

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
CC: Ceric, Olgica; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Nemser, Sarah
Sent: 5/1/2018 1:05:21 PM
Subject: 800.267-EON-345858-DCM Cluster
Attachments: DCM-Case Report Analysis-5.1.2018.xls; Fan-Sauer-Peas Cys-Met Content-1994.pdf; FYI -lentils--deficient in sulfur containing amino acids--methionine, tryptophan, and cysteine; Ko-Fascetti-Beet pulp Tau status-5.1.2018.pdf; Qiao-et al-Met to MetCys ratio-Pigs-2008.pdf; Sarwar-CysMet ratio Rats-1991.pdf

B5 I wonder about either

B5

B5

Thoughts?

Dave previously sent an email about information about peas (attached)

B5

I found the same

B5

B5

(<https://academic.oup.com/jn/article-abstract/112/11/2033/4554028?redirectedFrom=fulltext>).

In chickens (Sarwar article)

B5

B5

B5

B5

B5

Also-This is an older study in beagles

B5

(<https://academic.oup.com/jn/article-abstract/111/12/2117/4771254?redirectedFrom=fulltext>).

B5

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
Sent: 6/4/2018 4:58:23 PM
Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy
Attachments: 800.267-DCM-Grainfree analysis.pptx

Everyone,

B5

Thanks,
dave

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

B6



This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: Rotstein, David
Sent: Thursday, May 24, 2018 10:04 AM
To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

Good Morning,

B5

B5

To address this, CVM is planning the following:

B5

Thank you,

Dave

Brand	flavor	Firm	Location	FEI	Division
B4, B5					

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

B6





This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

All Medical Records

Client: **B6**
Address: **B6**

Patient: **B6**
Breed: Labrador Retriever
DOB: **B6**

Species: Canine
Sex: Female
(Spayed)

Home Phone: **B6**
Work Phone: () -
Cell Phone: **B6**

Referring Information

B6

Client: **B6**
Patient: **B6**

Initial Complaint:

Emergency

SOAP Text **B6** 1:23PM - **B6**

B6 12:13 PM NEW VISIT (ER)

Doctor: **B6** VMD

Presenting complaint: Right hind lameness

Diagnostics completed prior to visit: Recent blood work at rDVM per owner, normal results before dental cleaning

HISTORY:

Signalment: 3 yo FS Labrador retriever

Current history: Limping while playing fetch today, non-weight bearing on the right hind limb. Otherwise healthy.

Prior medical history: Left CCL rupture, surgically repaired in **B6**

Current medications: None

Diet: Acana, whole earth

Vaccination status/flea & tick preventative use: **B6**

EXAM:

B6

Client: B6
Patient: B6

B6

ASSESSMENT:

A1: B6

PLAN:

- 1) B6
- 2)
- 3)
- 4)

Client communication: B6 B6

B6

SOAP approved (DVM to sign): B6 VMD

B6 1:25:46 PM

Prescribed B6 - FHSA (5)

Instructions - Give 1/2 tablet orally every 12 hours. Give with food. - Expires B6 No Refills

Initial Complaint:

Cardiology DCM study

SOAP Text B6 3:09PM - Rush, John

Subjective

Objective

Assessment

Plan

Disposition/Recommendations

Client:

B6

Patient:

Client: **B6**
Patient: **B6**

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Client: **B6**
Veterinarian:
Patient ID: **B6**
Visit ID:

Patient:	B6
Species:	Canine
Breed:	Labrador Retriever
Sex:	Female (Spayed)
Age:	B6 Years Old

Lab Results Report

Accession ID:			
Test	Results	Reference Range	Units



4/7

B6

B6

Printed Sunday, February 24, 2019

Vitals Results

B6	12:21:40 PM	Heart Rate (/min)	B6
	12:21:41 PM	Respiratory Rate	
	12:21:42 PM	Temperature (F)	
	12:21:43 PM	Weight (kg)	

Patient History

B6	12:14 PM	UserForm	B6
	12:15 PM	UserForm	
	12:21 PM	Vitals	
	12:21 PM	Vitals	
	12:21 PM	Vitals	
	12:21 PM	Vitals	
	12:21 PM	Vitals	
	01:37 PM	Prescription	
	01:44 PM	UserForm	
	01:48 PM	Purchase	

Client: **B6**
Patient: **B6**

Patient History

B6	02:06 AM	Vitals
	02:06 AM	Vitals
	02:06 AM	Vitals
	02:06 AM	Vitals
	02:06 AM	Vitals
	11:40 AM	Email
	01:27 PM	Appointment
	01:30 PM	UserForm
	02:03 PM	Treatment
	03:14 PM	UserForm

B6

Best Available Copy

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-7951
<http://vetmed.tufts.edu/>

B6

Female (Spayed)

Canine, Labrador Retriever, Yellow

B6

B6

Dear **B6**

Thank you for referring **B6** with their pet **B6**.

If you have any questions, or concerns, please contact us at 508-887-4988.

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

From: Putnam, Juli </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45A45E85E6E94413A4BD2C9FDBB3DE1B-JULIANN.PUT>
To: Carey, Lauren; Hartogensis, Martine; Palmer, Lee Anne; DeLancey, Siobhan; Norris, Anne; Forfa, Tracey; Rotstein, David; Jones, Jennifer L
Sent: 7/13/2018 1:45:16 PM
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

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

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.

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

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>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi,

B5

Thanks,
Lauren

From: Putnam, Juli
Sent: Friday, July 13, 2018 9:04 AM
To: 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>
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.

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

Proposed response:

B5

From: Hartogenesis, 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: Hartogenesis, Martine <Martine.Hartogenesis@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

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: July 12, 2018 at 6:16:01 PM EDT

To: Hartogenesis, Martine <Martine.Hartogenesis@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

to date . Can't see whole steam - will send them read all

From: Hartogenesis, Martine <Martine.Hartogenesis@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

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

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:

- Were the foods from several brands or from one brand of dog food? Can you name the companies that produced the foods linked to the reports, and which foods exactly the dogs ate? Was there one particular food brand that was heavily linked to the unusual reports?

B5

B5

B5

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?
CVM, please advise.

From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Putnam, Juli; Carey, Lauren; Palmer, Lee Anne; DeLancey, Siobhan; Norris, Anne; Forfa, Tracey; Rotstein, David; Jones, Jennifer L
Sent: 7/13/2018 1:47:16 PM
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

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

Proposed response:

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From: Carey, Lauren
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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>
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I think Martine's example is good.

B5

B5

From: Hartogensis, Martine
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<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

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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.

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

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From: Carey, Lauren

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Hi,

B5

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.

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

Proposed response:

B5

From: Hartogenesis, 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
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To: Hartogenesis, Martine <Martine.Hartogenesis@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

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: July 12, 2018 at 6:16:01 PM EDT
To: Hartogenesis, Martine <Martine.Hartogenesis@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** 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

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

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:

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

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:

- Were the foods from several brands or from one brand of dog food? Can you name the companies that produced the foods linked to the reports, and which foods exactly the dogs ate? Was there one particular food brand that was heavily linked to the unusual reports?

B5

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?
CVM, please advise.

From: Putnam, Juli </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=45A45E85E6E94413A4BD2C9FDBB3DE1B-JULIANN.PUT>
To: Carey, Lauren; Hartogensis, Martine; Palmer, Lee Anne; DeLancey, Siobhan; Norris, Anne; Forfa, Tracey; Rotstein, David; Jones, Jennifer L
Sent: 7/18/2018 7:48:15 PM
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thank you Lauren!

From: Carey, Lauren
Sent: Wednesday, July 18, 2018 3:41 PM
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>; 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,

Sorry, so many emails that things are getting buried.

B5

B5

Thanks,
Lauren

From: Putnam, Juli
Sent: Wednesday, July 18, 2018 2:54 PM
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

Hi all, can you please confirm

B5

B5

Thanks!

Best,
Juli

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.

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

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>

Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi,

B5

B5

Thanks,
Lauren

From: Putnam, Juli
Sent: Friday, July 13, 2018 9:04 AM
To: 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>
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.

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

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>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: July 12, 2018 at 6:16:01 PM EDT

To: Hartogenesis, Martine <Martine.Hartogenesis@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 to date . Can't see whole steam - will send them read all

From: Hartogenesis, Martine <Martine.Hartogenesis@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

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>, Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>

Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

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Siobhan DeLancey, RVT, MPH

O: 240-402-9973

M: B6

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Sent: Thursday, July 12, 2018 4:52 PM

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Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

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M: **B6**

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Outlet: Bloomberg

Deadline: asap

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B5

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CVM, please advise.

patientid	patient	client	Diagnosis	wb taurine	plasma taurine	supplemented	improved	dob
Atypical breeds								
B6			DCM/CHF	not tested	not tested	yes	no	
			DCM/CHF	wnl	wnl	no		
			DCM/CHF	not tested	not tested	no (died in hosp)		
			DCM/CHF, RA mass	not tested	not tested	no		
			DCM/CHF	not tested	not tested	yes	will be rechecked soon	
			DCM/CHF	not tested	not tested	no		
			DCM/CHF	wnl	wnl	no		
			DCM	wnl	wnl	no		
			DCM/CHF	wnl	wnl	no		
			Murmur but no echo (in for GI issues)	not tested	not tested	no		
			DCM/CHF	wnl	wnl	yes	no	
			DCM +/- CHF, V tach	not tested	not tested	no		
			DCM	not tested	not tested	no		
			DCM/CHF	not tested	not tested	yes	yes	
			DCM/CHF	not tested	not tested	no (died in hosp)		
			DCM	wnl	wnl	no		
			DCM/CHF	B6		yes	no	
			DCM/CHF	not tested	not tested	no		
		DCM	B6		yes (just started)	?		
Confirmed taurine deficient in typical breeds								
B6			DCM	B6	not tested	yes (just started)	will recheck in 2 months	
			DCM		not tested	yes	yes	

B6

breed	visit date	sex	age	diet
PORTUGUESE WATER DOG	5/5/2017	SF	B6	Fromm Hasen Duckenpfeffer
LABRADOR CROSS	2/2/2018	CM		Supreme Source salmon meal & sweet potato receipt (salmon, pea, lentil, fava bean, sweet potato...)
SAMOYED	12/23/2015	CM		Vegan dog foods (various brands; currently Pet Guard Organic Vegan)
GOLDEN RETRIEVER	2/8/2018	CM		Holistic Select duck/rice
LABRADOR RETRIEVER	2/9/2018	CM		Canidae Pure LID Grain Free (duck/bison/wild boar) dry food or Merrick LID Grain Free (chicken, buffalo, or duck) dry f
GERMAN SHEPHERD	12/5/2015	CM		Canidae
BEAGLE CROSS	7/23/2016	CM		CA natural kangaroo/lentil
GERMAN SHORTHAIR POINTER	3/7/2017	M		Fromm various varieties (gamebird, lamb/lentil, Fromm Hasen Duckenpfeffer?)
AUSTRALIAN CATTLE DOG	4/11/2017	SF		Earthborn Holistic Meadow Feast (lamb, peas, tapioca, flaxseed)
MIX	3/21/2017	CM		Zignature kangaroo
LAB	4/2/2018	SF		Zignature kangaroo
PIT BULL	2/23/2018	CM		Purina One lamb and rice (maybe unrelated to diet but sending because of lamb)
PHAROAH HOUND	5/24/2017	F		4 Health grain free dry
PIT BULL	12/28/2015	CM		Zignature lamb
FRENCH BULLDOG	10/26/2016	CM		Zignature salmon
FRENCH BULLDOG	10/28/2016	SF		Zignature salmon
GOLDEN RETRIEVER	4/17/2015	CM		CA natural kangaroo/lentil
GOLDEN RETRIEVER	7/31/2015	SF		CA natural kangaroo/lentil
GOLDEN RETRIEVER	4/11/2018	SF		Zignature kangaroo
DOBERMAN PINSCHER	4/19/2018	CM	Blue Buffalo Basic salmon	
BOXER	7/7/2017	CM	Petcurean Go! Limited Ingredient dry, Petcurean Now Fresh, Stella & Chewy's raw patties,	

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Palmer, Lee Anne; Rotstein, David; Jones, Jennifer L; Reimschuessel, Renate; Edwards, David; Hartogensis, Martine; Burkholder, William; DeLancey, Siobhan
CC: Carey, Lauren; Lovell, Randall A; Ceric, Olgica; Nemser, Sarah; Conway, Charlotte; Atkinson, Krisztina Z; Hodges, April
Sent: 5/22/2018 1:23:46 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 9:13 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Norris, Anne
Sent: Tuesday, May 22, 2018 8:49 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 8:39 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:37 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

B5

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

B6





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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Jones, Jennifer L

Sent: Tuesday, May 22, 2018 8:31 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:25 AM

To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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

B6



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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

Just some food for thought... rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Edwards, David

Sent: Tuesday, May 22, 2018 7:54 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David

Sent: Monday, May 21, 2018 7:49 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A

<Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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

B6



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From: Hartogenesis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

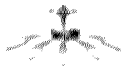
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Friday, May 18, 2018 11:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 6:42 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

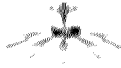
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

CVCA is not a part of Vet-LIRN

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogenesis, Martine

Sent: Thursday, May 17, 2018 7:52 PM

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work!

B5

they part of VET-LIRN?

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Date: May 17, 2018 at 2:27:35 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to B6 talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:06:04 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

From: Hartogenesis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

B5

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

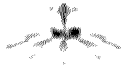
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 9, 2018 at 4:09:18 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 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>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with [B6] @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

[B5]

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!

B6

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

B5

B5

B5

Looping in Jen.

Thanks for the update!

dave

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

B6



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

B5

I was at DC Academy last week and spoke with a cardiology resident. They have been seeing DCM cases for the past 3 months and are considering writing up a paper. They are thinking the

B5

B5

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

Lee Anne will likely discuss at OSC **B5** But it does look like there is a relationship between the increased DCM reports and grain free diets.

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Date: May 7, 2018 at 1:03:13 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Norris, Anne; Palmer, Lee Anne; Rotstein, David; Reimschuessel, Renate; Edwards, David; Hartogensis, Martine; Burkholder, William; DeLancey, Siobhan
CC: Carey, Lauren; Lovell, Randall A; Ceric, Olgica; Nemser, Sarah; Conway, Charlotte; Atkinson, Krisztina Z; Hodges, April
Sent: 6/11/2018 4:05:44 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 800.267 Procedure Rationale-v2.docx; 800.267-draft-Sample Testing Procedures-v4.doc

Good morning everyone,

B5

Please let me know if you have feedback or comments by COB Friday (6/15).

Thank you,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Norris, Anne
Sent: Tuesday, May 22, 2018 9:24 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 9:13 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:49 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 8:39 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:37 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William

<William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

B5

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

B6



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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Jones, Jennifer L

Sent: Tuesday, May 22, 2018 8:31 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 22, 2018 8:25 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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

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From: Reimschuessel, Renate
Sent: Tuesday, May 22, 2018 8:18 AM
To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Just some food for thought... rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN
Phone 1-240-402-5404
Fax 301-210-4685
<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Edwards, David
Sent: Tuesday, May 22, 2018 7:54 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David

Sent: Monday, May 21, 2018 7:49 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

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

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From: Hartogensis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne

<LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A

<Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica

<Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>;

Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A

<Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica

<Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z

<Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Any other ideas or suggestions?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine
Sent: Friday, May 18, 2018 11:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

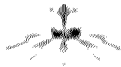
From: Jones, Jennifer L
Sent: Friday, May 18, 2018 6:42 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

CVCA is not a part of Vet-LIRN:

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 7:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work! One question they part of VET-LIRN?

B5

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Date: May 17, 2018 at 2:27:35 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:14:48 PM EDT
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan
Sent: Thursday, May 17, 2018 2:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to **B6** talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:06:04 PM EDT

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 11:59 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

B5

Martine

From: Jones, Jennifer L
Sent: Thursday, May 17, 2018 11:29 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

I do not know about **B5** Once we get a better handle on a specific cause, we can work on that.

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Date: May 14, 2018 at 9:09:17 AM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

Martine

From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>,

Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>,

Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine

Sent: Wednesday, May 9, 2018 2:17 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>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

B6

@ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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

B6



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was **B6**

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

B5

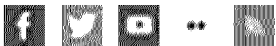
Looping in Jen.

Thanks for the update!

dave

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

B6



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

B5

Might be a good opportunity for us to partner with some cardiology folks...

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Jones, Jennifer L; Reimschuessel, Renate
CC: Rotstein, David
Sent: 6/11/2018 5:57:09 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought.

B5

B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 11, 2018 12:06 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Good morning everyone.

B5

Please let me know if you have feedback or comments by COB Friday (6/15).

Thank you,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Norris, Anne
Sent: Tuesday, May 22, 2018 9:24 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 9:13 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:49 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 8:39 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards,

David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:37 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

B5

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

B6



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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>;

Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Jones, Jennifer L

Sent: Tuesday, May 22, 2018 8:31 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:25 AM

To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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

B6



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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Just some food for thought... rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Edwards, David

Sent: Tuesday, May 22, 2018 7:54 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David

Sent: Monday, May 21, 2018 7:49 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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



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From: Hartogenesis, Martine
Sent: Monday, May 21, 2018 7:47 AM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William
Sent: Friday, May 18, 2018 5:04 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogenesis, Martine

Sent: Friday, May 18, 2018 11:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 6:42 AM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

CVCA is not a part of Vet-LIRN!

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine
Sent: Thursday, May 17, 2018 7:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work!

B5

B5

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Date: May 17, 2018 at 2:27:35 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:14:48 PM EDT
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to B6 talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:06:04 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

B5

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

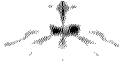
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

I do not know about **B5** Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting

B5

B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Friday, May 11, 2018 4:14 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic.

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 11, 2018 at 4:06:05 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 9, 2018 at 4:09:18 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 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>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

B5, B6

@ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison

CVM OSC/DC/CERT

7519 Standish Place

B6



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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was **B6**

B6

<https://www.cvcavets.com/>

B6

Keep us posted!

Thanks again!

Martine

B5

I'm happy to share more info as needed.

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

B5

Looping in Jen.

Thanks for the update!

dave

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

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From: Hartogenesis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

B5

Might be a good opportunity for us to partner with some cardiology folks....

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Date: May 7, 2018 at 1:03:13 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-RREIMSCH>
To: Hartogensis, Martine; Jones, Jennifer L
CC: Rotstein, David
Sent: 6/11/2018 6:25:07 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

We have done no evaluation of **B5** and like you – I raise my eyebrows a bit when **B5**
B5

I went on Alibaba website and there are many products... same with amazon – not sure how to chose what to test.

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN

Phone 1-240-402-5404 Fax 301-210-4685

Vet-LIRN <http://www.fda.gov/AnimalVeterinary/ScienceResearch/tcm247334.htm>

From: Hartogensis, Martine
Sent: Monday, June 11, 2018 1:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought. **B5**
B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 11, 2018 12:06 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Good morning everyone.

B5

Please let me know if you have feedback or comments by COB Friday (6/15).

Thank you,

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Norris, Anne

Sent: Tuesday, May 22, 2018 9:24 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 9:13 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:49 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 8:39 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:37 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

B5

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B6



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From: Norris, Anne
Sent: Tuesday, May 22, 2018 8:34 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Jones, Jennifer L
Sent: Tuesday, May 22, 2018 8:31 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:25 AM

To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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

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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

Just some food for thought... rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Edwards, David

Sent: Tuesday, May 22, 2018 7:54 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David
Sent: Monday, May 21, 2018 7:49 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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

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From: Hartogensis, Martine
Sent: Monday, May 21, 2018 7:47 AM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

B5

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel,

Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan

<Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David

<David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel,

Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

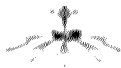
B5

Any other ideas or suggestions?

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Friday, May 18, 2018 11:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>;

Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel,

Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

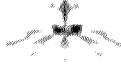
From: Jones, Jennifer L
Sent: Friday, May 18, 2018 6:42 AM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

CVCA is not a part of Vet-LIRN

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogenesis, Martine
Sent: Thursday, May 17, 2018 7:52 PM
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work!
they part of VET-LIRN

B5

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Date: May 17, 2018 at 2:27:35 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to **B6** talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:06:04 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

B5

From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

B5

B5

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Monday, May 14, 2018 10:22 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

I do not know about **B5** Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Date: May 14, 2018 at 9:09:17 AM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting.

B5

B5

Martine

From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 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>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with **B6**. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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

B6



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From: Hartogenesis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was B6

B6

<https://www.cvcavets.com/doctd>

B6

Keep us posted!

Thanks again!

Martine

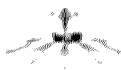
Hi Martine,

B5

I'm happy to share more info as needed.

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

B5

Looping in Jen.

Thanks for the update!

dave

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

B6



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From: Hartogenesis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

B5

Might be a good opportunity for us to partner with some cardiology folks....

Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Date: May 7, 2018 at 1:03:13 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Reimschuessel, Renate; Jones, Jennifer L
CC: Rotstein, David
Sent: 6/11/2018 6:36:44 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Ok, thank you Renate! Just thought it would be worth discussing ;)

Martine

From: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Date: June 11, 2018 at 2:25:11 PM EDT
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN
Phone 1- 240-402-5404 Fax 301-210-4685
Vet-LIRN <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Hartogenesis, Martine
Sent: Monday, June 11, 2018 1:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought

B5

B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 11, 2018 12:06 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica

<Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Good morning everyone,

B5

documents are attached.

Please let me know if you have feedback or comments by COB Friday (6/15).

Thank you,

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Norris, Anne

Sent: Tuesday, May 22, 2018 9:24 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 9:13 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

For example, [B4] (not a grain-free diet)

[B5]

B4

From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:49 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

That should be fine. I apologize if we already discussed this

[B5]

[B5]

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 8:39 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:37 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

[B5]

B5

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

B6



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From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancev@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carev@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Jones, Jennifer L

Sent: Tuesday, May 22, 2018 8:31 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancev@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carev@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:25 AM

To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison

CVM OSC/DC/CERT

7519 Standish Place

B6



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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Just some food for thought... rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

Phone 1- 240-402-5404

Fax 301-210-4685

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Edwards, David

Sent: Tuesday, May 22, 2018 7:54 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

B5

Thanks,
Dave

From: Rotstein, David

Sent: Monday, May 21, 2018 7:49 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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

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From: Hartogensis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

B5

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Bill

What Socrates is really supposed to have said: **“The only true wisdom is in knowing that you know nothing.”*

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>;

DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>;

Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Friday, May 18, 2018 11:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

<Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 6:42 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

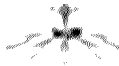
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

CVCA is not a part of Vet-LIRN

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 7:52 PM

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work!
they part of VET-LIRN?

B5

Are

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Date: May 17, 2018 at 2:27:35 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

B4, B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to B6 talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:06:04 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

From: Hartogenesis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

B5

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

I do not know about **B5**. Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting.

B5

B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 9, 2018 at 4:09:18 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 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>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with [B6]@ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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

[B6]



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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!

[B6]

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

B5

Looping in Jen.

Thanks for the update!

dave

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

B6



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From: Hartogenesis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

B5

Might be a good opportunity for us to partner with some cardiology folks...

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Reimschuessel, Renate; Jones, Jennifer L
Sent: 6/11/2018 6:39:51 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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

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From: Hartogensis, Martine
Sent: Monday, June 11, 2018 2:37 PM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Ok, thank you Renate! Just thought it would be worth discussing ;)

Martine

From: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Date: June 11, 2018 at 2:25:11 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN

Phone 1-240-402-5404 Fax 301-210-4685

Vet-LIRN <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Hartogensis, Martine

Sent: Monday, June 11, 2018 1:57 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought.

