) and established the importance of taurine in the family Canidae. In dogs, DCM diagnoses related to low whole blood taurine concentrations have been reported in Cocker Spaniels, Dalmatians, Boxers, Newfoundlands, Portuguese Water Dogs, English Setters, Alaskan Malamutes, and Scottish Terriers (Freeman et al., 1996; Kittleson et al., 1997; Pion et al., 1998; Alroy et al., 2000; Fascetti et al., 2003; Backus et al., 2006). In all these cases, taurine supplementation improved cardiac function. However, dogs, in contrast to cats, can endogenously synthesize taurine from methionine and cysteine (Figure 1). Therefore, the above-mentioned data do not unequivocally establish taurine intake as the underlying mechanism for the development of DCM in dogs, whether they are genetically predisposed. Dietary supply of precursor AAs necessary for taurine synthesis (i.e., methionine and cysteine), metabolic intermediates, and cofactors (such as methyl donors) cannot be ruled out as factors that contribute to the susceptibility of dogs to developing genetic and diet-related DCM. When DCM is diet-related, the formulation and the provision of all nutrients, including indispensable AAs, to facilitate optimum health and wellbeing of dogs should be considered.

Recent reports, including the statement by the FDA (2018), have implicated that lentils, peas, and other legumes seeds could be responsible for the development of DCM in dogs not genetically predisposed to this disease. Such statements and associations between pulse ingredients and incidence of DCM are, at the present time, premature. Animals, including dogs, have no minimum or maximum requirements for ingredients. Ingredients serve

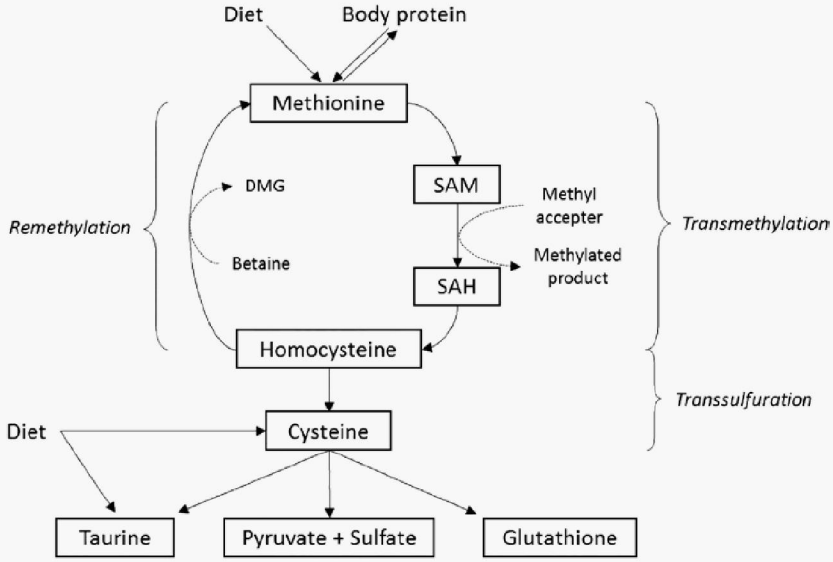

Figure 1. Metabolism of sulfur amino acids. DMG = dimethylglycine; SAH = S-denosylhomocysteine; SAM = S-adenosylmethionine.

as the vehicle to providing nutrients to animals. As such, animals have nutrient requirements, not ingredient requirements. In diets that have nutrient deficits, imbalances, or exceed maximums, the final nutrient composition of the diet, not the ingredients, should be critiqued. In addition, animal nutritionists should consider that the nutrient concentration of ingredients can vary, nutrient availability is not 100%, and diets formulated to marginally meet requirements could actually be deficient. Overall, it is the responsibility of nutritionists to use different ingredients to formulate diets that can be produced and safely meet the nutritional needs of animals.

Taurine Deficiency and the Development of Canine DCM

For dogs, taurine is a dispensable AA synthesized from methionine and cysteine primarily in the liver (Figure 1). Taurine is not incorporated into proteins. Instead, it is used as a mediator for various biological processes and is the most abundant free AA intracellularly (Huxtable, 1992). In the heart, taurine represents ~60% of the total AA free pool (Huxtable, 1992). The high concentration of taurine in cardiac cells may explain the role of a taurine deficiency in the development of DCM. It has been speculated that taurine contributes to the reabsorption of calcium by the sarcoplasmic reticulum and increases the sensitivity of the myofilaments to calcium (Bakker and Berg, 2002). Thus, low dietary taurine intake and/or reduced synthesis of taurine from methionine and cysteine can deplete calcium pools in the cardiac cells and impede proper contraction of the cardiac muscle tissue, resulting in DCM in dogs.

For diagnosing DCM in dogs and cats, among other diagnostic methods including electrocardiograms and echocardiography, it is common to measure taurine concentration in whole blood. Whole blood samples, and not plasma samples, should be used to assess circulating taurine concentrations. In plasma, free taurine concentrations are much lower compared with intracellular taurine. This suggests that the plasma pool is not representative of taurine in other pools (Schaffer et al., 2010). In platelets, taurine concentration is high and is considered a marker of taurine status. Taurine concentration in platelets is captured when whole blood is analyzed (Huxtable, 1992). However, platelet count can vary depending on the immune status of the animal and whole blood taurine concentration can be affected. In this scenario, whole blood taurine may not represent concentrations of taurine in muscle cells, including cardiac muscle. These additional variables related to the measurement of taurine status may explain why some dogs diagnosed with DCM have normal whole blood taurine concentrations.

As taurine can be synthesized endogenously in dogs, taurine is not considered an indispensable AA for the species Canidae. Thus, there are no recommendations on minimum dietary concentrations of taurine for dogs reported by the National Research Council (NRC, 2006) or AAFCO (2018). The lack of regulation on minimum taurine concentrations in commercial dog foods suggests that endogenous synthesis of taurine can meet the metabolic needs in all dogs and at all life stages. This assumption may not be accurate as studies have determined that synthesis of taurine is related to the size of dog (Ko et al., 2007), and some dietary factors can increase the physiological need for taurine (Story, 1978). Nutritional factors that increase the dietary requirement, reduce the supply, or increase the excretion of taurine in dogs are discussed in subsequent sections of this review and should be considered to avoid taurine deficiency in dogs and the risk of DCM.

Physiological factors can increase taurine utilization in dogs, and endogenous synthesis of taurine could be insufficient for meeting taurine requirements. For example, compared with smaller size dogs, synthesis of taurine in large dog breeds is up to 50% lower per unit of metabolic body weight (Ko et al., 2007). These results demonstrate that larger dogs are at higher risk for insufficient endogenous taurine synthesis, and dietary supplementation or fortification may be required, even when there is no minimum dietary taurine concentration according to current recommendations (AAFCO, 2018). Obesity and diabetes have also been related to lower concentrations of taurine in blood in humans and rats, respectively (Merheb et al., 2007; Nardelli et al., 2011; Ito et al., 2012), and may increase the requirement for sulfur AAs necessary for endogenous taurine synthesis. This is of importance given that approximately half of dogs in North America are obese (Linder and Mueller, 2014). Data from rats and cats suggest that age and sex could also affect whole body taurine status. Hepatic activity of cysteine sulfonate decarboxylase, the enzyme responsible for taurine synthesis, was shown to be 16 times higher in adult male rats vs. female rats. In the same study, the activity of cysteine sulfonate decarboxylase was higher in 5- to 6-wk-old kittens compared with 15-mo-old cats and in 8-wk-old mice compared with 16-wk-old mice; changes of

the enzyme activity in dogs have not been tested (Worden and Stipanuk, 1985). Overall, these studies suggest that, despite some capacity for endogenous synthesis, physiological need of taurine can be heavily dependent on breed, age, sex, and physiological status. These physiological factors could help us to predict the risk for developing DCM when genotypic and environmental factors, such as diet, are simultaneously considered to ensure that dogs maintain adequate concentrations of taurine and other sulfur AAs.