B5

B5

Martine

From: Jones, Jennifer L

Sent: Monday, June 11, 2018 12:06 PM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Good morning everyone,

B5

Please let me know if you have feedback or comments by COB Friday (6/15).

Thank you,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Norris, Anne

Sent: Tuesday, May 22, 2018 9:24 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey,

Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

From: Palmer, Lee Anne

Sent: Tuesday, May 22, 2018 9:13 AM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

For example,

B4

dry (not a grain-free diet)

B5

B5

B4

From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:49 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

That should be fine. I apologize if we already discussed this,

B5

B5

From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 8:39 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Rotstein, David
Sent: Tuesday, May 22, 2018 8:37 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

B5

B5

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

B6



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distribution, or copying is strictly prohibited. If you think you received this e-mail message in error, please e-mail the sender immediately at david.rotstein@fda.hhs.gov.

From: Norris, Anne

Sent: Tuesday, May 22, 2018 8:34 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Jones, Jennifer L

Sent: Tuesday, May 22, 2018 8:31 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, May 22, 2018 8:25 AM

To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

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

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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

Just some food for thought... rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

Phone 1-240-402-5404

Fax 301-210-4685

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Edwards, David

Sent: Tuesday, May 22, 2018 7:54 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David

Sent: Monday, May 21, 2018 7:49 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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

B6



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From: Hartogensis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>;

Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne
Sent: Friday, May 18, 2018 2:09 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks, Jen, very interesting issue!

B5

B5

B5

Lee Anne

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 1:54 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine
Sent: Friday, May 18, 2018 11:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

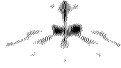
From: Jones, Jennifer L
Sent: Friday, May 18, 2018 6:42 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

CVCA is not a part of Vet-LIRN.

B4

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 7:52 PM

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work!
Are they part of VET-LIRN?

B5

Are

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Date: May 17, 2018 at 2:27:35 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to

B6

talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:06:04 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

From: Hartogenesis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

B5

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

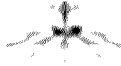
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

I do not know **B5** Once we get a better handle on a specific cause, we can work on that.

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting.

B5

B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Friday, May 11, 2018 4:14 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 11, 2018 at 4:06:05 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 9, 2018 at 4:09:18 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 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>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with **B6** @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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

B6



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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!

B6

B6

<https://www.cvcavets.com>

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

B5

B5

Looping in Jen.

Thanks for the update!

dave

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

B6



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From: Hartogenesis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

B5

B5

B5

Might be a good opportunity for us to partner with some cardiology folks....

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Rotstein, David; Reimschuessel, Renate; Jones, Jennifer L
Sent: 6/11/2018 6:42:48 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Excellent point!

Martine

From: Rotstein, David <David.Rotstein@fda.hhs.gov>
Date: June 11, 2018 at 2:39:55 PM EDT
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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

B6



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From: Hartogenesis, Martine
Sent: Monday, June 11, 2018 2:37 PM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Ok, thank you Renate! Just thought it would be worth discussing ;)

Martine

From: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Date: June 11, 2018 at 2:25:11 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN
Phone 1- 240-402-5404 Fax 301-210-4685
Vet-LIRN <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Hartogensis, Martine
Sent: Monday, June 11, 2018 1:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Hi Jen and Renate,

Just a crazy thought

B5

B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 11, 2018 12:06 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Good morning everyone,

B5

Please let me know if you have feedback or comments by COB Friday (6/15).

Thank you,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Norris, Anne
Sent: Tuesday, May 22, 2018 9:24 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining. Completely understand the sensitivity, was just curious. We can use a light touch in any preliminary communications.

From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 9:13 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

For example, **B4** dry (not a grain-free diet) **B4** but they are pretty far down the list:

B4

From: Norris, Anne
Sent: Tuesday, May 22, 2018 8:49 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David

<David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

That should be fine. I apologize if we already discussed this

B5

B5

From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 8:39 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Rotstein, David
Sent: Tuesday, May 22, 2018 8:37 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

B5

B5

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

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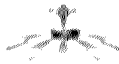
From: Norris, Anne
Sent: Tuesday, May 22, 2018 8:34 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

From: Jones, Jennifer L
Sent: Tuesday, May 22, 2018 8:31 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 22, 2018 8:25 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A

<Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah
<Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z
<Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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

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From: Reimschuessel, Renate

Sent: Tuesday, May 22, 2018 8:18 AM

To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

B5

Just some food for thought... rr

Renate Reimschuessel V.M.D. Ph.D. Vet-LIRN

Phone 1- 240-402-5404

Fax 301-210-4685

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Edwards, David

Sent: Tuesday, May 22, 2018 7:54 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David

Sent: Monday, May 21, 2018 7:49 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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

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From: Hartogensis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Bill

What Socrates is really supposed to have said: *‘‘The only true wisdom is in knowing that you know nothing.’’

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Friday, May 18, 2018 11:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L

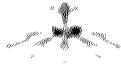
Sent: Friday, May 18, 2018 6:42 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 7:52 PM

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work!
they part of VET-LIRN?

B4, B5

Are

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Date: May 17, 2018 at 2:27:35 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B4, B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel,

Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to B6 talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:06:04 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

B5

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Please see the PPT for the rationale/summary

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Monday, May 14, 2018 10:22 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

I do not know about **B5** Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 14, 2018 at 9:09:17 AM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting
B5

B5

Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

B5

From: Rotstein, David
Sent: Wednesday, May 9, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 9, 2018 at 4:09:18 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 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>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with [B6] @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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



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From: Hartogenesis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!

[B6]

<https://www.cvcavets.com/>

[B6]

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

B5

B5

Looping in Jen.

Thanks for the update!

dave

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

B6



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From: Hartogenesis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

B5

Might be a good opportunity for us to partner with some cardiology folks....

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Burkholder, William
Sent: 6/20/2018 3:50:47 PM
Subject: slides shared with PFI
Attachments: 800.267-DCM-Grainfree analysis-UPDATED.pptx; DCM-Grainfree analysis-UPDATED-PFI-redacted.pptx

The PFI shared slides and our unredacted version.

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>



800.267
Grain free
versus
Non Grain Free Foods

Jones
Vet-LIRN


Grain Free products w/ reported DCM



Product Name	Grain free?	Species	Tau (%)
B4	Yes	Canine	0.26
	Yes	Canine	0.11
	Yes	Canine	0.14
	Yes	Canine	0.12
	Yes	Canine	0.2
	Yes	Canine	0.051
	Yes	Canine	0.25

- 6/7 products with sufficient Taurine levels
- Only 1 product- **B4** was low in Taurine
 - Feline AAFCO minimum Tau is 0.1% for extruded foods
 - No AAFCO minimum for dogs
 - Dog in this case had low Whole blood Tau
- Taurine is conditionally essential in dogs, because they can synthesize it from Cystine and Methionine.

Grain Free products w/ reported DCM



Product Name	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
B4	yes	Canine	0.26	0.26	0.64	0.9
	yes	Canine	0.11	0.26	0.61	0.87
	yes	Canine	0.14	0.28	0.86	1.14
	yes	Canine	0.12	0.36	0.69	1.05
	yes	Canine	0.2	0.34	0.51	0.85
	yes	Canine	0.051	0.33	0.4	0.73
	yes	Canine	0.25	0.38	0.7	1.08
	yes	Canine	0.25	0.38	0.7	1.08

AAFCO min: 0.33 to 0.35 % 0.65 to 0.7%

- All Grain Free Products contain Methionine and Methionine-Cystine % within the AAFCO requirements.
 - There is no AAFCO requirement for Cystine %
- The **B4** had the lowest Met and Met-Cys content, but it was still above AAFCO requirements (highlighted)
- The **B4** had the lowest Cys content (highlighted).

Non Grain Free Products w/o reported DCM

Product Name	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
B4	No	Canine	0.22	0.32	0.66	0.98
	No	Canine	0.11	0.3	0.57	0.87
	No	Canine	0.11	0.3	0.6	0.9
	No	Canine	0.11	0.31	0.58	0.89
	No	Canine	0.12	0.32	0.65	0.97
	No	Both	0.19	0.46	0.6	1.06
	No	Feline	0.24	0.42	0.78	1.2
	No	Feline	0.24	0.5	0.94	1.44

- In non-GF foods, the Taurine, Met, and Met-Cys levels were above AAFCO minimums.
 - Similar to Grain free foods.

Grain Free vs. Non Grain Free

Product Name	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Avg All GF foods	0.16	0.32	0.63	0.95
Avg All Non-GF Dog foods	0.14	0.34	0.61	0.95
Avg All Non-GF Cat Foods	0.22	0.46	0.77	1.23

- Average Tau, Cys, Met, and Met-Cys content in Grain Free dog foods is similar to the non-GF dog foods.
- The *non-GF cat foods* tend to have higher average levels, because they have greater minimum AAFCO requirements.

Overall Comparison

Product Name	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
	Yes	Canine	0.26	0.26	0.64	0.9
	Yes	Canine	0.11	0.26	0.61	0.87
	Yes	Canine	0.14	0.28	0.86	1.14
	Yes	Canine	0.12	0.36	0.69	1.05
	Yes	Canine	0.2	0.34	0.51	0.85
	Yes	Canine	0.051	0.33	0.4	0.73
	Yes	Canine	0.25	0.38	0.7	1.08
	No	Canine	0.22	0.32	0.66	0.98
	No	Canine	0.11	0.3	0.57	0.87
	No	Canine	0.11	0.3	0.6	0.9
	No	Canine	0.11	0.31	0.58	0.89
	No	Canine	0.12	0.32	0.65	0.97
	No	Both	0.19	0.46	0.6	1.06
	No	Feline	0.24	0.42	0.78	1.2
	No	Feline	0.24	0.5	0.94	1.44

B4

Because the Grain free and Non-GF foods have a similar Tau, Cys, Met, and Met-Cys content, we can look closely at **B4**

It has adequate Met and Met-Cys levels, which should enable a dog to make adequate Tau, without needing Tau in the food.

However, the dog eating this diet had low Whole blood Tau.

Ingredient comparison

Product Name	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
B4	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (5), peas (4), pea fiber (7)
	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	0.14	0.28	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	0.12	0.36	0.69	1.05	unknown	No	No	0	
	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
	0.25	0.38	0.7	1.08	unknown	Yes	No	1	peas (4)
	0.051	0.33	0.4	0.73	low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11)
	0.22	0.32	0.66	0.98		Yes	No	1	pea fiber (10)
	0.11	0.3	0.57	0.87		No	Met	0	
	0.11	0.3	0.6	0.9		No	Met	0	
	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
	0.19	0.46	0.6	1.06		Yes	No	2	pea protein (5), peas (9)

- Other products (stars) with normal Met and Met-Cys % and are not supplemented with Met in the ingredients like the **B4** (red box). The non GF diet **B4** had a comparable # legume sources, but its only legume source was low on the ingredient list and contained less legume sources than the **B4** respectively.
- The **B4** product contains Brown Rice and Rice, so isn't grain free. But the dog in this case had DCM. Not much is known about the case.
- If the Met-Cys and Met % are normal, then something is causing the **B4** **B4** dog's low blood Tau. Are there problems with nutrient uptake 0/7c of the amount and/or number of legumes in the product?

Ingredient comparison

Product Name	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
B4	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (5), peas (4), pea fiber (7)
	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	0.14	0.28	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	0.12	0.36	0.69	1.05	unknown	No	No	0	
	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
	0.25	0.38	0.7	1.08	unknown	Yes	No	1	peas (4)
	0.051	0.33	0.4	0.73	low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11)
	0.22	0.32	0.66	0.98		Yes	No	1	pea fiber (10)
	0.11	0.3	0.57	0.87		No	Met	0	
	0.11	0.3	0.6	0.9		No	Met	0	
	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
	0.19	0.46	0.6	1.06		Yes	No	2	pea protein (5), peas (9)

B4 product may be a red herring/separate issue or a clue about how the legume may affect the product

NCSU ACVIM Abstract-Dr. Adin

Methods: *retrospective evaluation* of dogs diagnosed with DCM who had diet recorded in the last 2 years. Dogs were lumped into Grain-free (further subdivided into California naturals and other) and Non-Grain free diets

Results: *-22 dogs ate grain free* (10 **B4** of these were Kangaroo and Lentil).

Taurine testing in 11 of these dogs did not show deficiency - carnitine testing in 4 did not show deficiency. Two sets of unrelated housemates were in this group.

-27 dogs ate non-grain free. Taurine testing in 11 of these and 5 were deficient (3 ate vegetarian diets)

- Dogs eating **B4** weighed less than the other groups (I interpret this to mean they are not the typical large breed DCM dog- 23 vs 35 kg P=0.03).

- Dogs eating **B4** had bigger hearts in diastole and systole and a more spherical heart than 1) dogs eating other grain free diets and 2) dogs eating nongrain free diets (all statistically significant).

- Dogs eating Grain free diets as a group had bigger hearts in diastole and systole and more spherical hearts on echo than dogs eating nongrain free diets (all statistically significant)

- presence of CHF was not different between groups

NCSU ACVIM Abstract-Dr. Adin

Methods: *retrospective evaluation* of dogs diagnosed with DCM who had diet recorded in the last 2 years. Dogs were lumped into Grain-free (further subdivided into Lentil).

Results: **BLUF: Taurine WNL for 11 of 27 dogs on GF diets with DCM**

Taurine did not

deficient

(I interquartile range P=0.03)

spherical hearts on echo

nongrain free diets (all statistically significant).

- *Dogs eating Grain free diets as a group had bigger hearts in diastole and systole and more spherical hearts on echo than dogs eating nongrain free diets (all statistically significant)*

- presence of CHF was not different between groups

ts

Lentil).

testing in 4

his group.

15 were

ther groups

- 23 vs 35 kg

a more

eating

Call with Cardiologists

Since the abstract:

- Dr. Adin has seen 36 DCM dogs on Grain Free diets.
- Taurine in 18 dogs was WNL.
 - The majority were supplemented.
- 7 were rechecked and *all* showed some improvement with *diet change*.
 - 1/7 not supplemented, only diet change:
 - not much echo change at 3 months but at 9 months had improved echo parameters.
 - 1/7 was changed to a **B4** Grain Free diet and had similar improvement to the dogs with diet change and Taurine supplementation at 3 months.

Call with Cardiologists

Since the abstract:

- Dr. Adin has seen 26 DCM dogs on Grain Free diets
- Tau BLUF: Taurine is normal in the dogs checked, but they may improve faster with Tau supplementation and diet change. with
- 7 w die
 - not much echo change at 3 months but at 9 months had improved echo parameters.
 - 1/7 was changed to a **B4** Grain Free diet and had similar improvement to the dogs with diet change and Taurine supplementation at 3 months.

GF Diet Ingredient comparison

Product Name	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
B4	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	unknown	No	No	0	
	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
	unknown	Yes	No	1	peas (4)
	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11), pea fiber (10)
		Yes	No	1	pea fiber (10)
		No	Met	0	
		No	Met	0	
		No	Met	1	green peas (22)
		No	Met	1	green peas (20)
		Yes	No	2	pea protein (5), peas (9)
		Yes	No	1	dried ground peas (12)
		Yes	No	0	

- Should we be looking at other dietary causes of DCM, whose GI uptake may be affected by these legume sources?
 - *Untested*: Thiamine, choline, erucic acid, vitamin E*, Polyunsaturated fatty acids*
 - Tested: Ca, Mg, P, Fe, Co, Cu, Zn, Se, Tau, Cys, Met, Iodine

*Courtesy Randall Lovell

GF Diet Ingredient comparison

Product Name	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
B4	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	unknown	No	No	0	
	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
	unknown	Yes	No	1	peas (4)
	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11), pea fiber (10)
		Yes	No	1	
		No	Met	0	
		No	Met	0	
		No	Met	1	green peas (22)
		No	Met	1	green peas (20)
		Yes	No	2	pea protein (5), peas (9)
		Yes	No	1	dried ground peas (12)
	Yes	No	0		

BLUF: Grain Free diets have many more legume species and legume sources closer to the beginning of the ingredient list than Non-GF diets.

Questions

- Are there properties to these legumes affecting Cys or Met uptake or Tau synthesis in dogs causing DCM?

Grain free
versus
Non Grain Free Foods

Jones
Vet-LIRN

Grain Free products w/ reported DCM

Product	Grain Free?	Tau (%)
Product A	Yes	0.26
Product A	Yes	0.11
Product A	Yes	0.14
Product B	Yes	0.12
Product C	Yes	0.2
Product D	Yes	0.051
Product E	Yes	0.25

- 6/7 GF products with sufficient Taurine levels
- Only 1 product was low in Taurine
 - Feline AAFCO minimum Tau is 0.1% for extruded foods
 - No AAFCO minimum for dogs
 - Dog in this case had low Whole blood Tau
- Taurine is conditionally essential in dogs, because they can synthesize it from Cystine and Methionine.

Grain Free products w/ reported DCM

Product	Grain Free?	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Product A	Yes	0.26	0.26	0.64	0.9
Product A	Yes	0.11	0.26	0.61	0.87
Product A	Yes	0.14	0.28	0.86	1.14
Product B	Yes	0.12	0.36	0.69	1.05
Product C	Yes	0.2	0.34	0.51	0.85
Product D	Yes	0.051	0.33	0.4	0.73
Product E	Yes	0.25	0.38	0.7	1.08

AAFCO min: 0.33 to 0.35 % 0.65 to 0.7%

- All Grain Free Products contain Methionine and Methionine-Cystine % within the AAFCO requirements.
 - There is no AAFCO requirement for Cystine %
- The low Tau product had the lowest Met and Met-Cys content, but it was still above AAFCO requirements (highlighted)
- One product had the lowest Cys content (highlighted).

Non Grain Free Products w/o reported DCM

Product	Grain Free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Product F	No	Canine	0.22	0.32	0.66	0.98
Product G	No	Canine	0.11	0.3	0.57	0.87
Product G	No	Canine	0.11	0.3	0.6	0.9
Product H	No	Canine	0.11	0.31	0.58	0.89
Product I	No	Canine	0.12	0.32	0.65	0.97
Product J	No	Both	0.19	0.46	0.6	1.06
Product K	No	Feline	0.24	0.42	0.78	1.2
Product L	No	Feline	0.24	0.5	0.94	1.44

- In non-GF foods, the Taurine, Met, and Met-Cys levels were above AAFCO minimums.
 - Similar to Grain free foods.

Grain Free vs. Non Grain Free

Product Name	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Avg All GF foods	0.16	0.32	0.63	0.95
Avg All Non-GF Dog foods	0.14	0.34	0.61	0.95
Avg All Non-GF Cat Foods	0.22	0.46	0.77	1.23

- Average Tau, Cys, Met, and Met-Cys content in Grain Free dog foods is similar to the non-GF dog foods.
- The *non-GF cat foods* tend to have higher average levels, because they have greater minimum AAFCO requirements.

Overall Comparison

Product	Grain Free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Product A	Yes	Canine	0.26	0.26	0.64	0.9
Product A	Yes	Canine	0.11	0.26	0.61	0.87
Product A	Yes	Canine	0.14	0.28	0.86	1.14
Product B	Yes	Canine	0.12	0.36	0.69	1.05
Product C	Yes	Canine	0.2	0.34	0.51	0.85
Product D	Yes	Canine	0.051	0.33	0.4	0.73
Product E	Yes	Canine	0.25	0.38	0.7	1.08
Product F	No	Canine	0.22	0.32	0.66	0.98
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Product I	No	Canine	0.12	0.32	0.65	0.97
Product J	No	Both	0.19	0.46	0.6	1.06
Product K	No	Feline	0.24	0.42	0.78	1.2
Product L	No	Feline	0.24	0.5	0.94	1.44

- Because the Grain free and Non-GF foods have a similar Tau, Cys, Met, and Met-Cys content, we can look closely at one product.
- It has adequate Met and Met-Cys levels, which should enable a dog to make adequate Tau, without needing Tau in the food.
- However, the dog eating this diet had low Whole blood Tau.

Ingredient comparison

Product	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
Product A	Yes	Canine	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.14	0.26	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product B	Yes	Canine	0.12	0.36	0.69	1.05	unknown	No	No	0	
Product C	Yes	Canine	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
Product D	Yes	Canine	0.25	0.38	0.7	1.08	unknown	Yes	No	1	peas (4)
Product E	Yes	Canine	0.051	0.33	0.4	0.73	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11)
Product F	No	Canine	0.22	0.32	0.66	0.98		Yes	No	1	pea fiber (10)
Product G	No	Canine	0.11	0.3	0.57	0.87		No	Met	0	
Product G	No	Canine	0.11	0.3	0.6	0.9		No	Met	0	
Product H	No	Canine	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
Product I	No	Canine	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
Product J	No	Both	0.19	0.46	0.6	1.06		Yes	No	2	pea protein (5), peas (9)
Product K	No	Feline	0.24	0.42	0.78	1.2		Yes	No	1	dried ground peas (12)
Product L	No	Feline	0.24	0.5	0.94	1.44		Yes	No	0	

- Other products (stars) with normal Met and Met-Cys % and are not supplemented with Met in the ingredients, like the low Tau product (red box). The non GF diet had a comparable # legume sources, but its only legume source was low on the ingredient list and contained less legume sources than the other starred GF products, respectively.
- The first starred product contains Brown Rice and Rice, so isn't grain free. But the dog in this case had DCM. Not much is known about the case.
- If the Met-Cys and Met % are normal, then something is causing the red box dog's low blood Tau. Are there problems with nutrient uptake b/c of the amount and/or number of legumes in the product?

Ingredient comparison

Product	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
Product A	Yes	Canine	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.14	0.28	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product B	Yes	Canine	0.12	0.36	0.69	1.05	unknown	No	★ No	0	
Product C	Yes	Canine	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
Product D	Yes	Canine	0.25	0.38	0.7	1.08	unknown	Yes	★ No	1	peas (4)
Product E	Yes	Canine	0.051	0.33	0.4	0.73	Low	No	★ No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11)
Product F	No	Canine	0.22	0.32	0.66	0.98		Yes	★ No	1	pea fiber (10)
Product G	No	Canine	0.11	0.3	0.57	0.87		No	Met	0	
Product G	No	Canine	0.11	0.3	0.6	0.9		No	Met	0	
Product H	No	Canine	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
Product I	No	Canine	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
Product J	No	Both	0.19	0.46	0.6	1.06		Yes	No	2	pea protein (5), peas (9)
Product K	No	Feline	0.24	0.42	0.78	1.2		Yes	No	1	dried ground peas (12)
Product L	No	Feline	0.24	0.5	0.94	1.44		Yes	No	0	

The low Tau product may be a red herring/separate issue or a clue about how the legume may affect the product

NCSU ACVIM Abstract-Dr. Adin

Methods: *retrospective evaluation* of dogs diagnosed with DCM who had diet recorded in the last 2 years. Dogs were lumped into Grain-free (further subdivided into Brand XXXX and other) and Non-Grain free diets

Results: *-22 dogs ate grain free* (10 Brand XXXX, 7 of these were Kangaroo and Lentil). *Taurine testing in 11 of these dogs did not show deficiency* - carnitine testing in 4 did not show deficiency. Two sets of unrelated housemates were in this group.

-27 dogs ate non-grain free. Taurine testing in 11 of these and *5 were deficient (3 ate vegetarian diets)*

- Dogs eating Brand XXXX weighed less than the other groups (I interpret this to mean they are not the typical large breed DCM dog- 23 vs 35 kg P=0.03).