Given that there are no recommendations for the minimum concentration of taurine in dog food, the concentration of taurine in dog foods can vary substantially depending on the ingredients used. Taurine is very low in plant-based ingredients (Table 1) but is higher in some algae and fungi species and is ubiquitously found in animal tissues, especially in the heart, brain, and white blood cells (Huxtable, 1992). This is relevant, as many grain-free and/or high legume dog foods attempt to limit the use of animal byproducts, which can substantially decrease the levels of dietary taurine. In the context of providing adequate and preventive nutrition, dog foods should include organ meat or animal byproducts or be fortified with taurine and/or its precursors (methionine and/or cysteine) to ensure the delivery of sufficient levels of taurine.

Effect of Dietary Fiber on Taurine Status and Risk of Canine DCM

Dietary fiber has been shown to affect the taurine status in dogs. For example, commercial diets formulated with lamb meal and rice bran were shown to cause taurine deficiency in part because of low bioavailable cysteine from lamb meal and possibly more importantly due to the effects of rice bran fiber on gastrointestinal metabolism of taurine (Johnson et al., 1998; Tôrres et al., 2003). It has been hypothesized that high-fiber diets can increase susceptibility to taurine deficiency by 2 mechanisms of action linked to obligatory bile acid conjugation with taurine in dogs (O'Mádille et al., 1965) and reliance on enterohepatic circulation for the reabsorption of bile acids and taurine. First, high-fiber diets may increase fecal output and losses of taurine-conjugated bile. This would require higher synthesis rates of bile in the liver, and consequently, higher utilization of taurine

Table 1. Crude protein (CP), fiber, selected amino acids, and carnitine contents in the principal legumes, cereals, and animal-derived ingredients used in dog food formulation

				α-amino acids, mg/g protein[1]				
Ingredients		CP, %	Crude fiber,[1] %	Lys	Met	Cys	Tau, mg/kg[2]	Carnitine, mg/kg[3]
Legumes	Fava beans	27.2	8.55	23.9	7.0	12.5	–	–
	Phaseolus beans	22.9	NR	72.9	12.7	12.7	–	–
	Kidney beans	20.0	6.40	26.5	14.0	12.0	–	–
	Lentils	26.0	NR	65.8	6.9	10.4	–	–
	Lupins	32.4	14.25	48.7	6.5	14.2	–	–
	Chick peas	20.3	6.16	69.4	14.8	21.6	–	–
	Soybean meal	47.7	3.89	62.0	13.8	14.7	–	–
Grains	Barley	11.3	3.90	35.3	17.7	22.9	–	–
	Corn, yellow dent	8.2	1.98	30.3	21.8	23.1	–	–
	Oats	11.2	2.20	43.9	60.9	32.3	–	–
	Rice	7.9	0.52	44.5	31.8	22.9	–	–
	Rye	11.7	2.71	36.9	13.7	16.3	–	–
	Sorghum	9.4	2.14	21.4	17.1	19.2	–	–
	Wheat hard, red	14.5	2.57	27.0	15.2	22.8	–	–
Animal-derived ingredients	Beef, meat	15.0	–	77.3	28.7	15.3	296	150
	Chicken, meat and skin	17.6	–	81.3	26.7	13.1	159	57
	Chicken, by product	59.0	–	48.1	17.3	16.8	3049	120
	Lamb, ground	16.6	–	88.0	25.9	12.0	473	282.3
	Rendered meat	54.1	2.50	53.8	14.2	11.3	NR	NR

Cys = cysteine; Lys = lysine; Met = methionine; NR = not reported; Tau = taurine.

Values are presented on as-fed basis.

[1]NRC, 2006; NRC, 2012.

[2]Spitze et al. 2003.

[3]Arslan, 2006.

(Story, 1978). Second, high consumption of fermentable fibers may increase the abundance of microbial populations that degrade taurine in the intestinal lumen (Kim et al., 1996a, 1996b). Either alone or together, increased excretion or degradation of taurine from high-fiber diets may decrease enterohepatic circulation and recycling of taurine. Given that taurine is the only AA used for bile acid conjugation in dogs, over time, high-fiber diets could increase the risk of taurine insufficiency in dogs and lead to DCM.

This should not be interpreted as dietary fiber being deleterious to the health of dogs. However, there may be a limit to the benefit for soluble fibers. Legume seeds contain an appreciable quantity of oligosaccharides which are known to be fermentable (Tosh and Yada, 2010). Thus, by a similar mechanism as described above, high levels of legume seed oligosaccharides could ostensibly contribute to taurine depletion via excretion in the feces as bile conjugation and degradation by colonic bacteria. In addition to the physiological benefits of high-fiber diets in certain dogs, formulators should also be cognizant of possible nutritional risks associated with high concentrations of fiber in dog foods. Consequently, dog foods with high concentrations of dietary fiber should be accompanied by higher supplies of taurine or sulfur AAs for endogenous taurine synthesis. Overall, the digestibility and bioavailability of taurine in ingredients used and the effect of other nutrients in taurine metabolism should be considered to avoid taurine deficiency and the development of DCM.

Carnitine Deficiency and Risk of Canine DCM

Carnitine is not nutritionally indispensable since it is endogenously produced in the liver and kidneys from lysine and methionine; it can also be attained exogenously from animal-based products. Carnitine is highly abundant in skeletal and cardiac muscles. Together, these represent >95% of the total carnitine in the body. Carnitine is essential for metabolism of fatty acids used for energy production (Hoppel, 2003). In the heart, where 60% of the energy is derived from fatty acid oxidation, carnitine facilitates the uptake of free fatty acids into the mitochondria to produce ATP (Hoppel, 2003). Plant-based ingredients do not contain carnitine (Table 1). Therefore, in commercial dog foods with reduced inclusion of animal-based ingredients, intakes of carnitine could be decreased if diets are not fortified. Reduced dietary carnitine intake translates into increased reliance on endogenous synthesis to meet physiological requirements.

Given that carnitine is required for sufficient energy production in cardiac muscle, it is not surprising that carnitine deficiency is associated with DCM. In 1991, a family of Boxers diagnosed with DCM were also diagnosed with carnitine deficiency (Keene et al., 1991). In dogs, carnitine deficiency can occur with aberrations of carnitine regulation in disorders such as cardiomyopathy (including DCM), diabetes, sepsis, and malnutrition (Flanagan et al., 2010). However, carnitine deficiency as a causative factor in the development of DCM or a consequence of cardiac malfunction remains as a subject of debate (Freeman and Rush, 2006). Despite the interest in this metabolite, little progress has been made on determining the effect of carnitine supplementation on alleviating risk of DCM. However, both taurine and carnitine are often supplemented in supraphysiological concentrations once DCM is diagnosed. This practice is supported by positive clinical outcomes, albeit without comparison groups (Kittleson et al., 1997; Sanderson et al., 2001). Concentrations of carnitine in the plasma are relatively insensitive to dietary carnitine, and more invasive techniques (biopsies) are required to determine the concentration of carnitine in muscle tissue (Flanagan et al., 2010; Răşanu et al., 2012). The invasive nature of testing for carnitine status is likely the reason why carnitine is rarely explored when investigating possible causes of canine DCM.

Preventing Diet-Mediated DCM in Dogs by Providing Adequate Sulfur AAs and Maximizing Endogenous Taurine Synthesis

Although taurine is considered a dispensable AA in dogs, endogenous taurine synthesis requires an adequate supply of bioavailable sulfur AA precursors cysteine or methionine (Figure 1). Thus, providing marginal concentrations of these 2 sulfur AAs, or providing sources with lower bioavailability, could increase the risk of taurine deficiency and facilitate the development of DCM. Contrary to taurine, methionine cannot be synthesized endogenously in dogs (NRC, 2006). Therefore, dogs depend on the provision of dietary methionine to meet daily sulfur AA requirements, which includes production of taurine. From an ingredient perspective, methionine and lysine are usually the first or second limiting AAs in dog diets formulated with soybean meal and rendered meats (NRC, 2006). In addition, methionine is particularly susceptible to damage, and subsequent reduction in bioavailability,

secondary to heat processing (Marshall et al. 1982; Hurrell et al., 1983). This suggests that the risk of methionine deficiency is more likely than any other indispensable AA in commercial dog diets. Although the primary role for methionine is protein synthesis, in pigs at least 50% of absorbed methionine acts as a methyl donor and a precursor in the production of cysteine, taurine, sulfate, and pyruvate (Robinson et al., 2016a; Figure 1). These functions of methionine become more crucial when dietary intake of cysteine, taurine, and/or dietary methyl donors (e.g., folate, betaine, and their precursors) is limited (Robinson et al., 2016b), and they need to be considered when nutritionists set criteria for delivery of sulfur AAs in pet foods.

Methionine and cysteine both contribute to the total sulfur AA requirements for humans and animals. For adult dogs at maintenance, the latest guidelines from the NRC (2006) recommend that adult dog foods contain 0.33% (on dry matter basis) methionine when cysteine is provided in excess, and 0.65% for methionine + cysteine. These NRC (2006) recommendations are not based on dose–response studies, but on a 4-yr study where adult dogs were fed low-crude protein diets (Sanderson et al., 2001). In that study, the lowest concentration of methionine in the diet that reported no observable deficiencies was used as the recommended requirement. As companion animals are typically fed a single static diet during adulthood, and for most of their lifespan, it is necessary that AA requirements of dogs should be measured empirically (Baker, 1986). In addition to the lack of empirical data corresponding to the AA requirements of dogs, it is equally important to understand how other dietary (e.g., dietary fiber), environmental, other physiological variables, and breed/genotype may alter AA requirements. The lack of recommendations for taurine in commercial dog food puts a higher stress on accurately meeting requirements for sulfur AAs, not only for protein synthesis, but also for the endogenous synthesis of taurine, for support of optimal methyl status, and for the synthesis of secondary metabolites.

Rethinking Indispensable AA Targets in Commercial Dog Foods

Currently, the ingredients permitted in pet foods and the corresponding nutrient targets are guided by recommendations made by AAFCO (2018). These recommendations are based on the peer-reviewed scientific literature and represented in the Nutrient Requirement of Dogs and Cats (NRC, 2006). However, AA recommendations made by AAFCO correspond to total AA content within the formulation and do not consider the true ileal digestibility of ingredients. True ileal digestibility of AAs is more representative of nutrient absorption capacity and bioavailability compared with fecal digestibility or total AA content in the diet (Columbus and de Lange, 2012). To account for the reduced digestibility and bioavailability of protein-bound AAs in food ingredients, AAFCO arbitrarily increases AA recommendations relative to those from the NRC to ensure that an adequate supply of AAs is provided, regardless of the ingredients and effects of processing (Table 2). However, this increment is only applied to lysine, threonine, and tryptophan and not applied to other indispensable AAs, including methionine (AAFCO, 2018). For example, the recommended allowance for lysine reported in NRC (2006) is 0.35% for adult dogs at maintenance, whereas the minimum content of lysine to meet AAFCO (2018) recommendations is 0.63%. Nonruminant animals, including dogs, absorb AAs from the duodenum to the terminal ileum (Columbus and de Lange, 2012). Hence, feeding diets with lower ileal digestibility coefficients could decrease actual concentrations of available indispensable AAs, even when meeting AAFCO recommendations. This is of special concern for dietary taurine and other sulfur AAs, considering that there is no regulated minimum threshold for taurine in dog foods and that AAFCO (2018) recommendations for sulfur AAs are not increased compared with NRC (2006) recommendations to account for potential ileal digestibility coefficients. There is a dearth of data in this area to justify empirical adjustments based on different dietary variables. As such, future research should pursue how AA requirements change under different dietary variables that can affect small intestinal digestibility and whole body availability.

It is worthwhile to note that minimum dietary nutrient contents for dog foods, as reported in AAFCO (2018), only consider differences between growth/reproduction and adult life stages. This lack of data places the pregnant bitch in the same group as growing animals. Moreover, most studies on nutrient requirements in dogs have been established using Beagles as a proxy for all dogs. Using a single breed creates a homogenous sample and likely does not account for nutritional variability across pure and mixed breeds, or those of different sizes. Unpublished data from Shoveller et al. investigated the minimum methionine (with excess cysteine) requirements of

Table 2. Recommended allowance (RA) and minimum dietary content suggested by AAFCO for crude protein and essential amino acids in dog food, and their physiological roles and potential interactions

Nutrient	NRC RA[1], % DM	AAFCO[2], % DM	Important physiological roles and potential interactions
Crude protein	10	18	Necessary for synthesis of nonessential amino acids
Arginine	0.35	–	Competes with lysine absorption, arginine should be increased when high lysine concentrations in the diet
Histidine	0.19	–	
Lysine	0.35	0.63	Highly reactive to reducing sugars during heating (Maillard reaction), reducing bioavailability
Methionine	0.33	0.33	Requirement increases when methyl donors/acceptors and cysteine are reduced in the diet
Methionine + cystine	0.65	0.65	Requirement is increased with low supply of taurine and during immune challenge
Phenylalanine	0.45	0.45	
Phenylalanine + tyrosine	0.74	0.74	
Threonine	0.43	0.48	Abundant in mucosal proteins (mucin), requirement increases when feeding high fermentable fibers
Tryptophan	0.14	0.16	Precursor for serotonin synthesis. Ratio of Trp: LNAA should be considered; lower ratios may deprive appetite
Valine	0.49	0.49	Abnormal Increment of valine, leucine, or isoleucine (BCAA) will cause catabolism of the other BCAA in the muscle
Isoleucine	0.38	–	
Leucine	0.68	0.68	

AAFCO = The Association of American Feed Control Officials; BCAA = branched chain amino acids; DM = dry matter; NRC = National Research Council; RA = recommended allowance; Trp:LNAA = tryptophan to large neutral amino acid ratio.

[1]Recommended Allowance requirements for adult dogs at maintenance, Nutrient Requirements of Dogs and Cats (NRC, 2006).

[2]Miminum dietary content, AAFCO (2018).