- Dogs eating Brand XXXX had bigger hearts in diastole and systole and a more spherical heart than 1) dogs eating other grain free diets and 2) dogs eating nongrain free diets (all statistically significant).

- Dogs eating Grain free diets as a group had bigger hearts in diastole and systole and more spherical hearts on echo than dogs eating nongrain free diets (all statistically significant)

- presence of CHF was not different between groups

NCSU ACVIM Abstract-Dr. Adin

Methods: *retrospective evaluation* of dogs diagnosed with DCM who had diet recorded in the last 2 years. Dogs were lumped into Grain-free (further subdivided into Lentil, Chickpea, and Pea) and Non-grain-free (further subdivided into Soybean Meal, Barley, and Oat).

Results: BLUF: Taurine WNL for 11 of 11 dogs tested on GF diets with DCM. Plasma taurine was significantly lower in dogs eating grain-free diets compared to dogs eating non-grain-free diets (P=0.03). Plasma taurine was significantly lower in dogs eating grain-free diets compared to dogs eating non-grain-free diets (P=0.03).

WB taurine is only a snapshot of the content. Paired plasma and WB are better indicators of overall body Taurine content. Dogs eating grain-free diets had significantly lower plasma taurine compared to dogs eating non-grain-free diets (P=0.03). Dogs eating grain-free diets had significantly lower plasma taurine compared to dogs eating non-grain-free diets (P=0.03).

- Dogs eating Grain free diets as a group had bigger hearts in diastole and systole and more spherical hearts on echo than dogs eating nongrain free diets (all statistically significant)

- presence of CHF was not different between groups

Call with Cardiologists

Since the abstract:

- Dr. Adin has seen 36 DCM dogs on Grain Free diets.
- Taurine in 18 dogs was WNL.
 - The majority were supplemented.
- 7 were rechecked and *all* showed some improvement with *diet change*.
 - 1/7 not supplemented, only diet change:
 - not much echo change at 3 months but at 9 months had improved echo parameters.
 - 1/7 was changed to a Large Manufacturer Grain Free diet and had similar improvement to the dogs with diet change and Taurine supplementation at 3 months.

Call with Cardiologists

Since the abstract:

- Dr. Adin has seen 36 DCM dogs on Grain Free diets.
- Taurine levels were checked in 7 weeks. **BLUF: Taurine is normal in the dogs checked, but they may improve faster with Tau supplementation and diet change.** with
- 1/7 was changed to a Large Manufacturer Grain Free diet and had similar improvement to the dogs with diet change and Taurine supplementation at 3 months. nths

GF Diet Ingredient comparison

Product	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
Product A	Yes	Canine	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.14	0.28	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product B	Yes	Canine	0.12	0.36	0.69	1.05	unknown	No	No	0	
Product C	Yes	Canine	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
Product D	Yes	Canine	0.25	0.38	0.7	1.08	unknown	Yes	No	1	peas (4)
Product E	Yes	Canine	0.051	0.33	0.4	0.73	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (3), green lentils (9), pea protein (11)
Product F	No	Canine	0.22	0.32	0.66	0.98		Yes	No	1	pea fiber (10)
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Product J	No	Both	0.19	0.46	0.5	1.06		Yes	No	2	pea protein (5), peas (9)
Product K	No	Feline	0.24	0.42	0.78	1.2		Yes	No	1	dried ground peas (12)
Product L	No	Feline	0.24	0.5	0.94	1.44		Yes	No	0	

- Should we be looking at other dietary causes of DCM, whose GI uptake may be affected by these legume sources?
 - *Untested*: Thiamine, choline, erucic acid, vitamin E*, Polyunsaturated fatty acids*
 - Tested: Ca, Mg, P, Fe, Co, Cu, Zn, Se, Tau, Cys, Met, Iodine

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Product E	Yes	Canine	0.051	0.33	0.4	0.73	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (3), green lentils (9), pea protein (11)
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Product G	No	Canine	0.11	0.3	0.57	0.87		No	Met	0	
Product G	No	Canine	0.11	0.3	0.5	0.9		No	Met	0	
Product H	No	Canine	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
Product I	No	Canine	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
Product J	No	Both	0.19	0.46	0.5	1.06		Yes	No	2	pea protein (5), peas (9)
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BLUF: Grain Free diets have many more legume species and legume sources closer to the beginning of the ingredient list than Non-GF diets.

Questions

- Are there properties to these legumes affecting Cys or Met uptake or Tau synthesis in dogs causing DCM?

From: Norris, Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=891982B43D804C9396555BAF36C73DE1-ANNE.NORRIS>
To: Jones, Jennifer L; Rotstein, David; Carey, Lauren; Hartogensis, Martine; Palmer, Lee Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/3/2018 6:38:15 PM
Subject: RE: Redacted complaint file for the DCM webposting
Attachments: 800.267-Product Indexing Results Summary.pptx

Thanks, Jen! + Bill.

From: Jones, Jennifer L
Sent: Tuesday, July 03, 2018 2:03 PM
To: Rotstein, David <David.Rotstein@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

I updated the slide deck with a summary from some great articles. Bottom line:

B5

B5

<https://academic.oup.com/in/article/131/2/276/4687012>

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



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



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>

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Sent: Monday, July 02, 2018 3:57 PM

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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>
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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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Carey, Lauren; Hartogensis, Martine; Norris, Anne; Palmer, Lee Anne
CC: DeLancey, Siobhan
Sent: 7/3/2018 6:40:06 PM
Subject: RE: Redacted complaint file for the DCM webposting

Jen,

This is very interesting.

B5

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

B6



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From: Jones, Jennifer L
Sent: Tuesday, July 03, 2018 2:03 PM
To: Rotstein, David <David.Rotstein@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>
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I updated the slide deck with a summary from some great articles. Bottom line:

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<https://academic.oup.com/in/article/131/2/276/4687012>

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Veterinary Medical Officer
Tel: 240-402-5421



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Leeanne.palmer@fda.hhs.gov



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To: Jones, Jennifer L; Rotstein, David; Carey, Lauren; Norris, Anne; Palmer, Lee Anne
CC: DeLancey, Siobhan
Sent: 7/3/2018 8:13:15 PM
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<Martine.Hartogenesis@fda.hhs.gov>

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Importance: High

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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: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Hartogensis, Martine; Rotstein, David; Carey, Lauren; Norris, Anne; Palmer, Lee Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/5/2018 11:01:43 AM
Subject: RE: Redacted complaint file for the DCM webposting

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine
Sent: Tuesday, July 03, 2018 4:13 PM
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B5

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To: Jones, Jennifer L; Rotstein, David; Carey, Lauren; Norris, Anne; Palmer, Lee Anne
CC: DeLancey, Siobhan; Burkholder, William
Sent: 7/5/2018 1:59:37 PM
Subject: RE: Redacted complaint file for the DCM webposting

Awesome! Thank you Jen!!

Martine

From: Jones, Jennifer L
Sent: Thursday, July 05, 2018 7:02 AM
To: Hartogenesis, Martine <Martine.Hartogenesis@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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Tel: 240-402-5767

Leeanne.palmer@fda.hhs.gov



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 5:49:46 PM
Subject: RE: Redacted complaint file for the DCM webposting

Hello – back from Monday and Tuesday **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. In the attachment, there are

B5

Thanks,
Anne

B5

Please ask me questions you have if I haven't made sense.

Thanks, Lee Anne

From: Hartogensis, Martine
Sent: Thursday, July 5, 2018 10:00 AM
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>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Awesome! Thank you Jen!!

Martine

From: Jones, Jennifer L
Sent: Thursday, July 05, 2018 7:02 AM
To: Hartogensis, Martine <Martine.Hartogensis@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>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Hartogensis, Martine
Sent: Tuesday, July 03, 2018 4:13 PM
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>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Redacted complaint file for the DCM webposting

Hi Jen,

This is excellent work!

B5

B5

Thanks again for all the excellent work!

Martine

From: Jones, Jennifer L
Sent: Tuesday, July 03, 2018 2:03 PM
To: Rotstein, David <David.Rotstein@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

I updated the slide deck with a summary from some great articles. Bottom line

B5

B5

B5

<https://academic.oup.com/in/article/131/2/276/4687012>

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



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



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

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: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Darcy Adin'
Sent: 7/20/2018 11:35:05 AM
Subject: RE: diet DCM

Thank you for the update, Darcy. I hope you are well!
Take care,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Wednesday, July 18, 2018 5:39 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: diet DCM

Hi Jennifer,

I was glad to see the FDA's statement earlier this week about a possible link between diet and canine DCM - it certainly is causing a buzz!

I just wanted to let you know that NBC news has asked to interview me this friday. I'm assuming they have interviewed someone from the FDA as well?

B5

B5

Just wanted you to know and open to any thoughts you might have!
Take care
Darcy

--
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

From: Andrea Fascetti <ajfascetti@ucdavis.edu>
To: Jones, Jennifer L
Sent: 5/20/2018 9:14:12 PM
Subject: Re: Question about aminoacid analysis-Matrices
Attachments: 002 Ko 2006 Cu Deficiency and Taurine Deficiency.pdf; **Not Responsive**; Backus 1995.pdf; Backus ACVN 2009 talk.pdf; Backus et al. 2006 J Nutr.pdf; Backus et al. JAVMA 2003.pdf; Backus JAVMA letter to editor.pdf; Delaney JAPAN.pdf; Fascetti javma.2003.223.1137.pdf; freeman_2001 vet therapeutics.pdf; J. Nutr.-2007-Ko-1171-5.pdf; JAAHA article 2005 Gold Ret DCM and taurine.pdf; Ko et al. J Nutr 2007.pdf; Nofs_et_al-2018-Journal_of_Animal_Physiology_and_Animal_Nutrition.pdf; Pacioretty article.pdf; Rogers taurine article.pdf; Sanderson 2001 AJVR.pdf; Sanderson_taurine_carnitine_K9_cardiomyopathy.pdf; Torres et al. JAPAN.pdf; Vollmar et al. J Vet Cardio 2013.pdf

Hi Jen - Here are a number of articles on dog taurine. I am sure you have many of them, but I am sending what I have just in case. The paper with the bile acid analysis was Ko 2016. Hope these help.

Andrea

On May 18, 2018, at 11:29 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Andrea,

I had a few questions unrelated to our contract.

Are you able to analyze amino acids in feces?

Is whole blood or plasma best for measuring amino acids in dogs?

-particularly taurine, cystine, and methionine.

Thank you in advance, and I hope you have a great weekend,

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>

<image001.png> <image004.png>

Copper Deficiency Does Not Lead to Taurine Deficiency in Rats¹

Kwang Suk Ko,² Cristina L. Tôrres,² Andrea J. Fascetti,² Martha H. Stipanuk,³ Lawrence Hirschberger,³ and Quinton R. Rogers^{2*}

²Department of Molecular Biosciences, School of Veterinary Medicine, University of California Davis, CA 95616 and ³Division of Nutritional Sciences, Cornell University, Ithaca, NY 14853

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 CuSO₄. At wk 16, the groups differed ($P < 0.05$) in the following variables (means \pm SEM, -Cu vs. +Cu): body weight (BW), 375 \pm 19 vs. 418 \pm 2.9 g; food intake, 16.2 \pm 0.7 vs. 18.5 \pm 0.4 g/d; hematocrit, 0.294 \pm 0.027 vs. 0.436 \pm 0.027; hemoglobin, 95.2 \pm 9 vs 134 \pm 10 g/L; liver Cu, 8.7 \pm 2.0 vs. 65.9 \pm 2.5 nmol/g; plasma Cu, 0.38 \pm 0.09 vs. 13.4 \pm 0.61 μ mol/L; plasma ceruloplasmin activity, 1.75 \pm 1.0 vs. 67.9 \pm 8.4 IU; relative heart weight, 0.56 \pm 0.04 vs. 0.35 \pm 0.02% BW; relative liver weight, 4.06 \pm 0.23 vs. 3.37 \pm 0.06% BW; and liver CSAD activity, 18.8 \pm 1.37 vs. 13.5 \pm 1.11 nmol \cdot min⁻¹ \cdot mg protein⁻¹. The groups did not differ at wk 16 in: plasma taurine, 249 \pm 14 vs. 298 \pm 63 μ mol/L; whole blood taurine, 386 \pm 32 vs. 390 \pm 25 μ mol/L; urinary taurine excretion, 82.5 \pm 15 vs. 52.0 \pm 8.3 μ mol/d; liver taurine, 2.6 \pm 0.7 vs. 2.8 \pm 0.4 μ mol/g; liver total glutathione, 6.9 \pm 0.48 vs. 6.3 \pm 0.40 μ mol/g; liver cyst(e)ine, 96 \pm 7.1 vs. 99 \pm 5.3 nmol/g and liver CDO activity, 2.19 \pm 0.33 vs. 2.74 \pm 0.21 nmol \cdot min⁻¹ \cdot 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 dysregulation 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 (CDAH), the School of Veterinary Medicine, University of California, Davis.

⁴ Abbreviations used: BW, body weight; CDO, cysteine dioxygenase; CSAD, cysteine sulfinic acid decarboxylase; +Cu, copper-adequate; -Cu, copper-deficient; DCM, dilated cardiomyopathy.

* To whom correspondence should be addressed. E-mail: qrrogers@ucdavis.edu.

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 CuSO₄. 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 wk¹

	-Cu	+Cu	<i>P</i> -value
Body weight, <i>g</i>	375 ± 19	418 ± 2.9	<0.05
Food intakes, ² <i>g/d</i>	16.2 ± 0.7	18.5 ± 0.4	<0.05
Relative heart wt, % <i>BW</i>	0.56 ± 0.04	0.35 ± 0.02	<0.01
Liver weights, % <i>BW</i>	4.06 ± 0.23	3.37 ± 0.06	<0.05
Hematocrit	0.294 ± 0.027	0.436 ± 0.027	<0.01
Hemoglobin, <i>g/L</i>	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, µmol · min⁻¹ · L⁻¹.

TABLE 3 Hepatic cysteine dioxygenase and cysteine sulfinic acid decarboxylase activities in rats fed -Cu and +Cu diets for 16 wk¹

	CDO			CSAD		
	-Cu	+Cu	P-value	-Cu	+Cu	P-value
$\mu\text{mol} \cdot \text{min}^{-1} \cdot \text{liver}^{-1}$	5.07 ± 0.95	5.53 ± 0.42	0.60	41.1 ± 1.31	27.3 ± 2.62	0.0008
$\mu\text{mol} \cdot \text{min}^{-1} \cdot \text{g liver}^{-1}$	0.33 ± 0.04	0.39 ± 0.02	0.19	2.78 ± 0.21	1.90 ± 0.15	0.005
$\text{nmol} \cdot 100 \text{ g BW}^{-1}$	1.29 ± 0.25	1.34 ± 0.11	0.83	11.0 ± 0.66	6.56 ± 0.59	0.0006
$\text{nmol} \cdot \text{min}^{-1} \cdot \text{mg protein}^{-1}$	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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Could Dietary Taurine Supplementation in Dogs Be Masking a Problem?

Robert C. Backus, MS, DVM, PhD, DACVN
Columbia, MO, USA

18689779

INTRODUCTION

The need for dietary protein relates to its constituent amino acids. Perhaps the most recognized need for dietary protein is for provision of amino acids used in the synthesis of body proteins, which constantly turnover, and the synthesis of non-protein substances, such as signaling molecules, pigments, antioxidants. Perhaps less well recognized about the need for dietary protein is for the provision of amino acids for support of metabolic pathways and products of amino acid catabolism, such amino nitrogen, methyl carbon, reduced sulfur, and the carbon- and nitrogen-containing skeletal elements of amino acids. The basis of the need for dietary protein is in essence reflective of needs for amino acids in a great variety of functions. Determining dietary adequacy in providing amino acids is then complicated by there being so many different functions that depend on the supply of amino acids. Hence, at times the dietary amino acid content needed to meet one function may not be great enough to meet the need for another function. For this reason, dietary protein and amino acid adequacies are evaluated from outcomes of a few different variables. Nitrogen balance and optimal growth rate and nitrogen retention are the most commonly evaluated variables. In some cases, other additional variables are evaluated because a physiological or metabolic function with a recognized health consequence requires a greater dietary concentration for optimization. One example used in dogs is urinary excretion of orotic acid. When dietary arginine is adequately provided, urinary excretion of orotic acid is minimized. Another variable that has come to light recent years is blood taurine concentration in dogs. Dietary protein provision that supports a minimal concentration of taurine in the blood of dogs is targeted to prevent development of cardiomyopathy. In the information presented below, the basis for evaluation of blood taurine in dogs will be described and the practice of taurine supplementation of diets for normal healthy dogs will be discussed.

TAURINE DEFICIENCY

Taurine is unique among dietary amino acids in that it is structurally a β -sulfonic amino acid and not bound in protein. Body needs for taurine may be met from dietary sources replete with taurine and by synthesis from sulfur-containing amino acids that are variably abundant in dietary protein, i.e., methionine and cyst(e)ine. Body needs for taurine have been realized from metabolic aberrations, dysfunction, and disease observed in experimental and natural depletions of body taurine caused by inadequate intake of methionine, cyst(e)ine, and or taurine. Body taurine reserves affect many functions, including fetal development, growth, reproduction, neuromodulation, vision, hearing, immunity, and cardiac performance.

Nutritional research that determined the cause of taurine deficiency in cats led to recognition that the synthesis of taurine from dietary methionine and cyst(e)ine is limited in strict carnivores. The limitation is so great that taurine must be included in the diets of cats and other carnivores to prevent deficiency disease. Low activity of a liver enzyme in the taurine biosynthetic pathway (cysteine dioxygenase and cysteine cysteinesulfinate decarboxylase) is among suggested causes for limited production of taurine in cats¹ (Figure 1). Most herbivores and omnivores, among which dogs are included, appear capable of meeting body taurine through *de novo* synthesis of taurine when dietary methionine and cyst(e)ine are adequately provided. It is for this reason that taurine is not considered to be an essential nutrient in dogs.

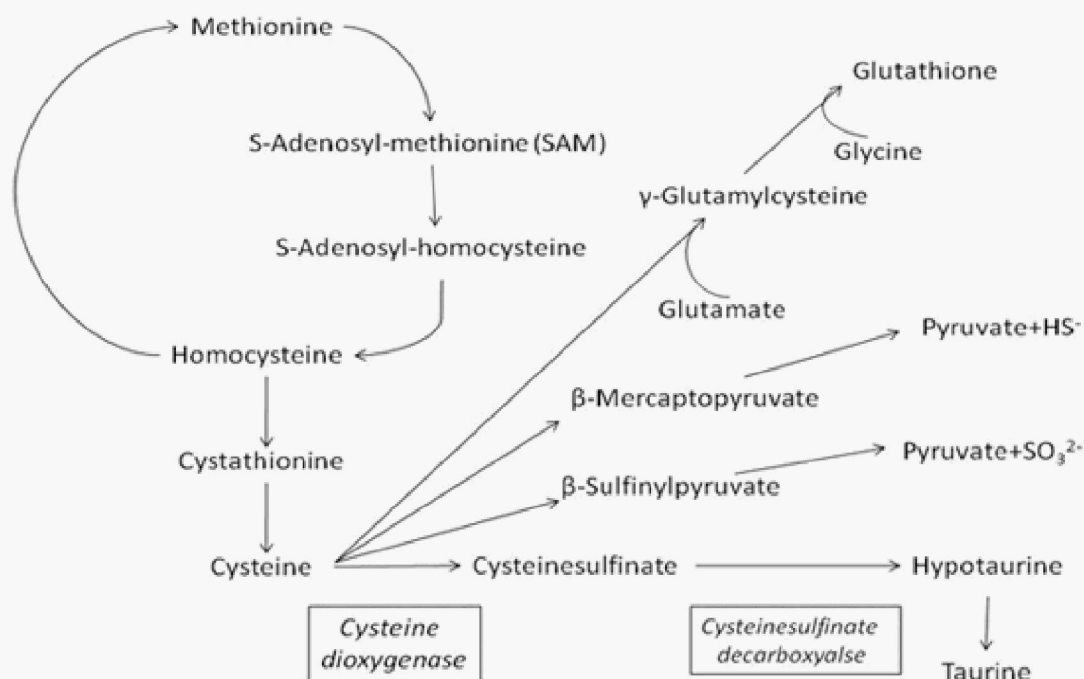
Nonetheless, taurine deficiency has been observed in dogs given diets apparently adequate in methionine and cyst(e)ine. At this time, taurine deficiency appears most clearly to affect heart function in dogs, seen clinically as a reversible dilated cardiomyopathy^{2,3}. Retinal degeneration as indicated from fundic exams has been described in few dogs⁴. Poor reproduction, small litters, and short-statured puppies have been anecdotally reported³. Correlation with low activity, health problems, and need for medications are also described⁵. Some of the taurine deficiency disease may be breed-specific. A dilated cardiomyopathy that appears to respond to taurine supplementation has been described in American Cocker Spaniels with low blood taurine concentration⁶. Low blood taurine concentration has been described in Newfoundlands with cystinuria⁷. In this case, urinary loss of biosynthetic precursor of taurine is surmised to explain the taurine deficiency. A

defect in renal tubular reabsorption of cystine from an inherited mutation of an amino acid transporter appears to underlie Newfoundland cystinuria⁸.

During the last 10 years, a taurine deficiency of nutritional origin has been described in dogs. One case in research Beagles clearly could be attributed to long-term feeding of a low protein diet⁹. Methionine and cyst(e)ine in the experimental diet were evidently inadequate because blood taurine concentrations among the dogs were low, and two dogs showed signs consistent with dilated cardiomyopathy that was improved by taurine supplementation. In other cases, clinically presented dogs of a variety of breeds are reported to have low blood taurine concentration and varying degrees of myocardial failure^{2,3,10,11}. Many of these dogs were of large body size and maintained on commercial diets in which lamb-meal and rice were the principal protein sources. The cause for the taurine deficiency among the dogs was initially unclear. Breed differences in protein digestibility have been reported but the differences did not seem consistent with body size¹². Chemical analyses of suspect diets revealed more than adequate dietary protein, methionine, and cyst(e)ine, and varying amounts of dietary taurine. However, taurine status could be improved by oral methionine or dietary change³. It seemed that bioavailabilities of either dietary protein, methionine, and or cyst(e)in were low.

The cause for the susceptibility of large-breed dogs to taurine deficiency has been investigated in recent years. The approach for this has involved comparisons between Beagles and larger dogs, about 3 times or greater in body weight. This research has produced several important findings. Gastrointestinal and not urinary taurine loss was found to be greater in large compared to small dogs given the same diet¹³. The cause for the size-difference was not clear but as indicated from fecal bile acid analysis it may have been related to differences in efficiency of bile acid reabsorption. Like cats, dogs conjugate their bile acids with taurine. Comparisons of taurine synthesis between large and small dogs revealed an impact of food intake and energy requirement of maintenance^{13,14}. Unlike that which is observed in cats, taurine status in dogs was found to increase with food intake and energy needed to maintain a healthy body weight^{15,16}. Together these findings indicated a greater need for taurine biosynthesis and precursor to support the biosynthesis in large compared to small dogs, especially in large dogs with a low maintenance energy requirement. This conclusion meant that a greater risk for taurine deficiency may be expected in large- than small-breed dogs if fed diets that are marginal protein content and or sulfur-containing amino bioavailability.

Figure 1. Metabolic pathways to taurine synthesis.