Miniature Dachshunds, Beagles, and Labrador Retrievers as proxies for small, medium, and large dog breeds and found that methionine requirements may differ across breeds or size of dogs and be greater than previously estimated. Thus, given the methods of derivation, single indispensable AA requirements for all dog populations, as presented in AAFCO (2018), may not consider variable AA requirements across dog phenotypes. Moreover, it is widely assumed that endogenous synthesis of dispensable AAs, such as taurine in the dog, is sufficient for meeting metabolic demands. However, recent studies suggest that under some metabolic conditions, dispensable AAs may also be required in diets (Hou et al., 2015). Taurine, as described in this commentary, is a clear example of this paradigm shift. Dietary taurine or the capacity for its adequate endogenous synthesis, especially in circumstances where excessive losses might occur, should be considered in the final formulation of dog foods to decrease the risk of canine DCM.

Nutritionists and regulatory agencies should be aware that, in the spectrum of nutrient requirements, dog populations with higher AA requirements relative to energy intake and other factors could be at a higher risk for a taurine deficiency. More precise categorization of requirements among different canine populations would help us to optimize nutritional adequacy and decrease risk of diseases, such as DCM, that are possibly linked to nutrient deficiencies.

Effect of Processing on Antinutritional Factors in Plant-Based Ingredients

Just as understanding the inherent nutritional characteristics and the interaction between ingredients is important for preventing nutritional imbalances in pet foods, the effects of processing on these factors are equally important. Raw cereals and legumes contain antinutritional factors such as trypsin inhibitors, phytates, hematoglutinins, and polyphenols that can decrease protein digestion, nutrient absorption, and/or cause illness. Some of these antinutritional factors are thermolabile and, under the right conditions, can be effectively destroyed during the extrusion process improving the overall quality of plant-based ingredients and the final diet (Patterson et al., 2017). Recent reviews across a variety of legumes and legume-derived ingredients show that the activities of trypsin inhibitor, chymotrypsin inhibitor, and hemagglutinating activity were decreased by up to 95% across a variety of thermal treatment conditions, including extrusion (Patterson et al., 2017; Avilés-Gaxiola et al., 2018). Extrusion had modest effects on levels of phytate with reductions ranging from 7% to 26% and varied by legume and extrusion conditions (Patterson

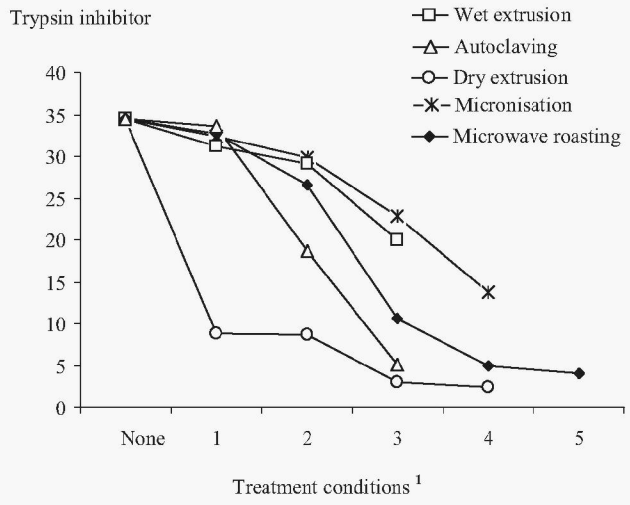

Figure 2. Effect of thermal processing methods on trypsin inhibitor levels (mg/g) soybean kernel. [1]Treatment conditions: None = no treatment; dry extrusion for 25 to 30 sec (1 = 100 °C; 2 = 125 °C; 3 = 140 °C; 4 = 150 °C); wet extrusion for 25 to 30 s with 6% to 8% added moisture (1 = 100 °C; 2 = 125 °C; 3 = 140 °C); micronization with near-infrared rays wavelength of 1.8 to 3.4 µm for 90 s (1 = 100 °C; 2 = 125 °C; 3 = 140 °C; 4 = 150 °C); microwave roasting at 800 W and 2450 MHz (1 = 1 min [kernel temp = 57 °C], 2 = 2 min [kernel temp = 88 °C], 3 = 3 min [kernel temp = 108 °C], 4 = 4 min [kernel temp =121 °C], 5 = 5 min [kernel temp = 132 °C]); Autoclaving at 120 °C and 1.2 bars (1 = 10 min, 2 = 20 min, 3 = 30 min). Reprinted with permission from Žilić et al. (2012).

et al., 2017). Figure 2 highlights the variability between processing methods and thermic conditions for decreasing antinutritional factors. For example, when soybeans were subjected to extrusion at increasing temperatures that ranged from 100 to 150 °C, trypsin inhibitor levels were incrementally decreased. At 140 °C, dry extrusion was considerably more effective at decreasing trypsin inhibitors (−91%) compared with wet extrusion (−44%). When the dry extrusion temperature was increased to 150 °C, reductions in trypsin inhibitors were further decreased by 94% (Žilić et al., 2012). Other thermal treatments, such as micronisation, microwave roasting, and autoclaving, also facilitated incremental reductions in trypsin inhibitors with increasing temperatures (Žilić et al., 2012). When formulating foods with higher concentrations of plant-based ingredients, consideration should also be given to the processing methods and the parameters used to effectively optimize the nutritional density and decrease antinutritional factors.

It is important to mention that, while temperature and pressure processing can greatly decrease antinutritional factors, they can also negatively affect bioavailability of AAs. The Maillard reaction is a well-known example of heat-damaged protein (Teodorowicz et al., 2017). In this reaction, lysine interacts with reducing sugars present in the diets forming the Maillard product. The complex formed can be digested and absorbed by the animal but cannot be utilized for metabolic processes (e.g., protein synthesis). Thus, in heat-damaged proteins, digestibility of AAs can greatly overestimate bioavailability (Moehn et al., 2005). Other products of heat damage on proteins include racemization of AAs (alteration from L to D form) and the formation of cross-linked AAs. Such components can decrease bioavailability of AAs and digestibility of proteins, and their effects on protein quality cannot usually be determined using conventional methods of AA analysis. Pet foods with higher levels of plant-based ingredients may also require optimization of processing methods to maximize their nutritional density and nutrient bioavailability.

Recommendations for Formulating Dog Food With Novel Ingredients

Considering the AA profile of dog foods. Feed formulation for agricultural and companion animals should be based on the ideal protein concept (Baker, 1991; Swanson et al., 2013). The ideal protein is defined as that in which all AAs are in perfect balance compared with the animal's AA requirements (mg/g protein). Hence, all indispensable AAs are equally limiting. However, this is impossible to achieve in practical animal feed formulation, and diets should be formulated considering the first limiting indispensable AA. The first limiting indispensable AA refers to the indispensable AA that is present in the lowest proportion compared with the animal's requirement. By meeting the first indispensable limiting AA requirement, requirements for all other indispensable AAs are also inherently satisfied. Moreover, to avoid the formulation of diets with excessive protein concentration or an excess of indispensable AAs relative to the requirements of dogs, animal nutritionists combine multiple ingredients that are complementary in their AA profiles. Commonly, dog foods are formulated with a higher proportion of animal-derived ingredients, and a lower proportion of plant-based ingredients to meet nutrient recommendations. More recently, however, cereal grains have been removed in some diet formulations or the proportion of animal-based ingredients has been reduced. The production of these types of formulations is often driven by consumer perception, rather than scientific evidence. Allowing consumers to direct the ingredient composition of dog foods, or other pet foods, could perpetuate nutrient deficits that affect the health of animals in the long term.

In the formulation of grain-free pet foods, cereal grains are replaced with alternative ingredient(s). Animal-derived ingredients are expensive relative to plant-based ingredients. Thus, pulses, a subset of legumes, are often used as the replacement. In addition to containing substantial fiber, pulses also contain significant concentrations of protein and are used to partly meet indispensable AA requirements. Of interest, soybean meal and pulses contain 48% and 25% crude protein, respectively, which is substantially greater than the average protein concentration for grains (11%; Table 1). Although the high-protein content in soybean meal and pulses is indicative of higher concentration of AAs compared with grains, it does not imply AA balance. Soybean meal and pulses are high in lysine (mg/g protein) but low in sulfur AAs (mg/g protein), whereas the reverse is true for cereals. Plant-based ingredients tend to have lower ileal digestibility coefficients for protein compared with protein from animal sources (FAO and WHO, 1991). Thus, dog foods that contain substantial amounts of pulses, lower proportions of animal-based ingredients, and do not address AA imbalances through the addition of alternate ingredients or fortification, may risk AA deficiencies. To mitigate this risk across the pet food industry and ensure the final pet diets are nutritionally adequate and balanced, it is prudent that the digestibility coefficients of all final pet food products be calculated.

Considering the addition of high-fiber ingredients to dog foods. By definition, dietary fiber is carbohydrates that are resistant to digestion by endogenous enzymes in the gastrointestinal tract (NRC, 2006). Typical fibers include arabinoxylan, raffinose, inulin, β-glucan, cellulose, and pectin (NRC, 2006). Common ingredients to increase fiber content in companion animal diets include beet pulp, corn fiber, rice bran, whole grains, and pulse fibers (de Godoy et al., 2013). Achieving an optimal fiber concentration in canine diets has diverse positive physiological effects in the gastrointestinal tract; for example, higher fermentable fiber intake has been shown to slow the transit time of digesta, increasing satiety of the animal (Haber et al., 1977). Moreover, high-fiber diets generally have lower energy density making them an important nutritional strategy for controlling body weight (Johnson et al., 2008) and reducing the incidence of diarrhea (Homann et al., 1994). Gut health is also improved with higher consumption of fiber; fermentable fiber can act as a prebiotic and increase the population of health-promoting microbiota including lactobacilli and bifidobacteria (Roberfroid, 2005). Although not required by AAFCO to fulfill the criteria of "complete and balanced," fiber is an important component of the diet, and depending on the type of fiber and the amount consumed, fiber can increase the gut health status. Adding the necessary amount and type of fiber in the diet is crucial for optimal dog nutrition.

Despite the benefits of fiber in the diet, fiber can also affect enterohepatic recycling of taurine (discussed above). In monogastric species, including humans, high dietary fermentable fiber may also decrease digestibility and availability of dietary AAs (Blackburn and Southgate, 1981; Degen et al., 2007) and, in some cases, increase the risk of DCM in dogs fed diets that marginally meet requirements for sulfur AAs. Moreover, higher concentrations of dietary fiber increase the size of the gastrointestinal tract in pigs and poultry (Nyachoti et al., 2000), increasing nutrient utilization in this organ. It has been determined in pigs that on average the gastrointestinal tract catabolizes 30% of dietary indispensable AAs during absorption, and this utilization represents ~50% for sulfur AAs (Stoll et al., 1998; Mansilla et al., 2018), further reducing precursor availability for taurine synthesis and increasing the risk for taurine deficiency. For some high-fiber diets, fortification of specific nutrients, including taurine and other sulfur AAs, might be beneficial to avoid nutrient deficiencies.

Compared with the pet food industry, in other industries where high-fiber ingredients (coproducts) are routinely used (e.g., swine industry), the effects of fiber on the absorption of nutrients have been given more attention when formulating diets (NRC, 2012). For example, highly fermentable fiber in swine diets increases the threonine requirement to compensate for the increase in mucus (mucin protein) production in the intestinal cell lining (Lien et al., 1997; Mathai et al., 2016). This has underpinned the development of "requirement models" (NRC, 2012) to tailor nutrient requirements for pigs while accounting for the different nutrient interactions. In contrast, in the pet food industry, the only concentrations of nutrients used for comparison are those recommended by AAFCO (2018). Such recommendations are static and may not encompass all the effects of the different nutrient combinations in the final diet. There is a clear need in companion animal nutrition to improve the understanding of the interactions of different ingredients and how these alter nutrient requirements for different breeds, age, and physiological status of dogs.

Other recent publications highlight the need for careful nutrient formulation. Several recent papers, both original research and reviews, likewise highlight the unknowns surrounding grain-free diets (typically legume or pulse-based, but sometimes also with "exotic" ingredients such as kangaroo, bison, or wild boar) and DCM. For example, Adin et al. (2019) examined 48 dogs of many breeds with diagnosed DCM and having a known diet history. Among grain-free diets being consumed in this study, 1 dog was particularly associated with DCM, possibly underscoring the importance of specific diet formulation. Furthermore, 2 dogs switched from that diet to other grain-free diets showed improvement in their DCM; it is unclear if those dogs were taurine deficient or if they also received taurine and/or carnitine supplementation. This suggests that grain-free composition per se may not be the root cause of DCM. Another recently published case series of 24 Golden Retrievers with DCM and known diet histories were evaluated, and an association between grain-free diets and DCM was suggested (Kaplan et al., 2018). Most dogs (15 of 24) were fed a single diet which was significantly associated with low blood taurine concentrations, again suggesting that specific diet formulation may play an important role. However, as in the previous study, soluble vs. insoluble fiber concentrations were not available for the diets, nor were taurine, methionine, or cysteine concentrations, meaning that the true nutrient profiles of the diets could not be assessed and reinforcing the point that diet formulation for nutrients—not ingredients—is essential. It also suggests that nutrient requirements may vary widely based on breed, diet, and other phenotypic data. Indeed, most of the dogs with DCM in the previously described study were consuming less energy compared with their predicted requirements (Kaplan et al., 2018). It also bears pointing out that the numbers in both studies were very low (representing less than 100 DCM-affected dogs between them), which surely represents a fraction of the dogs consuming grain-free, pulse-based diets. A recent thoughtful review supports these conclusions by reiterating the crucial need for plant-based diets for dogs to be formulated with sufficient quantities of bioavailable methionine and cysteine to support adequate taurine synthesis (Dodd et al., 2018). This can be achieved with the addition of purified AAs and other sources that are readily available (Gloaguen et al., 2014). Finally, a recent commentary carefully concludes that a true cause-and-effect relationship between grain-free diets and DCM has not been proven, and other factors may ultimately be more important (Freeman et al., 2018). Taken together, these recent publications may point to faulty nutrient formulation in some, but not all, grain-free diets.

CONCLUSIONS

Recently, it has been suggested that pulse ingredients in commercial dog foods are associated with a limited number of cases of DCM. Although pulse ingredients have been implicated for having negative effects on the taurine status in dogs (deficiency of which is a known cause of canine DCM) based on the available evidence, the relationship between pulses and canine DCM remains undefined. However, the FDA statement may harm consideration of protein alternatives, such as pulses, as quality ingredients in pet foods and undermine attempts to diversify ingredients used across the food chain as the global population continues to grow. Ingredients do not represent the nutritional composition of the diet, and therefore, nutrient deficiencies should not be attributed to individual ingredients. The authors of this commentary recognize the important role of endogenous, and perhaps exogenous, taurine in the prevention of DCM in some dogs. The assurance of appropriate concentrations of all indispensable sulfur AAs, including methionine and cysteine, is crucial for ensuring adequate endogenous synthesis of taurine and to meet the metabolic demands of dogs. Additional dietary factors, such as methyl donors required for sulfur AA metabolism, carnitine for energy production in muscle, and dietary fiber, as well as animal factors, such as breed, size, and health status, should also be investigated when nutrient deficiency-related DCM is suspected.