DIETARY SUPPLEMENTATION

As a result of finding causes for taurine deficiency in dogs, taurine was recognized to be a dispensable nutrient for dogs when inadequate quantities of sulfur-containing amino acids are provided¹⁷. An adequate intake of taurine for dogs was recommended for diets low in protein or known to be low in sulfur-containing amino acids. For other diets, the sulfur-containing amino acid allowance for dogs was substantially increased by the

NRC^{17,18}. Based on the extent of the increase in the allowance, it would seem that much of the sulfur-containing amino acid requirement in dogs is devoted to taurine synthesis. This condition can be appreciated by comparing recommendations for dogs with those for cats. The recommended allowance for methionine + cystine in diets for dogs (1.65 g/1000 kcal) in the maintenance state are now about twice that of cats (0.85 g/1000 kcal), a species in which taurine needs cannot be met by biosynthesis. Recommended allowances for most other amino acids in dogs are lower than those in cats.

In apparently responding to reports of taurine deficiency in dogs, pet food manufacturers have been supplementing some diets for dogs with taurine. The taurine supplementation is not limited to diets low in protein. This practice unfortunately eliminates application of a very useful means for evaluation of sulfur-containing amino acid bioavailability. As pointed out by Odle *et al.* over 15 years ago¹⁹, the monitoring of taurine status is potentially useful for determining the adequacy dietary sulfur-containing amino acid content in animals that synthesize taurine, such as dogs. The adequacy of dietary provision of methionine and cystine is not sensitively indicated by changes in plasma concentrations of methionine and cyst(e)ine. This appears to be a beneficial consequence of homeostatic regulation of the amino acids by liver. When in excess, methionine and cysteine compared to other dietary amino acids have a greater potential to be toxic. In contrast, taurine has low toxicity and its concentrations in plasma are observed to vary substantially with dietary sulfur amino acid concentration. End products of methionine and cysteine metabolism other than taurine could be monitored; however, they may not be as sensitive or as desirable to measure as taurine. Glutathione is a good example for comparison because glutathione synthesis utilizes methionine and cyst(e)ine. Glutathione, like taurine, occurs in high concentrations in many cell types, serves as an antioxidant, circulates in plasma, and has many vital functions. Low glutathione concentrations in tissues are believed to compromise cell function, to promote tissue damage, and increase morbidity under various disease conditions²⁰. Though glutathione is arguably important to consider in suspected dietary deficiency of sulfur-containing amino acids, taurine is a more sensitive indicator to monitor than glutathione for a least two reasons. First, the liver regulates concentrations of circulating glutathione like that observed for methionine and cyst(e)ine. And, second, the synthesis of taurine appears to have a lower priority than synthesis of glutathione. The Michaelis constant (K_m) for the rate controlling enzyme of glutathione synthesis is less than that of taurine synthesis¹.

The relative sensitivity of taurine as an indicator of adequacy of dietary sulfur-containing amino acids is evident from measurements in large dogs given commercial dog foods believed to have low sulfur-containing amino acid bioavailability^{15,16}. Plasma concentration of taurine was found to be significantly depressed while plasma glutathione concentration appeared unaffected and whole blood glutathione appeared only mildly depressed.

MONITORING ADEQUACY OF SULFUR-CONTAINING AMINO ACIDS

Commercial dog foods that have produced taurine deficiency appear to adequately support protein synthesis. Labeling claims for some diets indicate that the diet passed a feeding protocol in which acceptable changes in body weight, albumin, and hemoglobin concentration were observed. Evidence that protein synthesis is supported by such diets is still consistent with a low level of sulfur-containing amino acid intake. Under such a condition, catabolism of methionine and cysteine as with taurine synthesis is restricted while remethylation of homocysteine back to methionine and incorporation of cysteine into protein and glutathione given high priorities¹ (Figure 1). Hence, the monitoring of taurine status is tool that may be used to specifically assess sulfur-containing amino acid adequacy beyond that needed to achieve nitrogen balance. Such monitoring would seem worthwhile given the potential for producing diets deficient in sulfur-containing amino acids.

Methionine is often the first or second limiting amino acid in diets for dogs¹⁷ and cystine is usually present in diets in a limited range of proportions (~ 1:1 to 1:2) relative to methionine¹. Thus, because typical amino acid analyses of diets do not indicate bioavailability²¹, unrecognized, less than optimal amounts of methionine and cystine may occur in dog foods. This has been substantiated by studies of diets and ingredients in ileal-cannulated animals, where variable and low digestibilities of cystine are reported^{22,23}. The heat processing of diets and including the rendering process used in producing meat-meals is suggested to especially affect the cystine bioavailability. It should be noted that though heat processing has this effect, a few factors are mitigating. Digestibility effects of heat processing vary considerably with the temperature, time, and nature of the food matrix [e.g., 24]. Also, heat processing can increase digestibility of some proteins that contain sulfur-amino acids, such as protein from soybeans¹⁷.

For non-invasive convenient monitoring of taurine status, taurine concentrations in urine, blood, and plasma are useful. Of these concentrations, taurine to creatine ratio in free-catch urine samples appears to change most acutely with a dietary change¹³. Unfortunately, reference ranges are not reported for urine taurine to creatine ratio, and urine creatinine concentration varies with muscle mass and may scale differently with body size than taurine excretion. With daily urine collections over 5 days, taurine synthesis rate in dogs may be estimated after a single oral administration of stable isotopic taurine^{15,16}. Determination of taurine synthesis

rate is useful for distinguishing the cause of low taurine status. High loss of taurine could reduce taurine status, but so could low synthesis, as would occur with low intake or bioavailability of sulfur-containing amino acids. Low values thought to be indicative of taurine deficiency have been reported for blood and plasma taurine concentrations^{2,5,6}. These values are based on prevention of dilated cardiomyopathy. Greater values than these may be needed to optimize other functions dependant on taurine and other sulfur-containing amino acids. In the maintenance state, dietary amino acids concentrations that optimize variables like the immune response, wound healing, and health in old age have not been determined¹⁷.

CORRECTING DEFICIENCY

For diets that are not made intentional low in protein, as with some therapeutic diets, it seems inappropriate to add taurine to correct low taurine status induced by a diet. Correction by increasing methionine and cysteine bioavailability seems most appropriate. In making such a correction, monitoring of taurine status as described above may be used assess sulfur-containing amino acid bioavailabilities. Increasing the concentration of dietary protein with low sulfur-containing amino acid bioavailability is also not a desirable means of correction. This manipulation may increase fermentable residue if the protein is not well digested. Of relevance here is a report of many years ago demonstrating distal small intestinal fermentation in dogs given a high protein diet²⁵. The health significance of such fermentation is not known. Better options than increasing dietary protein would be to substitution of higher quality protein or supplementation with DL-methionine. It is interesting that the latter measure may especially support taurine synthesis while filling other needs for sulfur-containing amino acids. Research in rats show higher taurine formation and excretion in animals fed excess methionine than in those fed excess protein²⁶. With methionine compared to protein supplementation, the switch to formation of taurine more than sulfate is suggested to have the advantage of less perturbation of acid-base balance¹.

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Robert C. Backus, MS, DVM, PhD, DACVN

Columbia, MO, USA



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MAIN : AAVN/ACVN (Small Animal) : Taurine Supplementation

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Low Plasma Taurine Concentration in Newfoundland Dogs is Associated with Low Plasma Methionine and Cyst(e)ine Concentrations and Low Taurine Synthesis¹

Robert C. Backus,^{2*} Kwang Suk Ko,³ Andrea J. Fascetti,³ Mark D. Kittleson,⁴ Kristin A. MacDonald,⁴ David J. Maggs,⁵ John R. Berg,⁶ and Quinton R. Rogers³

²Department of Veterinary Medicine and Surgery, College of Veterinary Medicine, University of Missouri-Columbia, Columbia MO 65211; and ³Department of Molecular Biosciences, ⁴Department of Medicine and Epidemiology, ⁵Department of Surgical and Radiological Sciences, and ⁶Department of Chemistry, University of California, Davis, CA 95616

Abstract

Although taurine is not dietarily essential for dogs, taurine deficiency and dilated cardiomyopathy (DCM) are sporadically reported in large-breed dogs. Taurine status and husbandry were examined in 216 privately owned Newfoundlands, a giant dog breed with high incidence of idiopathic DCM (1.3–2.5%). Plasma taurine concentration was positively correlated ($P < 0.01$) with plasma cyst(e)ine ($r = 0.37$) and methionine ($r = 0.35$) concentrations and was similar across age, sex, neutering status, body weight, and body-condition scores. Plasma taurine concentration was low ($\leq 40 \mu\text{mol/L}$) in 8% of dogs. Dogs with low plasma taurine were older, less active, had more medical problems and treatments, and had lower plasma albumin, cyst(e)ine, tryptophan, and α -amino-n-butyric acid concentrations than the other dogs ($P < 0.05$). Of 9 taurine-deficient, clinically evaluated dogs, 3 had DCM that was reversed by taurine supplementation and 1 had retinal degeneration. When given a diet apparently adequate in sulfur amino acids (5.4 g/kg) for 3 wk, 6 Newfoundlands ($52.5 \pm 2.3 \text{ kg}$, 3.5–7 y), compared with 6 Beagles ($13.2 \pm 2.3 \text{ kg}$, 5.5 y), had lower ($P < 0.01$) concentrations of plasma taurine (49 ± 16 vs. $97 \pm 25 \mu\text{mol/L}$) and cyst(e)ine and blood glutathione, lower ($P < 0.01$) de novo taurine synthesis (59 ± 15 vs. $124 \pm 27 \text{ mg} \cdot \text{kg}^{-0.75} \cdot \text{d}^{-1}$), and greater ($P < 0.05$) fecal bile acid excretion (1.7 ± 0.2 vs. $1.4 \pm 0.2 \mu\text{mol/g}$). Newfoundlands would appear to have a higher dietary sulfur amino acid requirement than Beagles, a model breed used in nutrient requirement determinations. J. Nutr. 136: 2525–2533, 2006.

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Taurine deficiency in Newfoundlands fed commercially available complete and balanced diets

Robert C. Backus, DVM, PhD; Gabrielle Cohen, DVM; Paul D. Pion, DVM, DACVIM;
Kathryn L. Good, DVM, DACVO; Quinton R. Rogers, PhD, DACVN;
Andrea J. Fascetti, VMD, PhD, DACVN, DACVIM

Objective—To determine taurine status in a large group of Newfoundlands related by environment, diet, or breeding to a dog with dilated cardiomyopathy and taurine deficiency.

Design—Prospective study.

Animals—19 privately owned Newfoundlands between 5 months and 11.5 years old that had been fed commercial dry diets meeting established nutrient recommendations.

Procedure—Diet histories were obtained, and blood, plasma, and urine taurine concentrations and plasma methionine and cysteine concentrations were measured. In 8 dogs, taurine concentrations were measured before and after supplementation with methionine for 30 days. Ophthalmic examinations were performed in 16 dogs; echocardiography was performed in 6 dogs that were taurine deficient.

Results—Plasma taurine concentrations ranged from 3 to 228 nmol/mL. Twelve dogs had concentrations < 40 nmol/mL and were considered taurine deficient. For dogs with plasma concentrations < 40 nmol/mL, there was a significant linear correlation between plasma and blood taurine concentrations. For dogs with plasma concentrations > 40 nmol/mL, blood taurine concentrations did not vary substantially. Taurine-deficient dogs had been fed lamb meal and rice diets. Retinal degeneration, dilated cardiomyopathy, and cystinuria were not found in any dog examined for these conditions. The taurine deficiency was reversed by a change in diet or methionine supplementation.

Conclusions and Clinical Relevance—Results indicate a high prevalence of taurine deficiency among an environmentally and genetically related cohort of Newfoundlands fed apparently complete and balanced diets. Blood taurine concentrations indicative of taurine deficiency in Newfoundlands may be substantially less than concentrations indicative of a deficiency in cats. (*J Am Vet Med Assoc* 2003;223:1130–1136)

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Letters to the Editor

More feedback on taurine deficiencies in cats, dogs

I found the companion articles in the October 15, 2003, *JAVMA* (pp 1130–1141) issue regarding taurine deficiencies to be very educational and informative; however, I would like to question the last sentence of the second paragraph on page 1130 of the article that states, “In dogs, as in cats, bile acids are conjugated exclusively with taurine.” It is my understanding that dogs and cats conjugate primarily to taurine. However, dogs have the ability to convert to glycine conjugation, but cats undergo obligate conjugation with taurine.

Henry E. Childers, DVM
Cranston, RI

Dr. Backus responds:

Dr. Childers states, without a cited reference, that dogs have the ability to substitute glycine for taurine in the conjugation of bile acids. We know of no research that supports the suggestion that dogs will conjugate with glycine when taurine is low or absent in the liver. Glycine conjugates of bile acids are in the bile of many mammalian species,¹ including dogs and cats.² In normal healthy dogs, these conjugates reportedly are not in serum but are found in bile in a low concentration (< 2% of conjugates).³ These glycine conjugates are probably not synthesized. Feeding glycine to taurine-depleted dogs with biliary fistulas does not induce detectable concentrations of glycine conjugates in secreted bile.⁴ However, feeding preformed glycine conjugates will enrich bile with the conjugates. Hence, it is conceivable that glycine conjugates in dogs are ingested with food. In species in which glycine conjugates are found, the liver enzyme responsible for conjugation,

charyl-CoA:N-acyltransferase, has specificity for both glycine and taurine. Such an overlap of specificity is not found in dogs; the conjugating enzyme of dogs is quite specific for taurine.⁵

The conjugation of bile acids with taurine was discussed in the context of postulated causes for taurine deficiency. Several lines of experimental evidence indicate that diet-induced taurine deficiencies of cats result from excessive gastrointestinal loss of bile acids conjugated with taurine.⁶ During severe tissue depletion of taurine, cats continue to conjugate their bile acids with taurine rather than glycine. This specificity for taurine conjugation is so great that cats will secrete unconjugated bile acids over glycine conjugates. Because taurine conjugation of bile acids is as well defended in dogs as it is in cats, dietary factors that would accelerate bile loss in dogs would also increase the risk of taurine deficiency in dogs.

Robert C. Backus, PhD, DVM
Quinton R. Rogers, PhD, DACVN
Andrea J. Fascetti, VMD, PhD,
DACVN, DACVIM
Davis, Calif

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Additional input on feral cat debate

I am writing in response to the ongoing debate about the control of feral cats. Feral domestic cats are an exotic invasive species that should be humanely removed from the environment like any other pest. The only reason that trap-neuter-return (TNR) programs exist for feral cats is because it is the same species as a commonly kept domestic pet, hence the intense emotional bond some people feel toward these animals. For example, I am unaware of any TNR programs for other exotic environmentally destructive species such as nutria (*Myocastor coypus*) or mongooses.

Instructions for Writing a Letter to the Editor

Readers are invited to submit letters to the editor. Letters may not exceed 500 words and 6 references. Not all letters are published; all letters accepted for publication are subject to editing. Those pertaining to anything published in the *JAVMA* should be received within one month of the date of publication. Submission via e-mail (JournalLetters@avma.org) or fax (847-925-9329) is encouraged; authors should give their full contact information including address, daytime telephone number, fax number, and e-mail address.

Letters containing defamatory, libelous, or malicious statements will not be published, nor will letters representing attacks on or attempts to demean veterinary societies, their committees or agencies. Viewpoints expressed in published letters are those of the letter writers and do not necessarily represent the opinions or policies of the AVMA.

As an animal welfare proponent, I believe that adoption and euthanasia are preferable and more humane options than returning these cats to a potentially hostile environment. I question Dr. Wulff (*JAVMA*, November 1, 2003, pp 1255–1256) when he claims that this issue is “about cats, wildlife, and doing our best to serve both honorably....” Whose interests do TNR programs really serve, human or feline? I propose that TNR programs are more about satisfying human emotional needs than about safeguarding the welfare of feral cats.

*Jonathan M. Sleeman, VetMB,
DACZM
Waynesboro, Va*

Dr. Wulff responds:

I salute Dr. Sleeman on his honesty in stating that euthanasia is a solution to address the problem of free-roaming cats. Because a large percentage of these cats are healthy yet unadoptable, and because there are better options available, I do not agree with him.

In addition, I do not understand how it can be said that euthanasia is a humane solution.

Although it can be done humanely, I don't see it as a humane act for a healthy cat. I wish Dr. Sleeman luck in selling that idea to the cat-feeding public. I can't believe they'll buy the idea that we're doing the cats a favor. I'm sure PETA, Alley Cat Allies, and the various humane societies will share their feelings on the subject.

I agree 100% that trap-neuter-return (TNR) programs serve human emotional needs. It's called the human-animal bond. People love cats and feel sorry for them, and they want to protect and feed them. These people are not criminals; they are kind, well-meaning people with good hearts. They may be wrong in some peoples' eyes, but if so, it's with honorable intent that there are a lot of people feeding cats.

Dr. Levy showed that 12% of families were feeding free-roaming cats (*JAVMA*, July 15, 2003, pp 202–205), which accounts for approximately 30% of the population studied. This isn't about whose needs are being served as much that it is about what the public spurred on by animal rights groups will feel about vet-

erinarians if we favor killing these cats as a blanket policy. Dr. Levy has also shown that a TNR program combined with adoption reduced cat colonies by 66% (*JAVMA*, January 1, 2003, pp 42–46). Could anyone who has unlimited funds with, personnel and cooperation from the colony keepers accomplish a cat-free park, let alone a county or state? Who knows? No one has tried and published their results in a peer-reviewed journal. What in the world would it cost? Who would pay for it?

This is too important an issue to be decided on by our biases. I cannot agree to a blanket policy of adoption or death. I work with these cats—they're not house-pet material. Still, people love them and will not sit quietly and watch them be destroyed. They will not look kindly on those who support the killing. We are veterinarians, and we are supposed to find solutions that help animals if we can. We need to work out something in the middle and realize that the public will rightly hold us accountable.

*Rick Wulff, DVM
High Springs, Fla*

¹*Veterinary Medical Teaching Hospital;* ²*Department of Population Health and Reproduction and* ³*Department of Molecular Biosciences, School of Veterinary Medicine, University of California, Davis, CA, USA*

Plasma and whole blood taurine in normal dogs of varying size fed commercially prepared food

By S. J. DELANEY¹, P. H. KASS², Q. R. ROGERS³ and A. J. FASCETTI³

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 \pm SEM) and 266 ± 5.1 nmol/ml (mean \pm 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 \pm 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.

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Taurine deficiency in dogs with dilated cardiomyopathy: 12 cases (1997–2001)

Andrea J. Fascetti, VMD, PhD, DACVN, DACVIM; John R. Reed, DVM, MS, DACVIM;
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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Relationship Between Circulating and Dietary Taurine Concentrations in Dogs with Dilated Cardiomyopathy

Lisa M. Freeman, DVM, PhD^a

John E. Rush, DVM, MS^a

Donald J. Brown, DVM, PhD^a

Philip Roudebush, DVM^b

^a*Tufts University*

School of Veterinary Medicine

200 Westboro Road

North Grafton, MA 01536

^b*Hill's Science and Technology Center*

PO Box 1658

Topeka, KS 66601

■ 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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Taurine-Deficient Dilated Cardiomyopathy in a Family of Golden Retrievers

A reversible taurine-deficient dilated cardiomyopathy occurred in five related golden retrievers. An apical systolic heart murmur was the most common physical abnormality. According to fractional shortening and end-systolic diameter on echocardiography, significant improvements ($P < 0.005$) were recorded within 3 to 6 months of starting taurine supplementation. The dogs regained substantial systolic function, and four were weaned off all cardiac medications except taurine. This response to therapy was unusual, because canine dilated cardiomyopathy is generally progressive and fatal. *J Am Anim Hosp Assoc* 2005;41:284-291.

Marie C. Bélanger, DVM,
MS, Diplomate ACVIM

Mathieu Ouellet, DVM

Guillaume Queney, PhD

Maxim Moreau, M.Sc.

RS

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From the Companion Animal Research Group
(Bélanger, Ouellet, Moreau),
Department of Clinical Sciences,
Faculty of Veterinary Medicine,
University of Montreal,
St-Hyacinthe, Quebec, Canada, J2S 7C6
and Antagene (Queney),
Immeuble Le Meltem,
2 allée des Séquoias, 69760
Limonest, France.

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Differences in Taurine Synthesis Rate among Dogs Relate to Differences in Their Maintenance Energy Requirement¹⁻³

Kwang S. Ko,⁴ Robert C. Backus,^{6*} John R. Berg,⁵ Michael W. Lame,⁴ and Quinton R. Rogers⁴

Department of ⁴Molecular Biosciences and ⁵Department of Chemistry, University of California, Davis, CA 95616 and ⁶Department of Veterinary Medicine and Surgery, University of Missouri, Columbia, MO 65211

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 [1,2-²H₂]-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.

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Effect of increasing taurine and methionine supplementation on urinary taurine excretion in a model insectivore, the giant anteater (*Myrmecophaga tridactyla*)

S. A. Nofs¹ | E. S. Dierenfeld²  | R. C. Backus³ 

¹Nashville Zoo at Grassmere, Nashville, TN, USA

²Ellen S. Dierenfeld, LLC, St. Louis, MO, USA

³Department of Veterinary Medicine and Surgery, University of Missouri, Columbia, MO, USA

Correspondence

R. C. Backus, Department of Veterinary Medicine and Surgery, University of Missouri, Columbia, MO, USA.
Email: backusr@missouri.edu

Present address:

S. A. Nofs, Potter Park Zoo, 1301 S. Pennsylvania Ave., Lansing, MI 48912, USA

Funding information

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Summary

The giant anteater (*Myrmecophaga tridactyla*) is a highly specialized insectivore for which nutrient requirements are not clearly established, making diet formulation challenging for this species. Multiple clinical reports suggest anteaters have an obligate dietary taurine (TAU) requirement. Sulphur amino acid (SAA) metabolism in adult anteaters was evaluated using noninvasive methods to measure TAU synthesis potential from dietary methionine (MET) and a basal diet containing on a dry matter (DM) basis 1.7 mg TAU/kg DM and 6.9 g MET/kg DM. Urinary equilibrium times for TAU excretion were determined by feeding the basal diet with or without 1.5 g/kg DM supplemental TAU (crossover design; $n = 4$). Effects of supplemental dietary TAU (1.7, 2.0, 2.4, 2.7, 3.0, 3.3 g/kg DM) or MET (6.9, 9.0, 11.2 g/kg DM) on urinary TAU were evaluated (randomized block trials; $n = 5$ or 4 respectively). All urinary values (TAU, MET, unbound inorganic sulphate) were normalized to creatinine (CRT). Results indicate urinary TAU equilibrium in anteaters requires at least 2 weeks of feeding. Urinary ratio of TAU to CRT (TAU:CRT) increased as dietary TAU content increased from 1.7 to 3.0 g/kg DM, consistent with renal homeostatic modulation of TAU excretion. Our data indicate that TAU needs were met by TAU in the basal diet or by de novo synthesis. Supplemental MET resulted in ~five- to eightfold increases in urinary TAU:CRT excretion, further supporting existence of mechanisms for TAU synthesis from dietary SAA in anteaters. Adult anteaters appear able to synthesize TAU when diets contain adequate SAA, but dietary TAU may be critical if protein intakes are low or of poor quality. This study may provide guidance on choice of domestic canids vs. felids as suitable physiologic models for improved nutrition in giant anteaters, and also outlines a noninvasive method for assessing TAU status/metabolism that may be useful across species.

KEYWORDS

amino acids, insectivory, nutrition, tamandua, taurine requirement, urine sulphate

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Kinetics of taurine depletion and repletion in plasma, serum, whole blood and skeletal muscle in cats*

L. Pacioretty¹, M. A. Hickman², J. G. Morris, and Q. R. Rogers

Department of Molecular Biosciences, School of Veterinary Medicine,
University of California, Davis, California, U.S.A.