It is the responsibility of animal nutritionists to formulate balanced diets for dogs, and other animals, by looking beyond the goal of meeting AAFCO recommendations or satisfying unsubstantiated market trends. Pulses and other plant-based ingredients can be used to formulate nutritionally adequate dog foods, and final product formulations should be assessed for nutrient balance and bioavailability, especially when using a limited number of ingredients. Although dietary factors are important in the prevention of sulfur AA deficiency and development of DCM, empirical data and mechanistic studies are required to better understand the indispensable AA requirements of dogs and preventing DCM. In diets that contain high concentrations of dietary fiber, compensative inclusion

of dietary indispensable sulfur AAs, including exogenous taurine, might be required to offset the possibility of increased fecal excretion or microbial assimilation of taurine in the large intestine. Processing conditions may also require adjustments to ensure the presence or effects of antinutritional factors are minimized and nutrient bioavailability is not compromised. Greater awareness of AA balance is crucial for ensuring that AA requirements are met for dogs consuming static diets.

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From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Hartogensis, Martine; Putnam, Juli; DeLancey, Siobhan; Jones, Jennifer L; Reimschuessel, Renate; Carey, Lauren; Norris, Anne
CC: Forfa, Tracey; Rotstein, David; Eisenman, Theresa; Nemser, Sarah
Sent: 7/24/2018 1:32:11 PM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Lee Anne

From: Hartogensis, Martine
Sent: Tuesday, July 24, 2018 9:09 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

B5

Martine

From: Putnam, Juli
Sent: Tuesday, July 24, 2018 8:41 AM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: DeLancey, Siobhan
Sent: Monday, July 23, 2018 12:56 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
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B5

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From: Putnam, Juli
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To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Thanks for your guidance.
Best,
Juli

From: Jones, Jennifer L
Sent: Monday, July 23, 2018 6:48 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Jennifer Jones, DVM
Veterinary Medical Officer
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U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:27 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Renate!

Martine

From: Reimschuessel, Renate
Sent: Friday, July 20, 2018 11:26 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
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B5

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN
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From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:14 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Ok, thanks Juli! I am looping in Sarah Nemser and Renate in case they know, but no worries if not.

Thanks again!

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 11:02 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks, Martine. I got an out of office that Jen is out until Monday. However, if we are able to confirm this number before then, please send to my colleague Theresa Eisenman (copied on this email) and she will provide it to the NYT reporter. I am on leave the rest of today so Theresa will be able to help on any other follow-up we may have with NYT or Washington Post on DCM today.

Thanks, and hope everyone has a good weekend!

Best,
Juli

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 10:21 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

It sounds like there may be about **B5** Jen, can you confirm?

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 10:19 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: Carey, Lauren
Sent: Friday, July 20, 2018 9:50 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne

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Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Jen.

B5

Martine

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 20, 2018 at 6:47:01 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>
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B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

Just looping in the dream team again. Do any of you know if our **B5**

TIA!

Martine

From: Putnam, Juli
Sent: Thursday, July 19, 2018 3:58 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: Hartogensis, Martine
Sent: Thursday, July 19, 2018 3:43 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
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Great points, thank you Anne!

From: Norris, Anne
Sent: Thursday, July 19, 2018 3:42 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
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I know you haven't accepted yet, Martine, but wanted to throw these points out for you and Juli to consider for future interviews. We keep getting variations on the same questions over and over again from consumers, so it might be helpful to mention a variation of the information provided below to allay some of the consumer anxiety out there.

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Please advise.
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Reporter: Kate Furby
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She said her questions would just be standard ones about the FDA alert on dog food and canine heart health.

- Questions about DCM – what is it, what are symptoms, how is it detected, how common is it, etc.
- Questions about legumes and potatoes in dog diets.

Juli Putnam
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-0537 / B6
Juli.Putnam@fda.hhs.gov

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Carey, Lauren; Hartogensis, Martine; Putnam, Juli; Norris, Anne
CC: DeLancey, Siobhan; Forfa, Tracey; Rotstein, David
Sent: 7/20/2018 10:46:55 AM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Jennifer Jones, DVM
Veterinary Medical Officer
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U.S. FOOD & DRUG ADMINISTRATION

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Juli Putnam
Press Officer

Office of Media Affairs
Office of External Affairs

U.S. Food and Drug Administration
Tel: 240-402-0537 B6
Juli.Putnam@fda.hhs.gov

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To: Hartogensis, Martine; Carey, Lauren; Putnam, Juli; Norris, Anne
CC: DeLancey, Siobhan; Forfa, Tracey; Rotstein, David
Sent: 7/20/2018 12:07:18 PM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thank you for clarifying.

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Hartogensis, Martine; Reimschuessel, Renate; Putnam, Juli; Carey, Lauren; Norris, Anne
CC: DeLancey, Siobhan; Forfa, Tracey; Rotstein, David; Eisenman, Theresa; Nemser, Sarah
Sent: 7/23/2018 10:47:31 AM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:27 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Renate!

Martine

From: Reimschuessel, Renate
Sent: Friday, July 20, 2018 11:26 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN
Phone 1- 240-402-5404
Fax 301-210-4685
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:14 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Ok, thanks Juli! I am looping in Sarah Nemser and Renate in case they know, but no worries if not.

Thanks again!

Martine

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Thanks, Martine. I got an out of office that Jen is out until Monday. However, if we are able to confirm this number before then, please send to my colleague Theresa Eisenman (copied on this email) and she will provide it to the NYT reporter. I am on leave the rest of today so Theresa will be able to help on any other follow-up we may have with NYT or Washington Post on DCM today.

Thanks, and hope everyone has a good weekend!

Best,
Juli

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 10:21 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Hi Juli,

It sounds like there may be about **B5** Jen, can you confirm?

Martine

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Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Carey, Lauren
Sent: Thursday, July 19, 2018 4:12 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Jen should have an answer for you on that.

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Sent: Thursday, July 19, 2018 4:02 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

Just looping in the dream team again. Do any of you know if our **B5**

TIA!

Martine

From: Putnam, Juli
Sent: Thursday, July 19, 2018 3:58 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
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B5

From: Hartogensis, Martine
Sent: Thursday, July 19, 2018 3:43 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Great points, thank you Anne!

From: Norris, Anne
Sent: Thursday, July 19, 2018 3:42 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

I know you haven't accepted yet, Martine, but wanted to throw these points out for you and Juli to consider for

future interviews. We keep getting variations on the same questions over and over again from consumers, so it might be helpful to mention a variation of the information provided below to allay some of the consumer anxiety out there.

B5

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Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Martine,
Are you willing to do another interview on DCM tomorrow morning? Washington Post is now writing too.
Please advise.
Thanks!
Juli

Reporter: Kate Furby
Outlet: Washington Post
Deadline: 7/20
Background: Kate would like to write a story on FDA's alert regarding DCM and its potential link to dog food. This would be for the Health, Environment, Science section of the Post. She is contacting a few vets at universities now as well.
Questions:
She said her questions would just be standard ones about the FDA alert on dog food and canine heart health.

- Questions about DCM – what is it, what are symptoms, how is it detected, how common is it, etc.
- Questions about legumes and potatoes in dog diets.

Juli Putnam
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-0537 **B6**
Juli.Putnam@fda.hhs.gov

From: Putnam, Juli </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45A45E85E6E94413A4BD2C9FDBB3DE1B-JULIANN.PUT>
To: Hartogensis, Martine; DeLancey, Siobhan; Jones, Jennifer L; Reimschuessel, Renate; Carey, Lauren; Norris, Anne; Palmer, Lee Anne
CC: Forfa, Tracey; Rotstein, David; Eisenman, Theresa; Nemser, Sarah
Sent: 7/27/2018 1:25:59 PM
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/31

Hi all,
The Washington Post story got delayed and now the reporter (Kate Furby) is asking us for an updated case count for dogs without the genetic predisposition falling ill. She also wants an updated number on the dogs who may have passed away as a result. She saw that The New York Times mentioned that the FDA had reported three deaths. She is wondering if these deaths were just since the report came out, or if this is total number. (I know those were the # from our initial warning but not sure if more deaths have been reported to us since).

Are we able to provide an updated case count between now and next Tuesday? I will, of course, remind her that the numbers are constantly changing so they only represent a single point in time.

Best,
Juli

From: Hartogensis, Martine
Sent: Tuesday, July 24, 2018 9:09 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

B5

Martine

From: Putnam, Juli
Sent: Tuesday, July 24, 2018 8:41 AM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: DeLancey, Siobhan
Sent: Monday, July 23, 2018 12:56 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Siobhan DeLancey, RVT, MPH
O: 240-402-9973
B6
Siobhan.DeLancey@fda.hhs.gov

From: Putnam, Juli
Sent: Monday, July 23, 2018 12:45 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Thanks for your guidance.
Best,
Juli

From: Jones, Jennifer L
Sent: Monday, July 23, 2018 6:48 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

U.S. FOOD & DRUG ADMINISTRATION

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:27 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Renate!

Martine

From: Reimschuessel, Renate
Sent: Friday, July 20, 2018 11:26 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN
Phone 1- 240-402-5404
Fax 301-210-4685
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:14 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Ok, thanks Juli! I am looping in Sarah Nemser and Renate in case they know, but no worries if not.

Thanks again!

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 11:02 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Thanks, Martine. I got an out of office that Jen is out until Monday. However, if we are able to confirm this number before then, please send to my colleague Theresa Eisenman (copied on this email) and she will provide it to the NYT reporter. I am on leave the rest of today so Theresa will be able to help on any other follow-up we may have with NYT or Washington Post on DCM today.

Thanks, and hope everyone has a good weekend!

Best,
Juli

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 10:21 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

It sounds like there may be about **B5** Jen, can you confirm?

Martine

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To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne

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Thanks Jen.

B5

Martine

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 20, 2018 at 6:47:01 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>
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Outlet: Washington Post
Deadline: 7/20
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- Questions about DCM – what is it, what are symptoms, how is it detected, how common is it, etc.
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Juli Putnam
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-0537 / B6
Juli.Putnam@fda.hhs.gov

From:	Putnam, Juli </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45A45E85E6E94413A4BD2C9FDBB3DE1B-JULIANN.PUT>
To:	Palmer, Lee Anne; Carey, Lauren; Hartogensis, Martine; DeLancey, Siobhan; Jones, Jennifer L; Reimschuessel, Renate; Norris, Anne
CC:	Forfa, Tracey; Rotstein, David; Eisenman, Theresa; Nemser, Sarah
Sent:	7/27/2018 8:40:54 PM
Subject:	RE: Media inquiry request - Washington Post - DCM - Deadline: 7/31

Thanks!

From: Palmer, Lee Anne
Sent: Friday, July 27, 2018 4:12 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/31

Hi Juli – just a couple edits below to consider. I separated it into paragraphs only to make it easier for me to read.

B5

Thanks – have a great weekend! Lee Anne

From: Putnam, Juli
Sent: Friday, July 27, 2018 4:04 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
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Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/31

Thank you all – so I can say:

B5

From: Palmer, Lee Anne
Sent: Friday, July 27, 2018 3:33 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
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Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/31

Hi Juli,

B5

Thanks,
Lauren

From: Putnam, Juli
Sent: Friday, July 27, 2018 10:44 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/31

B5

Best,
Juli

From: Carey, Lauren
Sent: Friday, July 27, 2018 9:40 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/31

Hi Juli,

B5

Thanks,
Lauren

From: Putnam, Juli
Sent: Friday, July 27, 2018 9:26 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/31

Hi all,
The Washington Post story got delayed and now the reporter (Kate Furby) is asking us for an updated case count for dogs without the genetic predisposition falling ill. She also wants an updated number on the dogs who may have passed away as a result. She saw that The New York Times mentioned that the FDA had reported three deaths. She is wondering if these deaths were just since the report came out, or if this is total number. (I know those were the # from our initial warning but not sure if more deaths have been reported to us since).

Are we able to provide an updated case count between now and next Tuesday? I will, of course, remind her that the numbers are constantly changing so they only represent a single point in time.

Best,
Juli

From: Hartogensis, Martine
Sent: Tuesday, July 24, 2018 9:09 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman,

Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

B5

Martine

From: Putnam, Juli
Sent: Tuesday, July 24, 2018 8:41 AM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: DeLancey, Siobhan
Sent: Monday, July 23, 2018 12:56 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Siobhan DeLancey, RVT, MPH
O: 240-402-9973
B6
Siobhan.DeLancey@fda.hhs.gov

From: Putnam, Juli
Sent: Monday, July 23, 2018 12:45 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Thanks for your guidance.
Best,
Juli

From: Jones, Jennifer L
Sent: Monday, July 23, 2018 6:48 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:27 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Renate!

Martine

From: Reimschuessel, Renate
Sent: Friday, July 20, 2018 11:26 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN
Phone 1- 240-402-5404
Fax 301-210-4685
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 11:14 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Ok, thanks Juli! I am looping in Sarah Nemser and Renate in case they know, but no worries if not.

Thanks again!

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 11:02 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Eisenman, Theresa <Theresa.Eisenman@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks, Martine. I got an out of office that Jen is out until Monday. However, if we are able to confirm this number before then, please send to my colleague Theresa Eisenman (copied on this email) and she will provide it to the NYT reporter. I am on leave the rest of today so Theresa will be able to help on any other follow-up we may have with NYT or Washington Post on DCM today.

Thanks, and hope everyone has a good weekend!

Best,
Juli

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 10:21 AM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

It sounds like there may be about B5 Jen, can you confirm?

Martine

From: Putnam, Juli
Sent: Friday, July 20, 2018 10:19 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: Carey, Lauren
Sent: Friday, July 20, 2018 9:50 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: Hartogensis, Martine
Sent: Friday, July 20, 2018 8:02 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Thanks Jen.

B5

Martine

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Date: July 20, 2018 at 6:47:01 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG

From: Carey, Lauren
Sent: Thursday, July 19, 2018 4:12 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Jen should have an answer for you on that.

From: Hartogensis, Martine
Sent: Thursday, July 19, 2018 4:02 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Juli,

Just looping in the dream team again. Do any of you know if our **B5**

TIA!

Martine

From: Putnam, Juli
Sent: Thursday, July 19, 2018 3:58 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

B5

From: Hartogensis, Martine
Sent: Thursday, July 19, 2018 3:43 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Great points, thank you Anne!