Accepted November 2, 2000

Summary. The relationship between taurine concentrations of plasma, whole blood, serum and skeletal muscle during taurine depletion and repletion was investigated in cats, to identify the most useful indicators of taurine status. Sixteen cats were fed a purified diet containing either 0 or 0.15 g/kg taurine for 5 months. Treatments were then reversed and the taurine concentration was measured during repletion and depletion phases. Plasma taurine exhibited the fastest rate (slow component) of depletion ($t_{1/2} = 4.8$ wk), followed by serum (5.3 wk), whole blood (6.2 wk), and skeletal muscle (11.2 wk). Whole blood taurine was the first to replete at a rate of 0.74 wk to $1/2$ maximal repletion, followed by serum (2.1 wk), skeletal muscle (3.5 wk), and plasma (3.5 wk). Whole blood more closely reflected skeletal muscle taurine concentrations than plasma during depletion, while plasma taurine concentrations appear to be the most valuable predictor of skeletal muscle taurine concentrations during repletion. This study suggests that the best clinical method to evaluate the taurine status of the cat is the determination and interpretation of both plasma and whole blood taurine concentrations.

Keywords: Amino acids – Taurine – Taurine depletion – Taurine repletion – Cats – Feline

Introduction

Taurine deficiency is associated with a number of specific pathological conditions in cats, including feline central retinal degeneration (Hayes et al., 1975;

* A preliminary report of this research was presented (Morris, J. G., Q. R. Rogers and L. M. Pacioretty “Taurine: an essential nutrient for cats”) at the 18th Waltham International Symposium, Health, Nutrition and Disease in Clinical Practice, San Francisco, CA, March 26, 1990, pp. 16–22.

¹Current Address: BIONexus, Ltd., 30 Brown Road, Ithaca, NY 14850.

²Current Address: Pfizer Inc., Central Research Division, Eastern Point Road, Groton CT 06340.

Schmidt et al., 1976), reproductive failure in queens with associated congenital abnormalities in kittens (Sturman et al., 1986; Sturman and Messing, 1991) and dilated cardiomyopathy (Pion et al., 1987). Studies in normal humans have shown that plasma taurine concentration is subject to wide variation (Trautwein and Hayes, 1990; Vinton et al., 1986) and that sampling technique can have a marked affect on resulting values (Laidlaw et al., 1987; Trautwein and Hayes, 1990). Sampling discrepancies occur from contamination of plasma with taurine from intracellular blood sources, including platelets or granulocytes, which can have 300–400 fold greater taurine concentrations. In addition, the relatively small plasma taurine pool rapidly exchanges with the larger tissue taurine pools, which can lead to marked fluctuations in plasma taurine concentration (Sturman et al., 1975; Matsubara et al., 1985). Whole blood, an easily obtainable tissue to sample, has been investigated as an index of taurine status (Laidlaw et al., 1987; Trautwein and Hayes, 1990) and may prove to be a superior indicator of the taurine status of an animal than plasma taurine. However, the correlation between plasma, whole blood and other tissue taurine pools has not been thoroughly investigated.

Kinetic studies examining taurine metabolism and turnover in humans (Sturman et al., 1975), rats (Sturman, 1973), and the rhesus monkey (Matsubara et al., 1985), demonstrate the existence of at least two pools of whole body taurine, a relatively small pool that has a rapid turnover rate and a much larger pool with a slow turnover rate. Tissues that comprise the rapidly exchanging pool include the liver, kidney, intestine, spleen and lung, while the slower pool is comprised of brain, heart and skeletal muscle. The differences in taurine kinetics between tissues complicate the determination of whole body taurine status in an individual animal. This study was conducted to determine the relationship between taurine concentrations of plasma, whole blood, serum and skeletal muscle during taurine depletion and repletion in cats to identify the most useful indicators of taurine status. Previous studies have measured the concentrations of taurine in plasma and various tissues of taurine depleted kittens (Sturman et al., 1978), but no studies have investigated the time-course of taurine concentration changes during depletion and none have evaluated changes during taurine repletion. Preliminary studies in our laboratory (unpublished) suggest that taurine kinetics during repletion and depletion are not the same in all taurine pools. Because cats may be fed diets varying widely in taurine content, an individual animal may be undergoing taurine depletion or repletion at the time taurine status is evaluated. This study examined pools of taurine that may be clinically assayed with the objective of defining the most appropriate indicator of taurine status for an individual cat.

Materials and methods

Animals

Sixteen, 9-wk old cats (1,050–1,180 g), from the Nutrition and Pet Care Center, University of California at Davis, were used as experimental animals. Cats were housed in individual

stainless steel cages with food and water available at all times, in a light-controlled (14h light: 10h dark) room at $21 \pm 3^\circ\text{C}$. Care throughout the study was in compliance with the "Guide for The Use and Care of Laboratory Animals" developed by the Institute of Laboratory Animal Resources of the National Research Council. The experimental protocol was approved by the University of California at Davis, Animal Use and Care Administrative Advisory Committee, utilizing the guidelines provided by the American Association for Laboratory Animal Care.

Diets

Cats were fed two purified diets that were identical except for the taurine concentrations, 1,500 or 0 mg taurine/kg (Table 1). In the 0 mg taurine/kg diet, taurine was replaced by an equal weight of cornstarch. Food intake was measured daily.

Design

Cats were randomly assigned to two groups, with equal representation of males and females, and fed either the 1,500 or 0 mg taurine/kg purified diet for 5 mo. The dietary treatments were then reversed and the cats then fed the taurine-free diet were designated the depletion group and those fed the 1,500 mg taurine/kg diet were designated the repletion group. Changes in the concentration of taurine in plasma, whole blood, serum and skeletal muscle were then measured for 25 wk. Prior to the dietary change, 2 samples were taken from each cat at 4 day intervals with subsequent samples taken on d 1, 3, 6 and 13, and wk 5, 11, 17 and 25. Lean body mass was estimated at wk 24 by whole body counting of ^{40}K as previously described (Peacock et al., 1987).

Blood samples

Food was withheld from cats for 12h and then 3 mL blood samples were collected by jugular puncture in a heparin-coated plastic syringe and in a non-heparinized plastic syringe. Each heparinized blood sample was divided into 2 sub-samples, one was centrifuged at room temperature (15 min at $3,900 \times g$), and the other remained as whole blood.

Table 1. Composition of diets

Dietary component	g/kg
High nitrogen casein ¹	340
Corn oil ²	250
Cornstarch ³	195
Glucose monohydrate ⁴	150
Mineral Mix ⁵	50
Vitamin Mix ⁶	10
Choline chloride	3
Taurine	1.5

¹U.S. Biochemical Corp., Cleveland, OH. ²Mazola, CPC International Inc., Englewood Cliffs, NJ. ³Melojel, Bridgewater, NJ. ⁴International Corp., Englewood Cliffs, NJ. ^{5,6}For composition see Williams et al., 1987.

The non-heparinized sample remained at room temperature for 1 h to allow clot formation (in plastic tubes) and was then centrifuged (20 min at $3,900 \times g$) to separate the serum. All samples were stored at -20°C until analysis.

Muscle samples

Skeletal muscle samples were obtained under light anesthesia. The average length of anesthesia prior to sample collection was 5 minutes, a length of time unlikely to cause changes in taurine pools. Cats were pre-medicated with 0.5 mg acetylpromazine (Acepromazine, Tech America, Elwood, Kansas) and 0.12 mg atropine (Elkins-Sinn, Inc., Cherry Hill, New Jersey), subcutaneously, and anesthetized with 40 mg of intravenous ketamine hydrochloride (Vetalar, Parke-Davis, Morris Plains, New Jersey). Using aseptic technique, a 5 to 24 mg (mean 11.4 mg) sample of semitendinosus muscle was obtained percutaneously using a biopsy needle (Tru-Cut, Travenol Inc., Deerfield, IL). Biopsies were taken alternately from the left and right muscles and the sampling site located approximately 5 mm proximally with each sampling to avoid previous biopsy sites.

Sample analysis

Taurine concentration was determined in all samples by amino acid analysis (Beckman models 121MB or 7300, Fullerton, CA) after deproteinization with an equal volume of aqueous sulfosalicylic acid (60 g/L). Before deproteinization, whole blood was lysed by freezing and thawing twice and an equal volume of distilled water was mixed with each sample resulting in a 1:1 dilution. Muscle samples were weighed and diluted with 400–750 μL of distilled water, depending on sample size, and homogenized with a glass homogenizer (Duell 20, Kontes, Vineland, New Jersey). Following homogenization, each sample was sonicated for three seconds (Biosonik IV sonicator, Bronwill Scientific) to ensure total cell disruption. Samples were then deproteinized by the same procedure as for plasma, serum and whole blood.

Statistical analysis

Differences in weekly body weight and food intake over time were assessed using a repeated measures analysis of variance for unbalanced data (SAS – General Linear Model, Version 6, SAS Institute, Cary, NC). Taurine depletion data were analyzed using a least squares curve fitting and decision making program (Brown and Manno, 1978). A nonlinear least squares analysis was used to assess taurine repletion kinetics (IMTEC, 1983, Bowie, Maryland). In order to assess the relationship of taurine concentrations in whole blood, plasma and serum to muscle, a simple linear regression was performed with muscle taurine concentration as the dependent variable. Correlation coefficients were used as an index of association for each of the three independent variables with muscle taurine. The statistical procedures used to determine linear regressions were as described (Snedecor and Cochran, 1980). Values in the text are means \pm SEM, $n = 8$. Differences between means were considered statistically significant at $p < 0.05$.

Results

The mean body weight of cats in the repletion group increased from 2.5 to 2.9 kg, while the mean body weight of cats in the depletion group remained unchanged at 2.7 kg. Maximum body weight was attained at 17 weeks for the repletion group. Despite the small difference between groups in mean body

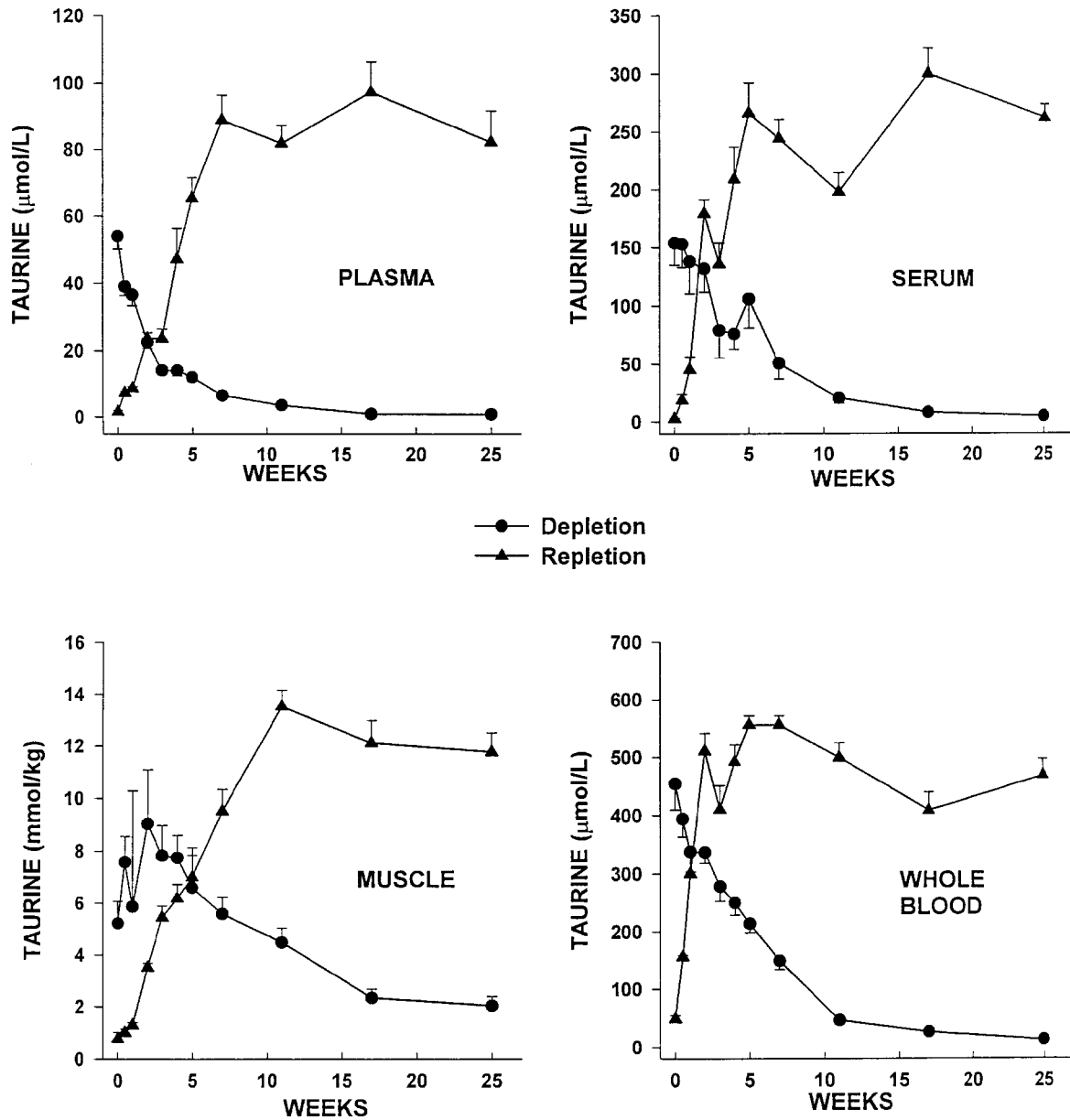


Fig. 1. Time course of taurine concentrations in plasma, serum, whole blood and skeletal muscle of cats during taurine depletion or taurine repletion. Values are means \pm SEM of 8 cats

weight, there was no difference in lean body mass as determined by percentage body potassium (taurine-repleted cats, $0.19 \pm 0.01\%$ compared to $0.18 \pm 0.005\%$ for the taurine-depleted cats). Food intakes were not different between the two groups following the dietary switch, nor did food intake change over the course of the experiment.

Kinetics of taurine depletion in plasma, serum and whole blood exhibited two components (Fig. 1). The rapid component of plasma taurine depletion had a half-life of 0.76 wk, depleting at a rate of $1.26 \mu\text{mol/L/wk}$ from an initial

Table 2. Taurine concentration, depletion rate and half-life in plasma, serum, whole blood and skeletal muscle of kittens¹

Tissue	Initial taurine	Rapid component		Slow component	
		Depletion rate	t _{1/2}	Depletion rate	t _{1/2}
	μmol/L, *μmol/kg (wet weight)	μmol/L/wk	wk	μmol/L/wk	wk
Plasma	59.3 ± 4.6 ^b	1.26 ± 0.31	0.876 ± 0.15 ^a	0.15 ± 0.01 ^b	4.77 ± 0.43 ^a
Serum	172 ± 18 ^c	1.11 ± 0.60	1.98 ± 0.41 ^{ab}	0.13 ± 0.01 ^b	5.3 ± 0.41 ^a
Whole blood	477 ± 84 ^d	1.53 ± 1.18	2.97 ± 0.69 ^b	0.12 ± 0.01 ^b	6.16 ± 0.58 ^a
Skeletal muscle*	9,800 ± 1,300 ^a			73 ± 10 ^a	11.2 ± 1.78 ^b

¹All values are mean ± SEM, n = 8. Means within each column not sharing a common superscript letter are significantly different at p < 0.05.

concentration of 59.3 μmol/L (Table 2). The rapid components of serum and whole blood taurine depletion had half-lives of 1.98 and 2.97 wk, respectively and the rates of depletion for these two pools were not different from plasma. Although the rates (μmol/L/wk) of taurine depletion did not differ, the half-life of the rapid component of plasma depletion was less than the half-life observed in whole blood taurine. No significant difference was observed between the half-life of the rapid component of plasma and serum, or serum and whole blood (p > 0.05).

Skeletal muscle taurine concentration exhibited only one component of depletion and actually appeared to increase early in the depletion period (Fig. 1). The rate of depletion and the half-life of skeletal muscle taurine was, therefore, determined from the last five samples, beginning 5 wk into the depletion period. The mean half-life for this period was 11.2 wk, with a depletion rate of 73 μmol/wk/kg (wet weight) from an initial concentration of 9,800 μmol/kg wet weight. During depletion the quantity of taurine lost from the muscle pool was greater than the other pools, because of the total size of the muscle pool. However, the half-life of the muscle pool was longer than the half-lives of the slow components of taurine depletion of the plasma, serum and whole blood pools.

The time for plasma taurine to replete to half-maximal concentration was 3.72 wk (Table 3), which was longer than the time for both serum and whole blood to reach half-maximal concentrations. The time to achieve half maximal repletion in skeletal muscle (3.49 wk), was similar to plasma (3.72 wk), but the maximum taurine concentration was much higher, 12,600 μmol/kg wet weight in muscle compared to 96.4 μmol/L in plasma. In addition, muscle size has several fold the volume of plasma.

The depletion characteristics of skeletal muscle (beginning 2 weeks into the depletion period) were significantly correlated with those of whole blood (r = 0.95), serum (r = 0.88) and plasma (r = 0.91) as illustrated in Fig. 2. While the depletion characteristics of skeletal muscle were highly correlated with those of whole blood, serum and plasma, the repletion characteristics of skeletal muscle most closely resembled plasma (r = 0.94). The relationship between the repletion of serum and skeletal muscle taurine, and between

Table 3. Taurine repletion variables in plasma, serum, whole blood and skeletal muscle in kittens¹

Tissue	Estimated maximal taurine concentration	Repletion rate	Time of half maximal repletion
	$\mu\text{mol/L}$, * $\mu\text{mol/kg}$ wet wt	$\mu\text{mol/L/wk}$	wk
Plasma	96.4 ± 10.2^b	0.39 ± 0.10^a	3.72 ± 0.2^c
Serum	273 ± 9.9^c	0.70 ± 0.08^b	2.06 ± 0.1^b
Whole blood	512 ± 21^d	1.95 ± 0.06^c	0.74 ± 0.1^a
Skeletal muscle*	$12,560 \pm 800^a$	410 ± 10^a	3.49 ± 0.2^c

¹ All values of mean \pm SEM, n = 8. Means in a column not sharing a common superscript letter are significantly different at $p < 0.05$.

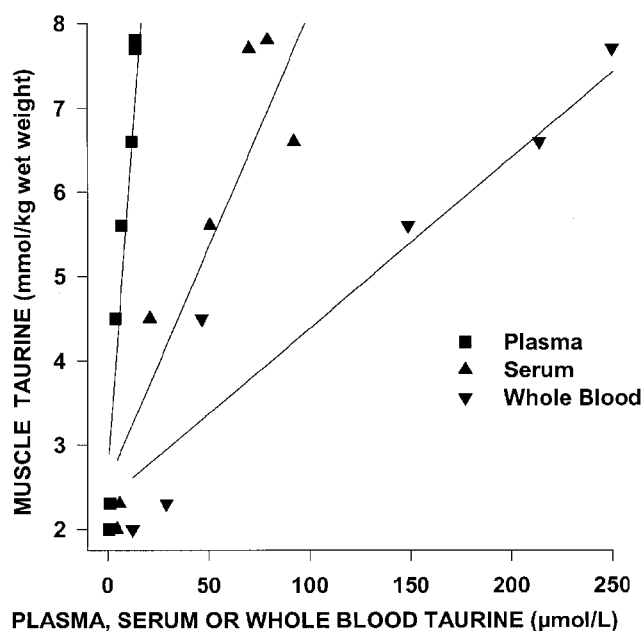


Fig. 2. Relationship between taurine concentrations of plasma ($r = 0.91$, $P < 0.001$), serum ($r = 0.88$, $P < 0.01$), whole blood ($r = 0.95$, $P < 0.001$) and taurine concentration of skeletal muscle during taurine depletion in cats. Each point represents mean data from 8 cats at each time point during depletion (from 2–25 weeks)

whole blood and skeletal muscle taurine were not as highly correlated, $r = 0.80$ and $r = 0.59$, respectively (Fig. 3). The low correlation between whole blood and skeletal muscle appears to be due to the rapid repletion of whole blood taurine compared to skeletal muscle.

Discussion

The major objective of this study was to compare the rates of taurine depletion and repletion and correlate the taurine concentrations of plasma, serum,

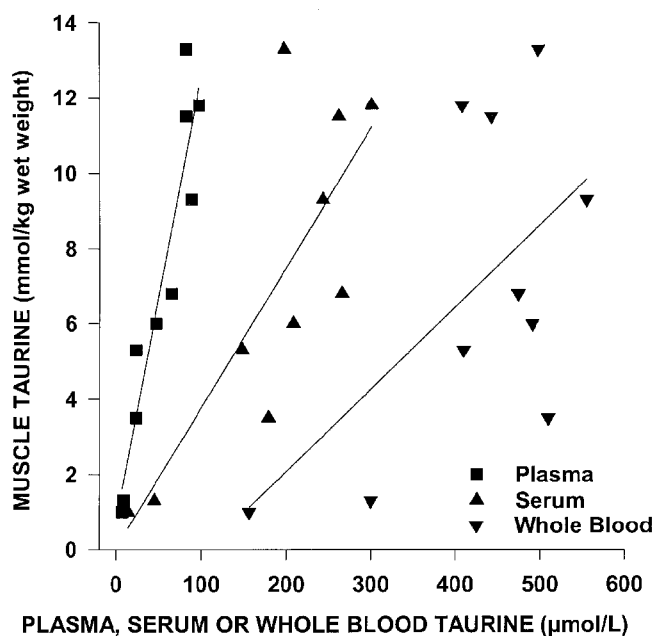


Fig. 3. Relationship between taurine concentrations of plasma ($r = 0.94$, $P < 0.001$), serum ($r = 0.80$, $P < 0.01$), whole blood ($r = 0.59$, $P < 0.1$) and taurine concentration of skeletal muscle during taurine repletion in cats. Each point represents mean data from 8 cats at each time point during repletion (from 0–25 weeks)

whole blood and skeletal muscle in order to identify the most useful clinical index of taurine status. The kinetics of depletion appear to be similar for plasma, serum and whole blood taurine concentrations with a more rapid decrease initially, followed by a slower phase of decline. In contrast, skeletal muscle taurine concentrations increased for the first 5 weeks of depletion and then demonstrated only a slow decrease. This is consistent with the findings of Sturman et al. (1978), who reported a greater half-life of taurine in feline gastrocnemius muscle than plasma, 10d compared to 2.5d, respectively. They also found that during taurine depletion, the half-life of taurine in gastrocnemius muscle remained unchanged while that of plasma increased to 10d, similar to the half-life observed in gastrocnemius muscle.

A change in plasma half-life during depletion could explain the initial rapid and slow terminal components of plasma taurine depletion observed in this study, with the slow component of plasma taurine depletion reflecting the increased $t_{1/2}$ of taurine. It is not known if the half-life of taurine in serum and whole blood changes during depletion, however, both of these fluids exhibit two components of taurine depletion similar to plasma.

The physiological role of taurine in skeletal muscle is unknown, but undoubtedly muscle taurine serves as a large reserve pool and supplies taurine to other tissues during depletion. Skeletal muscle might also be expected to replete at a slower rate, after full repletion of tissues having a higher affinity for taurine. This pattern of repletion was observed in skeletal muscle, with

rates of repletion significantly lower than whole blood or serum. The physiological make-up of the semitendinosus muscle may also influence the results due to fiber type and innervation (Iwata et al., 1986). "Normal" taurine concentrations in the semitendinosus muscle as determined in this study are consistent with the taurine concentrations in gastrocnemius muscle reported in previous feline studies (Knopf et al., 1978; Sturman et al., 1978, 1986; Sturman and Messing, 1991).