From: Norris, Anne
Sent: Thursday, July 19, 2018 3:42 PM
To: Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: RE: Media inquiry request - Washington Post - DCM - Deadline: 7/20

I know you haven't accepted yet, Martine, but wanted to throw these points out for you and Juli to consider for future interviews. We keep getting variations on the same questions over and over again from consumers, so it might be helpful to mention a variation of the information provided below to allay some of the consumer anxiety out there.

B5

Thanks,
Anne

From: Putnam, Juli
Sent: Thursday, July 19, 2018 3:33 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>
Subject: Media inquiry request - Washington Post - DCM - Deadline: 7/20

Hi Martine,
Are you willing to do another interview on DCM tomorrow morning? Washington Post is now writing too.
Please advise.
Thanks!
Juli

Reporter: Kate Furby
Outlet: Washington Post
Deadline: 7/20
Background: Kate would like to write a story on FDA's alert regarding DCM and its potential link to dog food. This would be for the Health, Environment, Science section of the Post. She is contacting a few vets at universities now as well.
Questions:
She said her questions would just be standard ones about the FDA alert on dog food and canine heart health.

- Questions about DCM – what is it, what are symptoms, how is it detected, how common is it, etc.
- Questions about legumes and potatoes in dog diets.

Juli Putnam
Press Officer

Office of Media Affairs
Office of External Affairs

U.S. Food and Drug Administration
Tel: 240-402-0537 B6
Juli.Putnam@fda.hhs.gov

From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Rotstein, David
CC: Norris, Anne; DeLancey, Siobhan; Putnam, Juli
Sent: 10/9/2018 6:59:05 PM
Subject: RE: Media Request - DCM - WUSA9 inquiry

Hi DCM Team!

See the media request below. This is mostly for Lee Anne's group to update numbers (if you have them), but Jen and Dave, please feel free to revise as well. I had one edit in red.

Thanks very much in advance!

Martine

From: Haake, Lindsay
Sent: Tuesday, October 09, 2018 2:48 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: FW: Media Request - DCM - WUSA9 inquiry

Good Afternoon Martine –

B5

When you get a chance, please review and let me know if you have any edits by COB Friday, October 12th.

Thanks!
Lindsay

Media Inquiry
****
Reporter: Whitney Wild
Media Outlet: WUSA9
Reporter Deadline: Requested an interview for the week of October 15th
Background: I'm reaching out from WUSA9 here in D.C. We are exploring a story about the growing concern about a possible link between grain-free dog food and dilated cardiomyopathy cited in this announcement: https://www.fda.gov/animalveterinary/newsevents/cvmupdates/ucm613305.htm
Is there anyone from the FDA we could speak with on-camera about the research the agency is doing, any conclusions and the complaints the agency has fielded surrounding this issue?
Questions/Proposed Responses:

B5

B5

Lindsay Haake
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-3007 / B6
Lindsay.Haake@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Appears this Way on Original

From: DeLancey, Siobhan </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A414BA562DCD4C8284B1120074969B9A-SDELANCE>
To: Hartogensis, Martine; Palmer, Lee Anne; Carey, Lauren; Jones, Jennifer L; Rotstein, David
CC: Norris, Anne; Putnam, Juli
Sent: 10/9/2018 7:01:00 PM
Subject: RE: Media Request - DCM - WUSA9 inquiry

B5

From: Hartogensis, Martine
Sent: Tuesday, October 09, 2018 2:59 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: RE: Media Request - DCM - WUSA9 inquiry

Hi DCM Team!

See the media request below. This is mostly for Lee Anne's group to update numbers (if you have them), but Jen and Dave, please feel free to revise as well. I had one edit in red.

Thanks very much in advance!

Martine

From: Haake, Lindsay
Sent: Tuesday, October 09, 2018 2:48 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: FW: Media Request - DCM - WUSA9 inquiry

Good Afternoon Martine –

B5

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Lindsay

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****
Reporter: Whitney Wild
Media Outlet: WUSA9
Reporter Deadline: Requested an interview for the week of October 15th
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Is there anyone from the FDA we could speak with on-camera about the research the agency is doing, any conclusions and the complaints the agency has fielded surrounding this issue?

Questions/Proposed Responses:

B5

Lindsay Haake
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-3007 / B6
Lindsay.Haake@fda.hhs.gov

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: DeLancey, Siobhan; Hartogensis, Martine; Carey, Lauren; Jones, Jennifer L; Rotstein, David
CC: Norris, Anne; Putnam, Juli
Sent: 10/9/2018 7:42:46 PM
Subject: RE: Media Request - DCM - WUSA9 inquiry

That sounds good – thanks! Just let us know if and when…I made one possible edit in green.

From: DeLancey, Siobhan
Sent: Tuesday, October 9, 2018 3:01 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: RE: Media Request - DCM - WUSA9 inquiry

B5

From: Hartogensis, Martine
Sent: Tuesday, October 09, 2018 2:59 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: RE: Media Request - DCM - WUSA9 inquiry

Hi DCM Team!

See the media request below. This is mostly for Lee Anne's group to update numbers (if you have them), but Jen and Dave, please feel free to revise as well. I had one edit in red.

Thanks very much in advance!

Martine

From: Haake, Lindsay
Sent: Tuesday, October 09, 2018 2:48 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Putnam, Juli <JuliAnn.Putnam@fda.hhs.gov>
Subject: FW: Media Request - DCM - WUSA9 inquiry

Good Afternoon Martine –

B5

When you get a chance, please review and let me know if you have any edits by COB Friday, October 12th.

Thanks!
Lindsay

Media Inquiry
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Reporter: Whitney Wild
Media Outlet: WUSA9
Reporter Deadline: Requested an interview for the week of October 15th
Background: I'm reaching out from WUSA9 here in D.C. We are exploring a story about the growing concern about a possible link between grain-free dog food and dilated cardiomyopathy cited in this announcement: https://www.fda.gov/animalveterinary/newsevents/cvmupdates/ucm613305.htm
Is there anyone from the FDA we could speak with on-camera about the research the agency is doing, any conclusions and the complaints the agency has fielded surrounding this issue?
Questions/Proposed Responses:

B5

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Lindsay Haake
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-3007 / B6
Lindsay.Haake@fda.hhs.gov

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Carey, Lauren; Hartogensis, Martine; Norris, Anne; Palmer, Lee Anne
CC: DeLancey, Siobhan
Sent: 7/3/2018 6:02:52 PM
Subject: RE: Redacted complaint file for the DCM webposting
Attachments: 800.267-Product Indexing Results Summary.pptx

I updated the slide deck with a summary from some great articles. Bottom line: B5

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https://academic.oup.com/jn/article/131/2/276/4687012

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Rotstein, David
Sent: Tuesday, July 03, 2018 8:26 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Please check your calendar, if you don't see it, I'll resend the invite.

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 3, 2018 at 8:19:29 AM EDT
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
U.S. FOOD & DRUG ADMINISTRATION

From: Carey, Lauren
Sent: Monday, July 02, 2018 5:59 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Martine,

B5

Thanks,
Lauren

From: Hartogensis, Martine
Sent: Monday, July 02, 2018 5:28 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

B5

Martine

From: Norris, Anne
Sent: Monday, July 02, 2018 3:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: FW: Redacted complaint file for the DCM webposting
Importance: High

Hi Jen and Dave,

B5

Thanks,
Anne

From: Palmer, Lee Anne
Sent: Friday, June 15, 2018 8:51 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Redacted complaint file for the DCM webposting

Hi – all set with the complaint file. I hope to have a last look today at the DCM piece. Hopefully this AM, but may creep into the afternoon at this point…

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Team Leader HFV-242, Supervisory VMO

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