Repletion characteristics of plasma taurine were similar to that of skeletal muscle and suggest that plasma may also replete only after taurine provision to other tissues. In contrast, whole blood repleted rapidly compared to plasma and skeletal muscle and depleted more slowly than plasma. This likely reflects differences in active transport systems for taurine (Ahtee et al., 1974; Jacobson et al., 1986) and may be related to the important functions of taurine demonstrated in blood cells such as leukocytes and platelets (Hayes et al., 1989; Schuller-Levis et al., 1990). Changes in whole blood taurine during repletion and depletion reflect changes in the taurine content of leukocytes and platelets and not in erythrocytes.

Serum taurine concentrations were more closely correlated with whole blood taurine concentrations during depletion than plasma, but serum may be of questionable clinical value because of the variation in the time of clotting and method of separation of serum at various times and in various laboratories. Taurine is extruded from platelets during platelet aggregation and a prolonged clotting time may allow for a greater extrusion by the platelets. The rate of clot formation is dependent on many factors including temperature and type of tube used, variables which were controlled in this study. In previous studies, the variability observed in serum taurine concentrations was greater than that in plasma taurine concentration (unpublished observations). Because of these limitations and since serum is not a true compartment, we do not recommend the use of serum taurine concentration as an index of the taurine status.

It can be concluded from the comparison of depletion and repletion rates that whole blood taurine concentrations more closely reflects skeletal muscle taurine concentrations than plasma during depletion. However, plasma taurine concentrations appear to be the better predictor of skeletal muscle taurine concentrations during repletion. These findings suggest that the cytoplasmic membranes of muscle, leukocytes and platelets have the ability to retain taurine against a concentration gradient in plasma, a common feature of many cells containing active transport systems. However, the mechanism whereby different tissues sense and maintain appropriate intracellular taurine concentrations is unclear. The differential ability of tissues to extract taurine from plasma and to retain taurine against a concentration gradient during depletion may be related to the affinities of the membrane transporters for taurine, differences in number of transporters or differential rates of passive diffusion of taurine out of cells.

The concentration of taurine in soft tissues, whole blood and organs is greater than that of plasma, and their depletion and repletion kinetics differ. These differences make it difficult to evaluate, using a single clinical sample,

the taurine status of the cat. However, this study suggests that the best clinical method to evaluate taurine status may be the determination and interpretation of both plasma and whole blood taurine concentrations. When cats are undergoing active repletion or depletion, a single sample may give misleading results, either overestimating or underestimating body taurine. Therefore, we recommend that clinicians submit both plasma and whole blood taurine samples for analysis to evaluate taurine status. In cases where either plasma or whole blood values are not normal, serial samples should be monitored to ensure that cats are maintaining adequate taurine status. Until both plasma and whole blood taurine concentrations are normalized, cats should be considered at risk for taurine deficiency related diseases.

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Authors' address: Dr. Quinton R. Rogers, Department of Molecular Biosciences, School of Veterinary Medicine, University of California, One Shields Avenue, Davis, CA 95616-8741, U.S.A., Fax: (530) 750-4698, E-mail: qrrogers@ucdavis.edu

Received October 9, 2000



Differences in Taurine Synthesis Rate among Dogs Relate to Differences in Their Maintenance Energy Requirement¹⁻³

Kwang S. Ko,⁴ Robert C. Backus,^{6*} John R. Berg,⁵ Michael W. Lame,⁴ and Quinton R. Rogers⁴

Department of ⁴Molecular Biosciences and ⁵Department of Chemistry, University of California, Davis, CA 95616 and ⁶Department of Veterinary Medicine and Surgery, University of Missouri, Columbia, MO 65211

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 [1,2-²H₂]-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.

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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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From the Department of Small Animal Medicine, College of Veterinary Medicine, University of Georgia, Athens, GA 30602 (Sanderson, Calvert, Jacobs); Hill's Pet Nutrition, PO Box 1658, Topeka, KS 66601 (Gross, Lowry); and the Department of Small Animal Clinical Sciences, College of Veterinary Medicine, University of Minnesota, St. Paul, MN 55108 (Ogburn, Bird, Koehler, Swanson).

Supported by a grant from Hill's Pet Nutrition, Topeka, Kan.

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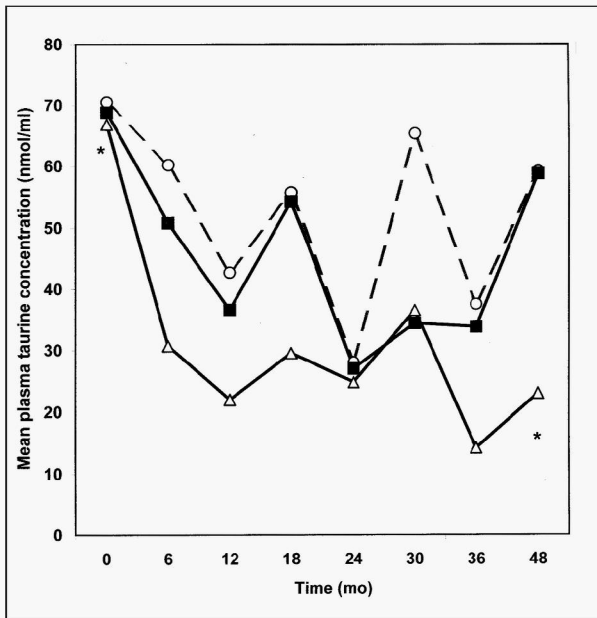


Figure 1—Within-group effect of 3 protein-restricted diets on plasma taurine concentrations in healthy Beagles. *Significant ($P < 0.05$) decrease over time within the high-fat diet group. Circles—Low-fat diet. Squares—High fat plus carnitine supplemented diet. Triangles—High-fat diet.

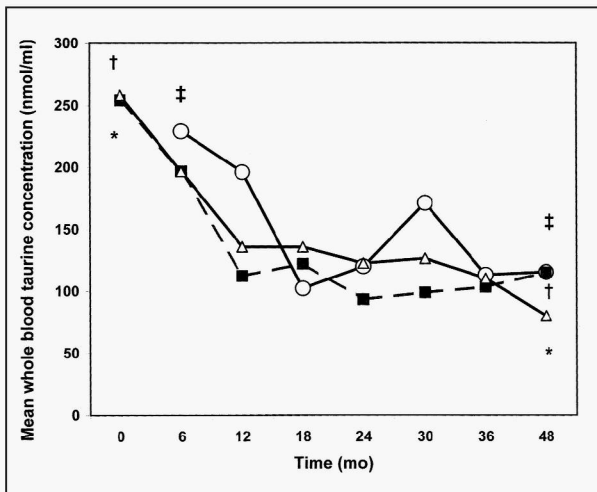


Figure 2—Within-group effect of 3 protein-restricted diets on whole blood taurine concentrations in healthy Beagles. *, †, ‡Significant ($P < 0.05$) difference over time within the low-fat diet, high-fat plus carnitine supplemented diet, and high-fat diet groups, respectively. See Figure 1 for key.

dogs in the HF groups had WBTC below reference range at 48 months.

Echocardiographic findings—At baseline, significant differences were not detected among the 3 diet groups regarding percentage of fractional shortening (FS%), EPSS, left ventricular diameter at end systole (LVDs), and left ventricular diameter at end diastole (LVDd). At 6 and 42 months, significant differences were detected in FS% among the 3 diet groups. Results of the least significant difference test and diet group means (Table 2) revealed that at 6 months, FS% was significantly higher in the LF group than in

the HF + C and HF groups, and at 42 months, FS% was significantly higher in the LF group than in the HF + C group. Significant differences in LVDs were detected at 42 months among the 3 diet groups. Results of the least significant difference test and diet group means revealed that mean LVDs was significantly higher in the HF + C group than in the LF and HF groups. At 24 months, results of 2-way ANOVA revealed a significant difference in LVDd among the 3 groups. Results of the least significant difference test and diet group means revealed that LVDd was significantly higher in the HF + C group than in the LF and HF groups.

Results of linear regression analysis revealed no significant differences in FS%, EPSS, LVDs, and LVDd over time in the LF and HF groups. However, significant differences were detected in FS% and LVDs over time in the HF + C group; mean FS% decreased and mean LVDs increased over time in this group.

None of the dogs in the LF or HF diet groups had evidence of DCM by the end of the 48-month study. However, by the end of the study, 1 of 5 dogs in the HF + C diet group met all 4 criteria for the diagnosis of DCM (Table 3). At 12 months, echocardiography revealed mild left ventricular dilatation, suggestive of early DCM. By 42 months, all criteria established for the diagnosis of DCM were met. This dog developed PTC and WBTC below the reference range at 12 months, which persisted through 48 months. Because the dog was fed a carnitine-supplemented diet, plasma and cardiac muscle carnitine concentrations were above reference range limits. At 48 months, taurine supplementation (500 mg, PO, q 12 h) was initiated, and 3 months later, echocardiography revealed FS% and EPSS had normalized, with persistence of mild left ventricular dilatation during systole and diastole. The dog subsequently developed a thickened mitral valve (endocarditis).

A second dog in the HF + C diet group did not meet all the criteria for DCM but had a mildly decreased FS% (26.0%; reference range, 28 to 44%) and slightly increased LDVs (26.7 mm; reference range, 17.5 to 23.7 mm) that began at 42 months and persisted through 48 months. At 48 months, PTC was still within reference range limits (81.8 nmol/ml; reference range, 41 to 97 nmol/ml); however, WBTC was below reference range (126.8 nmol/ml; reference range, 155 to 347 nmol/ml). This dog was also fed a carnitine-supplemented diet, and, therefore, plasma and cardiac carnitine concentrations were above reference range limits. Plasma-free, short-chain acyl, long-chain acyl, and total carnitine were 99.9 nmol/ml (reference range, 9.0 to 36.0), 10.5 nmol/ml (reference range, < 7.0), 3.4 nmol/ml (reference range, < 2.0), and 113.8 nmol/ml (reference range, 12.0 to 40), respectively. Cardiac muscle free, short-chain acyl, long-chain acyl, and total carnitine were 16.9 nmol/mg NCP (reference range, 3.5 to 11.5), 4.0 nmol/mg NCP (reference range, < 5.0), 0 (reference range, < 0.66), and 20.9 nmol/mg NCP (reference range, 4.5 to 14.0), respectively. Taurine supplementation was not initiated in this dog.

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Taurine and Carnitine in Canine Cardiomyopathy

Sherry Lynn Sanderson, DVM, PhD

Department of Physiology and Pharmacology, University of Georgia, College of Veterinary Medicine, 501 DW Brooks Drive, Athens, GA 30602, USA

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].

DCM is particularly challenging to veterinarians because the cause is often unknown and can vary among dog breeds [10]. Because most cases of DCM in dogs are classified as idiopathic, most therapies can be classified as “Band-Aid therapies” that palliate the effects of this disease for a short duration but do little to address the primary disease process. Therefore, DCM is almost always a progressive disease, and most dogs will eventually succumb to their disease. Survival times in dogs with DCM are variable and can be influenced by several factors, including breed. However, the prognosis for survival of dogs with DCM remains poor, with reported survival rates of 17.5% at 1 year and 7.5% at 2 years [11–13]. Until recently, reported cases of DCM reversal in dogs were very rare.

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Department of Molecular Biosciences, School of Veterinary Medicine, University of California, Davis, CA, USA

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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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Andrea Fascetti'
Sent: 5/21/2018 10:42:57 AM
Subject: RE: Question about aminoacid analysis-Matrices

Thank you, Andrea!

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Andrea Fascetti [mailto:ajfascetti@ucdavis.edu]
Sent: Sunday, May 20, 2018 5:14 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Question about aminoacid analysis-Matrices

Hi Jen - Here are a number of articles on dog taurine. I am sure you have many of them, but I am sending what I have just in case. The paper with the bile acid analysis was Ko 2016. Hope these help.

Andrea

On May 18, 2018, at 11:29 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Andrea,

I had a few questions unrelated to our contract.

Are you able to analyze amino acids in feces?

Is whole blood or plasma best for measuring amino acids in dogs?

-particularly taurine, cystine, and methionine.

Thank you in advance, and I hope you have a great weekend,

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>

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From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Jones, Jennifer L
Sent: 5/21/2018 3:19:28 PM
Subject: RE: FYI-Articles from Fascetti-Taurine handling

Wow! Thanks. Some light reading!

From: Jones, Jennifer L
Sent: Monday, May 21, 2018 11:15 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: FYI-Articles from Fascetti-Taurine handling

The articles from Andrea.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Andrea Fascetti [<mailto:aifascetti@ucdavis.edu>]
Sent: Sunday, May 20, 2018 5:14 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
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Veterinary Medical Officer
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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>
<[image001.png](#)> <[image004.png](#)>

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Ceric, Olgica; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 5/25/2018 11:32:55 AM
Subject: Action Item: Please Review-800.267-DCM draft testing plan
Attachments: 800.267-draft-Sample Testing Procedures-v1.doc

Please review by COB 6/1.

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Palmer, Lee Anne; Jones, Jennifer L; Queen, Jackie L
Sent: 5/23/2018 9:00:47 AM
Subject: Re: DCM Firms

Martine,

Thank you.

B5

Dave

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 22, 2018 at 9:56:42 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: Re: DCM Firms

Thank you Dave! What is the

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I am heading **B6** but let's regroup then and come up with a plan! Thanks again!

Martine

From: Rotstein, David <David.Rotstein@fda.hhs.gov>
Date: May 22, 2018 at 4:11:39 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM Firms

B4, B5

firms.

B5

Brand	flavor	Firm	Location	FEI	Division
B4					

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



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From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Rotstein, David; Jones, Jennifer L; Hartogensis, Martine; Queen, Jackie L
Sent: 5/22/2018 8:13:01 PM
Subject: RE: DCM Firms

Thanks Dave! So a **B4, B5** Very interesting!

From: Rotstein, David
Sent: Tuesday, May 22, 2018 4:12 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM Firms

B5

B4, B5

Brand	flavor	Firm	Location	FEI	I
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B4

David Rotstein, DVM, MPVM, Dipl. ACVP
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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Darcy Adin
CC: Jones, Jennifer L; Joshua A Stern; Fries, Ryan C [REDACTED] Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 5/27/2018 7:25:28 PM
Subject: RE: diet related DCM - revised protocol
Attachments: protocol NP 5-27-18.docx

Hi everyone

[REDACTED]

B4, B5

Best,
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: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Friday, May 25, 2018 5:26 PM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Joshua A Stern <istern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu> [REDACTED] 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: diet related DCM - a couple forms

Thank you Lisa! Those look very helpful.
We have several Great Danes with DCM eating [REDACTED] must be popular with owners of that breed!
Hope you have a good weekend,
Darcy

On Thu, May 24, 2018 at 3:21 PM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:
Hi everyone

[REDACTED]

B5

[REDACTED]

B5

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 <istern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>

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, in lieu of submitting Consumer Complaints, you can just email me a spreadsheet with the data.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



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 <istern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>

B6

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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>

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

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Veterinary Medical Officer
Tel: 240-402-5421



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>; [redacted] 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

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[redacted] 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

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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>

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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

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NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Darcy Adin <dbadin@ncsu.edu>
To: Freeman, Lisa
CC: Jones, Jennifer L; Joshua A Stern; Fries, Ryan C; [REDACTED]; Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 5/25/2018 9:25:30 PM
Subject: Re: diet related DCM - a couple forms

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Hi everyone

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B5

[REDACTED]

B5

Thanks

Lisa

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Professor

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B6

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Veterinary Medical Officer

Tel: 240-402-5421



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B6

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B6

<Jennifer.Jones@fda.hhs.gov>; Jones, Jennifer L

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

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

Sincerely,

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NC State Veterinary Hospital

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Raleigh, NC 27607

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From: [redacted] **B6**
To: Freeman, Lisa
CC: Jones, Jennifer L; Darcy Adin; Joshua A Stern; Fries, Ryan C; [redacted] **B6** Rotstein, David;
Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 5/30/2018 2:09:26 AM
Subject: Re: diet related DCM - a couple forms

Thank you so much for all your work Lisa! I just diagnosed a golden today with DCM that eats [redacted] **B4** too. I am having the owners fill out the diet history form and will follow your protocol as above. [redacted] **B5**

B5

Thanks,

[redacted] **B6**

On Thu, May 24, 2018 at 3:21 PM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:

Hi everyone

B5

B5

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

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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>; [REDACTED] B6

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Subject: RE: hold-call with Dr. Adin re: DCM cases

Importance: High

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Veterinary Medical Officer

Tel: 240-402-5421



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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>; [REDACTED] B6

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To: Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jsstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>;
[REDACTED] B6 [REDACTED]; Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>

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[REDACTED] B6 [REDACTED]

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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>

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Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

B6

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: [B6]
CC: Jones, Jennifer L; Darcy Adin; Joshua A Stern; Fries, Ryan C [B6] Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica
Sent: 5/30/2018 10:08:30 AM
Subject: RE: diet related DCM - a couple forms

Hi all
We had another case yesterday on [B4, B5] I'll get that submitted to FDA today.

Happy to have you share the protocol and diet history. The protocol was designed for internal use so might be good to modify a few things:

[B5]

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: [B6]
Sent: Tuesday, May 29, 2018 10:09 PM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Darcy Adin <dbadin@ncsu.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [B6]; 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>
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[B5]

Thanks,
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Thanks
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Lisa M. Freeman, DVM, PhD, DACVN
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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>; [REDACTED] 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. [REDACTED] B6 Freeman, [REDACTED] B6, Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

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

[REDACTED] 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>

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--

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

B6

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Queen, Jackie L
Sent: 5/30/2018 11:20:22 AM
Subject: FW: diet related DCM - a couple forms

Jen,

This is the second **B4** it used to made by **B4**. If we can get lot info, we can look into that.

B4 manufactures a lot of product and does so according to each firm's specifications, but they do run a lot of different products (brands) on the same line .

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

B6



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From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]

Sent: Wednesday, May 30, 2018 6:09 AM

To: **B6**

Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Darcy Adin <dbadin@ncsu.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; **B6** 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: diet related DCM - a couple forms

Hi all

We had another case yesterday on **B4, B5** I'll get that submitted to FDA today.

Happy to have you share the protocol and diet history. The protocol was designed for internal use so might be good to modify a few things:

B5

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: [REDACTED] **B6**
Sent: Tuesday, May 29, 2018 10:09 PM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Darcy Adin <dbadin@ncsu.edu>; Joshua A Stern <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] **B6**; 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: diet related DCM - a couple forms

Thank you so much for all your work Lisa! I just diagnosed a golden today with DCM that eats [REDACTED] **B4**, too. I am having the owners fill out the diet history form and will follow your protocol as above. [REDACTED] **B5**

[REDACTED] **B5**

Thanks,
[REDACTED] **B6**

On Thu, May 24, 2018 at 3:21 PM, Freeman, Lisa <Lisa.Freeman@tufts.edu> wrote:
Hi everyone

[REDACTED] **B5**

[REDACTED] **B5**

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 <istern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>

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, in lieu of submitting Consumer Complaints, you can just email me a spreadsheet with the data.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



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 <istern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>

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



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 <istern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>

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

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

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

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

Sincerely,
Darcy Adin

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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>

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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

B6

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 5/30/2018 10:00:32 AM
Subject: reporting diet/DCM dogs

Hi Jennifer

The dog eating **B4, B5** that I reported last Friday died **B6** How should I report that? Owners are holding food for analysis. We have new one on **B4** that I'll submit today

Also, did you have thoughts **B5** Especially when it's a situation in which **B5**

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 </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
CC: Rotstein, David
Sent: 5/30/2018 11:48:34 AM
Subject: RE: reporting diet/DCM dogs

Thank you, Lisa. Please submit the new case (not deceased) as a Pet Food Report using the online safety reporting portal.

I'll update the case file that the dog has died. Are there any tissues left or the possibility of a necropsy? We could coordinate one and would pay for it.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Wednesday, May 30, 2018 6:01 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: reporting diet/DCM dogs

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Thanks

Lisa

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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: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 5/30/2018 7:19:31 PM
Subject: RE: reporting diet/DCM dogs

Hi Jennifer

Sorry to bug you but can you clarify what information you're looking for in these sections below (location of reportable food and location of the reportable food – contact information). This has confused me on my past submissions.

This is for another dog food being fed to a dog with DCM [B4]. The owner is holding the food so is this section supposed to be filled out with the owner's information? Or something else? The options for organization type make it look like this should be something else entered here.

Thanks
Lisa

6-3323-2018-10-23 14:18:11:36:38

Safety Reporting Portal Safety Reporting Portal Safety Reporting Portal

Canada Academia Canada USA Vet Med Search Vitae Petfoodology USDA TUSK Library IT Web Request Form Tufts VMware Tufts VPN MeisterTask

Other Phone

Fax

Location of the Reportable Food

The Location of the Reportable Food is where the food is located within the responsible party's organization or company.

*** Organization Name** [B6]

*** Organization Type (select all that apply)**

Official Establishment Inventory (OEI) Development and Maintenance Procedures

- Acidified Food Processor
- Caterer/Catering Point
- Certified Shellfish Establishment
- Commissary
- Contract Sterilizer
- Grower
- Labeler/Relabeler
- Low Acid Canned Processor
- Manufacturer
- Own Label Distributor
- Repacker/Packer
- Salvage Operation
- Shipper
- Warehouse-Ambient Storage
- Warehouse-Frozen Storage
- Warehouse-Refrigerated Storage

*** Country**

*** Street Address Line 1**

Street Address Line 2

*** City/Town**

*** State**

*** ZIP/Postal Code**

Location of the Reportable Food - Contact Information

*** First Name**

*** Last Name**

*** Job Title**

*** Email**

*** Confirm Email**

*** Primary Phone**

Other Phone

Fax

*** Is this the food facility where the problem originated?** Please select

Organization Type (select all that apply) : *Required

Lisa M. Freeman, DVM, PhD, DACVN
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From: Freeman, Lisa
Sent: Wednesday, May 30, 2018 6:01 AM
To: Jennifer.Jones@fda.hhs.gov
Subject: reporting diet/DCM dogs

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Thanks
Lisa


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Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Carey, Lauren; Queen, Jackie L; Rotstein, David; Jones, Jennifer L; Ceric, Olgica; Reimschuessel, Renate; Burkholder, William; Atkinson, Krisztina Z
Sent: 6/5/2018 1:29:50 PM
Subject: FW: Tufts article
Attachments: vetnutrition.tufts.edu-A broken heart Risk of heart disease in boutique or grain-free diets and exotic ingredients.pdf

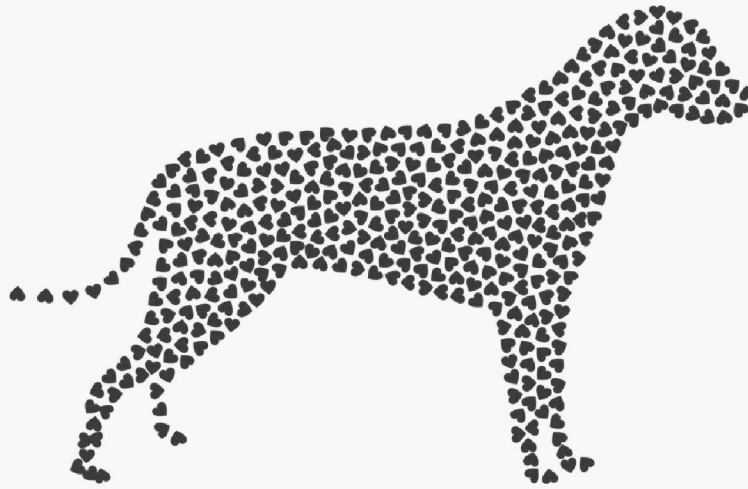
Hi there – kind of a decent new piece for pet owners from Tufts. Just FYI. And I'll attach a copy as well if that's easier (my highlighting was just for my notes).

<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>

A broken heart: Risk of heart disease in boutique or grain-free diets and exotic ingredients

 vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients

June 4, 2018



Earlier this year, Peanut, a 4-year-old male Beagle/Lab mix was diagnosed with a life-threatening heart disease at our hospital. Peanut had been lethargic, not eating well, and occasionally coughing. The veterinary cardiologist seeing him asked what he was eating and found that his owner, in a desire to do the best thing for Peanut, was feeding a boutique, grain-free diet containing kangaroo and chickpeas. Peanut required several medications to treat his heart failure but the owner also changed his diet. And today, now 5 months later, Peanut's heart is nearly normal!

Heart disease is common in our companion animals, affecting *10-15% of all dogs and cats*, with even higher rates in Cavalier King Charles Spaniels, Doberman Pinschers, and Boxer dogs. Most nutritional recommendations focus on treating dogs and cats with heart disease and there is much less information on the role of diet in causing heart disease. However, a recent increase in heart disease in dogs eating certain types of diets may shed light on the role of diet in causing heart disease. It appears that diet may be increasing dogs' risk for heart disease because owners have fallen victim to the many myths and misperceptions about pet food. If diet proves to be the cause, this truly is heart-breaking to me.

In my 20 years as a veterinary nutritionist, I've seen vast improvements in our knowledge about pet nutrition, in the quality of commercial pet foods, and in our pets' nutritional health (other than the unfortunate rise in obesity). However, in the last few years I've seen more

cases of nutritional deficiencies due to people feeding unconventional diets, such as unbalanced home-prepared diets, raw diets, vegetarian diets, and boutique commercial pet foods. The pet food industry is a competitive one, with more and more companies joining the market every year. Marketing is a powerful tool for selling pet foods and has initiated and expanded fads, that are unsupported by nutritional science, including grain-free and exotic ingredient diets. All this makes it difficult for pet owners to know what is truly the best food for their pet (as opposed to the one with the loudest or most attractive marketing). Because of the thousands of diet choices, the creative and persuasive advertising, and the vocal opinions on the internet, pet owners aren't able to know if the diets they're feeding have nutritional deficiencies or toxicities – or could potentially even cause heart disease.

Dilated cardiomyopathy

Dilated cardiomyopathy or DCM occurs in cats where it is associated with a nutritional deficiency (see below). DCM is a serious disease of the heart muscle which causes the heart to beat more weakly and to enlarge. DCM can result in abnormal heart rhythms, congestive heart failure (a build-up of fluid in the lungs or abdomen), or sudden death. In dogs, it typically occurs in large- and giant-breeds, such as Doberman pinschers, Boxers, Irish Wolfhounds, and Great Danes, where it is thought to have a genetic component. Recently, some veterinary cardiologists have been reporting increased rates of DCM in dogs – in both the typical breeds and in breeds not usually associated with DCM, such as Miniature Schnauzers or French Bulldogs. There is suspicion that the disease is associated with eating boutique or grain-free diets, with some of the dogs improving when their diets are changed. The US Food and Drug Administration (FDA) Center for Veterinary Medicine and veterinary cardiologists are currently investigating this issue.

Is diet the cause?

It's not yet clear if diet is causing this issue. The first thought was a deficiency of an amino acid called taurine. DCM used to be one of the most common heart diseases in cats but in 1987, it was discovered that feline DCM was caused by insufficient taurine in the diet. It was shown that DCM in cats could be reversed with taurine supplementation, and now all reputable commercial cat foods contain enough taurine to prevent the development of this lethal disease. We still occasionally see taurine deficiency-induced DCM in cats but it is usually when owners are feeding a vegetarian or home-prepared diet, supplemental diets, or a diet made by a manufacturer with inadequate nutritional expertise or quality control.

In dogs, Golden Retrievers and Cocker Spaniels were found to be at risk for DCM caused by taurine deficiency, and one study showed that Cocker Spaniels with DCM improved when given taurine supplementation. Since then, additional studies have shown associations between dietary factors and taurine deficiency in dogs, such as lamb, rice bran, high fiber diets, and very low protein diets. And certain other breeds were found to be at increased risk for taurine deficiency and DCM, including Newfoundlands, St. Bernards, English Setters, Irish Wolfhounds, and Portuguese Water Dogs. The reasons for taurine deficiency in dogs are not

completely understood but could be reduced production of taurine due to dietary deficiency or reduced bioavailability of taurine or its building blocks, increased losses of taurine in the feces, or altered metabolism of taurine in the body.

No matter what the reason, the number of dogs with taurine deficiency and DCM subjectively appeared to decrease since the early 2000's. However, recently, some astute cardiologists noticed higher rates of DCM including Golden retrievers and in some atypical dog breeds. They also noticed that both the typical and atypical breeds were more likely to be eating boutique or grain-free diets, and diets with exotic ingredients – kangaroo, lentils, duck, pea, fava bean, buffalo, tapioca, salmon, lamb, barley, bison, venison, and chickpeas. Even some vegan diets have been associated. It has even been seen in dogs eating raw or home-prepared diets.

So, is this latest rash of DCM caused by taurine deficiency? Most of these affected dogs were eating boutique, grain-free, or exotic ingredient diets. Some of the dogs had low taurine levels and improved with taurine supplementation. But even some of those dogs that were not taurine deficient improved with taurine supplementation and diet change. Fortunately, cardiologists reported the issue to the FDA which is currently investigating this issue. [Note: Dr. Joshua Stern from the University of California Davis is conducting research on taurine deficiency and DCM in Golden Retrievers.

It's not so simple

Currently, it seems that there may be two separate problems occurring – one related to taurine deficiency and a separate and yet unknown problem (with a third group of dogs likely having DCM completely unrelated to diet). Identifying the potential dietary factors contributing to DCM in the non-taurine deficient dogs is more difficult, but the FDA and cardiologists are hard at work trying to solve it. What seems to be consistent is that it does appear to be more likely to occur in dogs eating boutique, grain-free, or exotic ingredient diets.

Exotic ingredients are on the rise

Why are pet owners feeding these exotic ingredients? I think is it primarily because pet owners are falling victim to marketing which portrays exotic ingredients as more natural or healthier than typical ingredients. There is no truth to this marketing – and there is no evidence that these ingredients are any more natural or healthier than more typical ingredients. This is just good marketing that preys on our desire to do the best for our pets.

There is no proof that grain-free is better!

Many pet owners have, unfortunately, also bought into the grain-free myth. The fact is that food allergies are very uncommon, so there's no benefit of feeding pet foods containing exotic ingredients. And while grains have been accused on the internet of causing nearly every disease known to dogs, grains do not contribute to any health problems and are used in pet food as a nutritious source of protein, vitamins, and minerals.

Exotic ingredients are more difficult to use

Not only are the more exotic ingredients unnecessary, they also require the manufacturer to have much more nutritional expertise to be nutritious and healthy. Exotic ingredients have different nutritional profiles and different digestibility than typical ingredients, and also have the potential to affect the metabolism of other nutrients. For example, the bioavailability and metabolism of taurine is different in a lamb-based diet compared to a chicken-based diet or can be affected by the amount and types of fiber in the diet.

Small pet food manufacturers might be better at marketing than at nutrition and quality control

Making high quality, nutritious pet food is not easy! It's more than using a bunch of tasty-sounding ingredients. The right nutrients in the right proportions have to be in the diet, the effects of processing (or not processing) the food need to be considered, and the effects of all the other ingredients in the food need to be addressed, in addition to ensuring rigorous quality control and extensive testing. Not every manufacturer can do this.

How could diet be increasing the risk for DCM?

What is the consistent factor between the diets being implicated in diet-related DCM? It may be related to companies' inadequate nutritional expertise or rigorous quality control. We published a study several years ago in which we measured a single nutrient in 90 canned cat foods that all claimed to be nutritionally complete and balanced. We found that 15% of the diets were deficient in that nutrient (all of those diets were made by small companies). If companies don't have the quality control to ensure all nutrients are at the minimum levels, deficiencies could occur and could contribute to DCM. However, these problems could also be related to problems with bioavailability or interaction with other ingredients in the diet (especially the more exotic ingredients, which are not as well studied or understood). And DCM could even be the result of an ingredient in the diet that is toxic to the heart. The FDA is investigating this potential association between diet and DCM but, in the meantime, there are some things you can do.

What should you do?

- Reconsider your dog's diet. If you're feeding a boutique, grain-free, or exotic ingredient diets, I would reassess whether you could change to a diet with more typical ingredients made by a company with a long track record of producing good quality diets. And do yourself a favor – stop reading the ingredient list! Although this is the most common way owners select their pets' food, it is the least reliable way to do so. And be careful about currently available pet food rating websites that rank pet foods either on opinion or on based on myths and subjective information. It's important to use more objective criteria (e.g., research, nutritional expertise, quality control in judging a pet food). The best way to select what is really the best food for your pet is to ensure the manufacturer has excellent nutritional expertise and rigorous quality control standards (see our "Questions you should be asking about your pet's food" post).
- If you're feeding your dog a boutique, grain-free, or exotic ingredient diet, watch for early

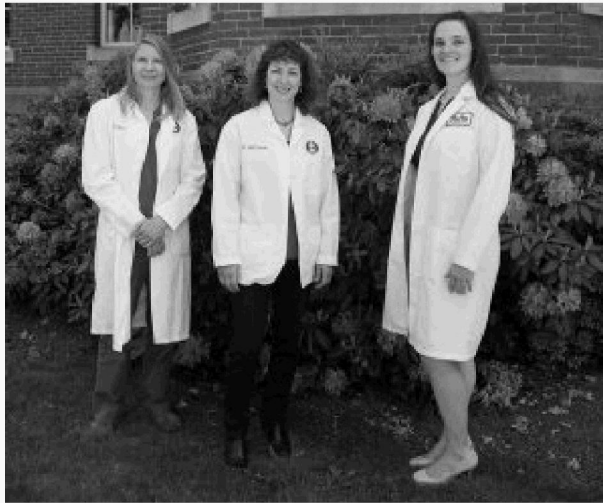
signs of heart disease – weakness, slowing down, less able to exercise, short of breath, coughing, or fainting. Your veterinarian will listen for a heart murmur or abnormal heart rhythm and may do additional tests (or send you to see a veterinary cardiologist), such as x-rays, blood tests, electrocardiogram, or ultrasound of the heart (echocardiogram).

- If your dog is diagnosed with DCM and eating one of these diets, I'd recommend the following steps:
 - Ask your veterinarian to test whole blood and plasma taurine levels (I recommend the University of California Davis [Amino Acid Laboratory](#))
 - [Report it to the FDA](#). This can be done either online or by telephone. The FDA may be able to help with testing costs for your dog. Reporting it will also help us to identify and solve this current problem.
 - Change your dog's diet to one made by a well-known reputable company and containing standard ingredients (e.g., chicken, beef, rice, corn, wheat). Changing to a raw or homecooked diet will not protect your dog from this issue (and may increase the risk for other nutritional deficiencies). If your dog requires a homecooked diet or has other medical conditions that require special considerations, be sure to talk to a veterinarian or a veterinary nutritionist ([acvn.org](#)) before making a dietary change. You can contact the Cummings Nutrition Service to schedule an appointment (vetnutrition@tufts.edu)
 - Start taurine supplementation. Your veterinarian or veterinary cardiologist can recommend an appropriate dose for your dog. Be sure to use a brand of taurine with [good quality control](#).
 - Any improvements in your dog's DCM can take 3-6 months. Your dog will need regular monitoring and may require heart medications during this time. There's no guarantee she'll improve but is certainly worth a try.
 - Make sure your dog is getting the best combination of medications to treat his heart disease, as this can make a difference in his outcome. You can find a board-certified veterinary cardiologist near you on this website: <http://find.vetspecialists.com/>

Sometimes, the changes we make in pet nutrition advance our knowledge and the health of our pets. In other cases, we can take a step in the wrong direction when the marketing outpaces the science. Hopefully, identifying this current issue will allow us to set a new, more science-based approach to the optimal nutrition of our pets.

For more information about heart disease in dogs, please see our [HeartSmart](#) website.

Why Trust Us?



As you're on this website right now, we can assume that you love pets and likely have a special dog or cat (or many) in your life. We love them, too! And not only do we love the pets, we also love their people, and you are our reason for making this site.

[Learn more about the Clinical Nutrition Team at Tufts](#)

The Clinical Nutrition Service at Foster Hospital for Small Animals offers in-person and telephone appointments to pet owners and case consultations to veterinarians within the Foster Hospital and throughout the country.

MAKE AN APPOINTMENT

The Tufts Obesity Clinic for Animals specializes in customized weight management plans that allow for safe weight loss with expert guidance from a board-certified veterinary nutritionist within the Clinical Nutrition Service.

MAKE AN APPOINTMENT

From: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-RREIMSCH>
To: Graham, John; Edwards, David; Jones, Jennifer L; Ceric, Olgica; Nemser, Sarah
Sent: 6/6/2018 7:13:45 PM
Subject: RE: dog nutrition

We are on it.

B5

Renate Reimschuessel V.M.D. Ph.D., Director: Vet-LIRN
Phone 1-240-402-5404 Fax 301-210-4685
Vet-LIRN <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>

From: Graham, John
Sent: Wednesday, June 6, 2018 1:33 PM
To: Edwards, David <David.Edwards@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: FW: dog nutrition

FYI only, just passing it along.

From: Mendrick, Donna
Sent: Wednesday, June 06, 2018 1:14 PM
To: Graham, John <John.Graham@fda.hhs.gov>
Subject: dog nutrition

This was brought to my attention by a vet friend in AR. Are you aware of this?

<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>

From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:21:12 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi Jen and Dave,

Thanks so much for the update. Can we do a

B5

B5

B5

Martine

From: Jones, Jennifer L
Sent: Monday, June 04, 2018 1:01 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

I received results from Covance, and I need to update this powerpoint. After further investigation, the lab ran the wrong test, and we'll have new Cys/Met results for the Grain Free foods. Please stay tuned.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Monday, June 04, 2018 12:58 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@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>
Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

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

B5

(BB)



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From: Rotstein, David
Sent: Thursday, May 24, 2018 10:04 AM
To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

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B4 Some additional information is attached.

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

CVM is drafting a webposting to indicate that this is under investigation. In addition, B5

B5

Thank you,

Dave

B4

B4

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

B6 (BB)



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To: Rotstein, David; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:23:18 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi Dave,

Are you talking about the ORA Divisions? If so, great idea and ok with me to send.

Martine

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Sent: Monday, June 04, 2018 12:58 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@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>
Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

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

B6 (BB)



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From: Rotstein, David
Sent: Thursday, May 24, 2018 10:04 AM
To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

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B5

Some additional information is attached.

B5

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

B5

Thank you,

Dave

B4, B5

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



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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Hartogensis, Martine; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:24:25 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Ok, I'm updating the values and powerpoint now.

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:24 PM
To: Hartogensis, Martine <Martine.Hartogensis@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>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Martine,

Yes-I think that would work.

B5

Dave

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

B6

(BB)



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From: Hartogensis, Martine
Sent: Tuesday, June 05, 2018 2:21 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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B5

B5

B5

Martine

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Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

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Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David

Sent: Monday, June 04, 2018 12:58 PM

To: Hartogensis, Martine <Martine.Hartogensis@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>

Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

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

B6 (BB)



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From: Rotstein, David

Sent: Thursday, May 24, 2018 10:04 AM
To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

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B5

Some additional information is attached.

B5

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B5

Thank you,

Dave

B4, B5

B4, B5

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



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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Hartogensis, Martine; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:31:13 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Sure. Just let me know when it's ready and we will replace it with the newer version.

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

B6 (BB)



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From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Dave, will you hold on the powerpoint? I'd like to give you an updated version.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 PM
To: Hartogensis, Martine <Martine.Hartogensis@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>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

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From: Hartogensis, Martine

Sent: Tuesday, June 05, 2018 2:23 PM

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Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

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Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

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

B6 (BB)



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B5

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B5

Thank you,

Dave

B4, B5

B4, B5

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

B6

(BB)



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To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:31:27 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Yes, sorry Jen and good idea!

From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Dave, B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 PM
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Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

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



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From: Rotstein, David

Sent: Thursday, May 24, 2018 10:04 AM

To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>

Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

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B5

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B5

Thank you,

Dave

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison

CVM OSC/DC/CERT
7519 Standish Place
B5 (BB)



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From: Hartogensis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:50:50 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

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Thanks again!

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Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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Dave, **B5**

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



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David Rotstein, DVM, MPVM, Dipl. ACVP
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Everyone,

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Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

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To: Hartogensis, Martine; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:52:41 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Martine,

I'm available.

Thank you!!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
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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
Sent: 6/5/2018 7:19:03 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

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Dave **B5**

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



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dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Palmer, Lee Anne; Hartogensis, Martine; Rotstein, David; Carey, Lauren
Sent: 6/6/2018 3:23:28 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy
Attachments: 800.267-DCM-Grainfree analysis-UPDATED.pptx

Here is the updated powerpoint **B4** the grain free diets and non-grain free diets have similar Tau, Cys, and Met content.

B5

is in progress.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Palmer, Lee Anne
Sent: Tuesday, June 05, 2018 3:19 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>
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800.267
Grain free
versus
Non Grain Free Foods

Jones
Vet-LIRN


Grain Free products w/ reported DCM



Product Name	Grain free?	Species	Tau (%)
B4, B5	Yes	Canine	0.26
	Yes	Canine	0.11
	Yes	Canine	0.14
	Yes	Canine	0.12
	Yes	Canine	0.2
	Yes	Canine	0.051
	Yes	Canine	0.25

- 6/7 products with sufficient Taurine levels
- Only 1 product- **B4, B5** Essentials was low in Taurine
 - Feline AAFCO minimum Tau is 0.1% for extruded foods
 - No AAFCO minimum for dogs
 - Dog in this case had low Whole blood Tau
- Taurine is conditionally essential in dogs, because they can synthesize it from Cystine and Methionine.

Grain Free products w/ reported DCM



Product Name	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
B4, B5	Yes	Canine	0.26	0.26	0.64	0.9
	Yes	Canine	0.11	0.26	0.61	0.87
	Yes	Canine	0.14	0.28	0.86	1.14
	Yes	Canine	0.12	0.36	0.69	1.05
	Yes	Canine	0.2	0.34	0.51	0.85
	Yes	Canine	0.051	0.33	0.4	0.73
	Yes	Canine	0.25	0.38	0.7	1.08

AAFCO min: 0.33 to 0.35 % 0.65 to 0.7%

- All Grain Free Products contain Methionine and Methionine-Cystine % within the AAFCO requirements.
 - There is no AAFCO requirement for Cystine %
- The **B4, B5** had the lowest Met and Met-Cys content, but it was still above AAFCO requirements (highlighted)
- The **B4, B5** had the lowest Cys content (highlighted).

Non Grain Free Products w/o reported DCM

Product Name	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
B4, B5	No	Canine	0.22	0.32	0.66	0.98
	No	Canine	0.11	0.3	0.57	0.87
	No	Canine	0.11	0.3	0.6	0.9
	No	Canine	0.11	0.31	0.58	0.89
	No	Canine	0.12	0.32	0.65	0.97
	No	Both	0.19	0.46	0.6	1.06
	No	Feline	0.24	0.42	0.78	1.2
	No	Feline	0.24	0.5	0.94	1.44

- In non-GF foods, the Taurine, Met, and Met-Cys levels were above AAFCO minimums.
 - Similar to Grain free foods.

Grain Free vs. Non Grain Free

Product Name	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Avg All GF foods	0.16	0.32	0.63	0.95
Avg All Non-GF Dog foods	0.14	0.34	0.61	0.95
Avg All Non-GF Cat Foods	0.22	0.46	0.77	1.23

- Average Tau, Cys, Met, and Met-Cys content in Grain Free dog foods is similar to the non-GF dog foods.
- The *non-GF cat foods* tend to have higher average levels, because they have greater minimum AAFCO requirements.

Overall Comparison

Product Name	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
	Yes	Canine	0.26	0.26	0.64	0.9
	Yes	Canine	0.11	0.26	0.61	0.87
	Yes	Canine	0.14	0.28	0.86	1.14
	Yes	Canine	0.12	0.36	0.69	1.05
	Yes	Canine	0.2	0.34	0.51	0.85
	Yes	Canine	0.051	0.33	0.4	0.73
	Yes	Canine	0.25	0.38	0.7	1.08
	No	Canine	0.22	0.32	0.66	0.98
	No	Canine	0.11	0.3	0.57	0.87
	No	Canine	0.11	0.3	0.6	0.9
	No	Canine	0.11	0.31	0.58	0.89
	No	Canine	0.12	0.32	0.65	0.97
	No	Both	0.19	0.46	0.6	1.06
	No	Feline	0.24	0.42	0.78	1.2
	No	Feline	0.24	0.5	0.94	1.44

B4, B5

Because the Grain free and Non-GF foods have a similar Tau, Cys, Met, and Met-Cys content, we can look closely at **B4, B5**

It has adequate Met and Met-Cys levels, which should enable a dog to make adequate Tau, without needing Tau in the food.

However, the dog eating this diet had low Whole blood Tau.

Ingredient comparison

Product Name	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (5), peas (4), pea fiber (7)
	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	0.14	0.28	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	0.12	0.36	0.69	1.05	unknown	No	No	0	
	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
	0.25	0.38	0.7	1.08	unknown	Yes	No	1	peas (4)
	0.051	0.33	0.4	0.73	low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11)
	0.22	0.32	0.66	0.98		Yes	No	1	pea fiber (10)
	0.11	0.3	0.57	0.87		No	Met	0	
	0.11	0.3	0.6	0.9		No	Met	0	
	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
	0.19	0.46	0.6	1.06		Yes	No	2	pea protein (5), peas (9)

B4, B5

- Other products (stars) with normal Met and Met-Cys % and are not supplemented with Met in the ingredients, like the **B4, B5** (red box). The non GF diet **B4, B5** had a comparable # legume sources, but its only legume source was low on the ingredient list and contained less legume sources than the **B4, B5** respectively.
- The **B4, B5** meal product contains **B4, B5** so isn't grain free. But the dog in this case had DCM. Not much is known about the case.
- If the Met-Cys and Met % are normal, then something is causing the **B4, B5** **B4, B5** dog's low blood Tau. Are there problems with nutrient uptake b/c of the amount and/or number of legumes in the product?

Ingredient comparison

Product Name	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (5), peas (4), pea fiber (7)
	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	0.14	0.28	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	0.12	0.36	0.69	1.05	unknown	No	No	0	
	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
	0.25	0.38	0.7	1.08	unknown	Yes	No	1	peas (4)
	0.051	0.33	0.4	0.73	low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11)
	0.22	0.32	0.66	0.98		Yes	No	1	pea fiber (10)
	0.11	0.3	0.57	0.87		No	Met	0	
	0.11	0.3	0.6	0.9		No	Met	0	
	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
	0.19	0.46	0.6	1.06		Yes	No	2	pea protein (5), peas (9)

B4, B5

B4, B5 product may be a red herring/separate issue or a clue about how the legume may affect the product

NCSU ACVIM Abstract-Dr. Adin

Methods: *retrospective evaluation* of dogs diagnosed with DCM who had diet recorded in the last 2 years. Dogs were lumped into Grain-free (further subdivided into **B4, B5** and other) and Non-Grain free diets

Results: *-22 dogs ate grain free* (10 **B4, B5** 7 of these were Kangaroo and Lentil).

Taurine testing in 11 of these dogs did not show deficiency - carnitine testing in 4 did not show deficiency. Two sets of unrelated housemates were in this group.

-27 dogs ate non-grain free. Taurine testing in 11 of these and 5 were deficient (3 ate vegetarian diets)

- Dogs eating **B4, B5** weighed less than the other groups (I interpret this to mean they are not the typical large breed DCM dog- 23 vs 35 kg P=0.03).

- Dogs eating **B4, B5** had bigger hearts in diastole and systole and a more spherical heart than 1) dogs eating other grain free diets and 2) dogs eating nongrain free diets (all statistically significant).

- Dogs eating Grain free diets as a group had bigger hearts in diastole and systole and more spherical hearts on echo than dogs eating nongrain free diets (all statistically significant)

- presence of CHF was not different between groups

NCSU ACVIM Abstract-Dr. Adin

Methods: *retrospective evaluation* of dogs diagnosed with DCM who had diet recorded in the last 2 years. Dogs were lumped into Grain-free (further subdivi

Results: **B4** Taurine WNL for 11 of 27 dogs on GF diets with DCM

Taurine did not

deficien

(I inter
P=0.03)

spheric
nongrain

WB taurine is only a snapshot of the content. Paired plasma and WB are better indicators of overall body Tau content.

- Dogs eating Grain free diets as a group had bigger hearts in diastole and systole and more spherical hearts on echo than dogs eating nongrain free diets (all statistically significant)

- presence of CHF was not different between groups

ts

Lentil).

testing in 4

his group.

5 were

ther groups

- 23 vs 35 kg

a more

eating

Call with Cardiologists

Since the abstract:

- Dr. Adin has seen 36 DCM dogs on Grain Free diets.
- Taurine in 18 dogs was WNL.
 - The majority were supplemented.
- 7 were rechecked and *all* showed some improvement with *diet change*.
 - 1/7 not supplemented, only diet change:
 - not much echo change at 3 months but at 9 months had improved echo parameters.
 - 1/7 was changed to a **B4** Grain Free diet and had similar improvement to the dogs with diet change and Taurine supplementation at 3 months.

Call with Cardiologists

Since the abstract:

- Dr. Adin has seen 26 DCM dogs on Grain Free diets
- Tau **B4** Taurine is normal in the dogs checked, but they may improve faster with Tau supplementation and diet change. with
- 7 w *die*
 - not much echo change at 3 months but at 9 months had improved echo parameters.
 - 1/7 was changed to a **B4, B5** Grain Free diet and had similar improvement to the dogs with diet change and Taurine supplementation at 3 months.

GF Diet Ingredient comparison

Product Name	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
B4, B5	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	unknown	No	No	0	
	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
	unknown	Yes	No	1	peas (4)
	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11), pea fiber (10)
		Yes	No	1	
		No	Met	0	
		No	Met	0	
		No	Met	1	green peas (22)
		No	Met	1	green peas (20)
		Yes	No	2	pea protein (5), peas (9)
		Yes	No	1	dried ground peas (12)
		Yes	No	0	

- Should we be looking at other dietary causes of DCM, whose GI uptake may be affected by these legume sources?
 - *Untested*: Thiamine, choline, erucic acid, vitamin E*, Polyunsaturated fatty acids*
 - Tested: Ca, Mg, P, Fe, Co, Cu, Zn, Se, Tau, Cys, Met, Iodine

*Courtesy B6

GF Diet Ingredient comparison

Product Name	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
	unknown	No	No	0	
	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
	unknown	Yes	No	1	peas (4)
	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11), pea fiber (10)
		Yes	No	1	pea fiber (10)
		No	Met	0	
		No	Met	0	
		No	Met	1	green peas (22)
		No	Met	1	green peas (20)
		Yes	No	2	pea protein (5), peas (9)
		Yes	No	1	dried ground peas (12)
		Yes	No	0	

B4, B5

B4 Grain Free diets have many more legume species and legume sources closer to the beginning of the ingredient list than Non-GF diets.

Questions

- Are there properties to these legumes affecting Cys or Met uptake or Tau synthesis in dogs causing DCM?

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
Sent: 6/7/2018 12:17:08 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

I heard back from the Divisions that cover

B5

B5

B6

from B6 is a vet, so I think that she has a professional interest.

thanks

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



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From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:53 PM
To: Hartogensis, Martine <Martine.Hartogensis@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>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Martine,

I'm available.

Thank you!!

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





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From: Hartogensis, Martine
Sent: Tuesday, June 05, 2018 2:51 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>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi!

B5

Does that work for

everyone?

They will set up a Go To meeting and I will forward.

Thanks again!

Martine

From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Dave,

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 PM
To: Hartogensis, Martine <Martine.Hartogensis@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>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Thank you.

I am going to send these out and also include the information Tuft's sent out to give them a more complete picture of it all.

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

B6

(BB)



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From: Hartogensis, Martine
Sent: Tuesday, June 05, 2018 2:23 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>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi Dave,

Are you talking about the ORA Divisions? If so, great idea and ok with me to send.

Martine

From: Rotstein, David
Sent: Monday, June 04, 2018 12:58 PM
To: Hartogensis, Martine <Martine.Hartogensis@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>
Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

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

B6 (BB)



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From: Rotstein, David
Sent: Thursday, May 24, 2018 10:04 AM
To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

Good Morning,

CVM has been investigating reports of dilated cardiomyopathy (DCM), a condition involving thinning of the heart muscle, in dogs. Some breeds involved (Golden Retrievers) are predisposed to DCM. Cases were brought to the attention of CVM by veterinary colleges and private veterinary cardiologists. Grain free dog foods appear to be a common factor. CVM is exploring diagnostic investigations through FDA CVM Vet-LIRN and also epidemiological evaluation by the CVM Division of Veterinary Product Safety. In cats, the condition is associated with low taurine and there have been sporadic recalls relating to low taurine cat food. B5

B5 Some additional information is attached.

Because of the increased reports/cases at veterinary colleges, there has been a larger web presence among professionals and the public including a Facebook page concerning the issue.

B5

Thank you,

Dave

B4, B5

B4, B5

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

B6 (BB)



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From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Burkholder, William; Stamper, Carmela; Rotstein, David; Queen, Jackie L; Jones, Jennifer L; Atkinson, Krisztina Z; Palmer, Lee Anne
CC: Norris, Anne; Glover, Mark; Conway, Charlotte
Sent: 6/7/2018 4:57:15 PM
Subject: RE: Grain-Free Diet Effects
Attachments: Bednar - Starch and fiber fractions in selected food and feed ingredients.pdf; Murray - Evaluation of selected high-starch flours as ingredients in canine diets.pdf; Spears - Resistant starch as related to companion animal nutrition.pdf

I can only find abstracts for two. I have one other paper requested through ILL. I'll forward it once I have it. It was the one I found most interesting in regards to digestibility, etc.

B5

From: Carey, Lauren
Sent: Thursday, June 07, 2018 12:42 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

B5

From: Burkholder, William
Sent: Thursday, June 07, 2018 10:49 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones,

Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>

Subject: Grain-Free Diet Effects

This is from Charlotte Conway who has contacts within the pet food formulation business:

"In follow-up to Dr. Freeman's article, I got a call from [B6] this morning - so passing along his thoughts [B6]
[B6]
[B6] Passing along because I said I would."

Some things to think about.

Bill Burkholder

Starch and Fiber Fractions in Selected Food and Feed Ingredients Affect Their Small Intestinal Digestibility and Fermentability and Their Large Bowel Fermentability In Vitro in a Canine Model^{1,2}

Geoff E. Bednar, Avinash R. Patil, Sean M. Murray, Christine M. Grieshop, Neal R. Merchen and George C. Fahey, Jr.³

Department of Animal Sciences, University of Illinois, Urbana, Illinois 61801

ABSTRACT The digestion of legumes, cereal grains, cereal and potato flours and grain-based foods in dogs was studied using two in vitro model systems. The first simulated the stomach and small intestine through the additions of acid and enzymes and large bowel fermentation through use of fecal inocula from dogs, and the second simulated small intestinal fermentation using canine ileal chyme as the bacterial source. All substrates were analyzed for total dietary fiber (TDF) including insoluble and soluble components, and starch fractions: rapidly digestible starch, slowly digestible starch, resistant starch (RS) and total starch. Legumes had high TDF and RS concentrations (mean 36.5 and 24.7%, respectively), resulting in lower ileal digestible starch and total digestible starch concentrations (mean 21 and 31%, respectively). Seventy-four percent of the TS in the cereal grains group was rapidly digestible starch plus slowly digestible starch compared with the flour group, where the corresponding value was 95%. This related to the processing of cereals to flours, in which TDF and RS concentrations were reduced markedly. This increased ileal digestible starch concentrations in the flour group (65%) versus the cereal grains group (60%). Ileal digestion of starch in grain-based food products like macaroni and spaghetti was high (96 and 92%, expressed as a percentage of TS, respectively). Fermentation of substrates with ileal microflora was influenced by substrate chemical composition, with the flour group exhibiting the highest organic matter disappearance values. The legume group had a high total short-chain fatty acid concentration (7.8 mmol/g organic matter fermented), perhaps as a result of fermentation of TDF as well as starch components. A database such as this one provides information about utilization of foods and feeds in the dog and potentially in humans. *J. Nutr.* 131: 276–286, 2001.

KEY WORDS: • starch • total dietary fiber • digestion • fermentation • in vitro • dog

Starch is the primary digestible carbohydrate found in plants. It is an important source of energy in the diets of humans and animals. Starch is a cost-effective means of supplying dietary energy. It is digested primarily in the small intestine by enzymatic degradation, but some can escape digestion and be fermented in the large bowel.

Although most fermentation occurs in the large bowel, a few studies (Rusler-van Embden et al. 1992, Zentek 1995) suggest that fermentative activity can occur in the small intestine. Aman et al. (1995) indicated that substantial degradation of mixed-linked β -glucans may occur in ileostomy subjects, presumably due to bacterial fermentation in the small intestine. The ileum of humans has been reported to contain bacteria in concentrations of 10^5 – 10^6 colonies/g of contents (Drasar and Hill 1974). Small intestinal bacteria ostensibly

could affect digestive processes occurring at this site. Relatively little data are available on the effects of starch and fiber fractions in selected food and feed ingredients on small intestinal and large bowel digestibility characteristics.

The objectives of this research were to first compile a starch and fiber fraction database for common food and feed ingredients. The general categories studied were legumes, cereal grains, cereal and potato flours, grain-based food products and reference substrates. Second, in vitro ileal digestible starch (IDS)⁴ and total tract digestible starch (TDS) values were determined using a monogastric starch digestion model. Finally, the ileal disappearance and fermentative characteristics of selected food and feed ingredients were determined using ileal microbes from dogs in an in vitro model. Information gained in this experiment will aid in the understanding of effects of microbes in the distal small intestine on the starch and fiber fraction of food and feed ingredients. The dog was

¹ This article must therefore be hereby marked "advertisement" in accordance with 18 USC section 1737 solely to indicate this fact.

² The authors acknowledge the Council on Food and Agricultural Research (C-FAR) for their support of this research.

³ To whom correspondence should be addressed at Department of Animal Sciences, University of Illinois, 132 Animal Sciences Laboratory, 1207 W. Gregory Drive, Urbana, IL 61801. E-mail: g-fahey@uiuc.edu

⁴ Abbreviations used: CP, crude protein; DM, dry matter; FG, free glucose; I, insoluble fiber; IDS, ileal digestible starch; OM, organic matter; OMD, organic matter disappearance; RDS, rapidly digestible starch; RS, resistant starch; SCFA, short-chain fatty acids; SDS, slowly digestible starch; S, soluble fiber; TDF, total dietary fiber; TDS, total digestible starch; TS, total starch.

used in the *in vitro* experiments as an animal model for humans. Both dogs and humans are omnivorous monogastrics. The lower gastrointestinal tract of the dog, like that of humans, contains numerous endogenous species of bacteria (Balish et al. 1977; Davis et al. 1977) that contribute significantly to colonic fermentation (Banta et al. 1979). The contribution of the large bowel to total digestive tract volume is also similar in the dog (14%) and the human (17%), in contrast to that in the pig (48%) and the rat (61%) (van Soest 1995).

MATERIALS AND METHODS

All experiments were conducted under protocols approved by the Laboratory Animal Care Advisory Committee, University of Illinois, Urbana-Champaign.

Chemical analyses. All substrates (legumes, cereal grains, cereal and potato flours, grain-based food products and reference substrates) were analyzed for dry matter (DM), organic matter (OM), Kjeldahl nitrogen (N) (Association of Official Analytical Chemists 1985) and total dietary fiber (TDF) (Prosky et al. 1984). Insoluble fiber (I) was determined according to the method of Prosky et al. (1992). Soluble fiber (S) was calculated by subtracting the I from the TDF. Total fat content was determined by acid hydrolysis followed by ether extraction according to the American Association of Cereal Chemists (1983) and Budde (1952).

Starch fractions [free glucose (FG), rapidly digestible starch (RDS), slowly digestible starch (SDS) and resistant starch (RS)] of samples were determined according to the methods of Muir and O'Dea (1992 and 1993). Total starch (TS) values were determined according to the method of Thivend et al. (1972). Both starch fractionation and TS assays used dimethyl sulfoxide to disassociate the retrograded amylose (Englyst and Cummings 1984).

Experiment 1: Quantification of starch and fiber fractions and *in vitro* IDS and TDS values for common food and feed ingredients

Substrates. Substrates used in the *in vitro* experiment consisted of seven legumes (black beans, red kidney beans, lentils, navy beans, black-eyed peas, split peas and northern beans) and nine cereal grains (barley, corn, white rice, brewer's rice, brown rice, wheat, millet, oats and sorghum), all purchased from local vendors. The substrates were ground through a 2-mm screen in a Wiley mill. Seven flours (corn, wheat, rice, potato, soy, barley and sorghum) were obtained from a pet food manufacturer. Flours had been prepared according to the normal methods of grinding, fine milling, sieving and steam processing. Other substrates included six prepared grain-based food products (macaroni, spaghetti, corn meal, rice bran, rolled oats and hominy grits) purchased from local vendors. The final set of samples included three reference substrates: corn starch (73% amylopectin, 27% amylose; Sigma Chemical Co., St. Louis, MO), potato starch (approximately 80% amylopectin, 20% amylose; Sigma Chemical Co.) and amylo maize (Crystalean; almost 100% amylose; Opta Food Ingredients, Bedford, MA). These standards were included as part of each fractionation method to validate the efficacy of the experimental conditions imposed (i.e., a database containing information on key response criteria measured in this experiment was available for these standards, and any deviations in results obtained with these standards resulted in invalidation of the entire set of substrates being studied).

Donors. Two mixed-breed purpose-bred mature female ileally cannulated dogs (Walker et al. 1994) with hound bloodlines had ad libitum access twice daily to a commercial diet (Diamond Petfoods, Meta, MO) containing ~21% crude protein (CP) and 12% fat for 14 d before the collection of feces. Major ingredients in the diet included ground corn, poultry by-product meal, chicken fat and beet pulp. Dogs were housed in a temperature-controlled room in 1.2 × 3.1-m solid-floor pens. Free access to water was provided at all times.

Monogastric *in vitro* digestion model. This model represents a combination of three assays used to determine the amount of digestible starch at the ileum and in the total gastrointestinal tract. The

TABLE 1

Composition of medium used for *in vitro* fermentation of food and feed ingredients

Component	Concentration in medium
	mL/L
Solution A ¹	330.0
Solution B ²	330.0
Trace mineral solution ³	10.0
Water-soluble vitamin mix ⁴	20.0
Folate/biotin solution ⁵	5.0
Riboflavin solution ⁶	5.0
Hemin solution ⁷	2.5
Short-chain fatty acid mix ⁸	0.4
Resazurin ⁹	1.0
Distilled H ₂ O	296.0
	g/L
Yeast extract	0.5
Trypticase	0.5
Na ₂ CO ₃	4.0
Cysteine HCl · H ₂ O	0.5

¹ Composition (g/L): NaCl, 5.4; KH₂PO₄, 2.7; CaCl₂ · H₂O, 0.16; MgCl₂ · 6H₂O, 0.12; MnCl₂ · 4H₂O, 0.06; CoCl₂ · 6H₂O, 0.06; and (NH₄)₂SO₄, 5.4.

² Composition: K₂HPO₄, 2.7 g/L.

³ Composition (mg/L): EDTA (disodium salt), 500; FeSO₄ · 7H₂O, 200; ZnSO₄ · 7H₂O, 10; MnCl₂ · 4H₂O, 3; H₃PO₄, 30; CoCl₂ · 6H₂O, 20; CuCl₂ · 2H₂O, 1; NiCl₂ · 6H₂O, 2; Na₂MoO₄ · 2H₂O, 3.

⁴ Composition (mg/L): thiamin · HCl, 100; *d*-pantothenic acid, 100; niacin, 100; pyridoxine, 100; *p*-aminobenzoic acid, 5; vitamin B-12, 0.25.

⁵ Composition (mg/L): folic acid, 10; *d*-biotin, 2; NH₄HCO₃, 100.

⁶ Composition: riboflavin, 10 mg/L in 5 mmol/L of HEPES.

⁷ Hemin, 500 mg/L in 10 mmol/L NaOH.

⁸ 250 mL/L each of *n*-valerate, isovalerate, isobutyrate and DL- α -methylbutyrate.

⁹ Resazurin, 1 g/L in distilled H₂O.

method of Muir and O'Dea (1993) was used to determine the amount of starch digestion in the stomach and small intestine by measuring glucose in the supernatant resulting from acid-enzyme digestion of the substrate. Each substrate in triplicate was exposed to pepsin/hydrochloric acid, amyloglucosidase and α -amylase. Tubes containing reagents but no substrate were run as blanks. Glucose concentrations then were determined on the supernatant. Glucose was measured according to a glucose oxidase method (Glucose Test Kit 510-A; Sigma Chemical Co.). Glucose concentration was determined by reading the absorbance of individual samples at 450 nm on a DU 640 spectrophotometer (Beckman Instruments, Schaumburg, IL) and comparing those values against a glucose standard curve. IDS was determined by subtracting (FG × 0.9) from (total glucose/original sample weight) present in the supernatant after 15 h of digestion. The 0.9 used in the calculation of IDS is a correction factor for the difference in weight between an FG unit and a glucose residue in starch. Because the measurement of glucose is used to determine starch content, the correction factor is needed. The substrate remaining after simulated stomach and small intestinal digestion then was used in a model that simulated large bowel fermentation (Bourquin et al. 1993). Freshly voided feces from two dogs was diluted (1:10) in anaerobic diluting solution. This inoculum was used to inoculate all substrates individually for each dog. Substrates were incubated in an *in vitro* medium (Table 1) at 39°C for 12 h. TS was determined in the pellet that remained after simulated large bowel fermentation according to the method of Thivend et al. (1972) with dimethyl sulfoxide solubilization of amylose. TDS was determined by subtracting [(total glucose/original sample weight) × 0.9] in the remaining sample from the percentage TS.

Experiment 2: Determination of the ileal disappearance and fermentative characteristics of selected food and feed ingredients

Substrates. All substrates were the same as those described for expt. 1.

Donors and collection methods. Six mixed breed purpose-bred female ileally cannulated dogs (Walker et al. 1994) had ad libitum access twice daily to the diet used in expt. 1 for a 14-d period before the collection of ileal effluent. Dogs were housed in a temperature-controlled room in 1.2 × 3.1-m clean-floor pens. Free access to water was provided at all times. Fresh ileal fluid was collected from each dog for 15-min intervals in a Whirlpak bag (Pioneer Container Corp., Cedarburg, WI) until sufficient amounts needed to inoculate all tubes were obtained. At the end of each 15-min period, the bags were removed and replaced with new ones. Bags containing samples were sealed immediately after expressing excess air, placed inside a pre-warmed thermos (37°C) and transported to a laboratory within the same building for processing.

Medium composition and substrate fermentation. The composition of the medium used to culture the ileal microflora is presented in Table 1. All medium components except the vitamin mixes were added before autoclaving. The vitamin mixes were aseptically added after they were filter-sterilized.

On arrival in the laboratory, fresh ileal samples were immediately pooled under anaerobic conditions and diluted 1:10 (v/v) in a 39°C anaerobic dilution solution (Bryant and Burke 1953) by blending for 10 s in a Waring blender. Blended, diluted ileal effluent was filtered through four layers of cheesecloth, and the filtrate was sealed in 125-mL serum bottles under CO₂. Appropriate sample and blank tubes containing 26 mL of medium and 300 mg of substrate were aseptically inoculated with 4 mL of diluted ileal effluent. Tubes were flushed with CO₂ and capped with stoppers equipped with one-way gas release valves. Blank tubes contained 4 mL of inoculum and 26 mL of medium but did not contain any substrate.

Triplicate tubes were placed in a forced air incubator at 39°C with periodic mixing for each fermentation time period (2.5, 5 and 7.5 h). At the appropriate time, tubes were removed from the incubator and processed immediately. A 2-mL aliquot was removed from each tube for short-chain fatty acid (SCFA) and lactate analyses. The remaining 28 mL was combined with 112 mL of 95% ethanol and allowed to set for 1 h to precipitate the soluble polysaccharide fractions. To recover unfermented residues, samples were filtered through tared Whatman 541 filter paper and washed sequentially with 78% ethanol, 95% ethanol and acetone. Samples then were dried at 105°C, weighed, ashed in aluminum weigh boats (500°C) and weighed again to determine OM disappearance (OMD). In vitro OMD (percentage) was calculated as $\{1 - [(OM \text{ residue} - OM \text{ blank}) / \text{original OM}]\} \times 100$, where OM residue is the OM recovered after 2.5, 5 or 7.5 h of fermentation; OM blank is the OM recovered in the corresponding blank after the same fermentation times; and original OM is the OM of the substrate placed in the tube. Corrected OMD was calculated as the 2.5-, 5- and 7.5-h OMD minus the 0-h OMD.

The 2-mL aliquot of fluid removed from the sample tubes for SCFA and lactate analyses was immediately added to 0.5 mL of metaphosphoric acid (250 g/L), precipitated for 30 min and centrifuged at 20,000 × g for 20 min. The supernatant was decanted and frozen at -20°C in microfuge tubes. After freezing, the supernatant was thawed and centrifuged in microfuge tubes at 10,000 × g for 10 min. Concentrations of acetate, propionate and butyrate were determined in the supernatant using a Hewlett-Packard 5890A Series II gas-liquid chromatograph and a glass column (180 cm × 4 mm i.d.) packed with 10% SP-1200/1% H₃PO₄ on 80:100 mesh Chromosorb WAW (Supelco, Bellefonte, PA). SCFA concentrations were corrected for by the blank tube production of SCFA. The supernatants also were analyzed for lactate concentration according to the spectrophotometric method described by Barker and Summerson (1941).

Statistical analysis. The General Linear Models procedures of SAS (1994) were used to analyze data from these experiments. In expt. 1, the experimental design was a randomized complete block design with the two fecal donors serving as blocks. Donor × substrate was used in the statistical model. In expt. 2, the experimental design was a factorial arrangement of substrates within groups (legumes,

cereal grains, cereal and potato flours, grain-based food products and reference substrates) and fermentation times (0, 2.5, 5 and 7.5 h). Arithmetic means are reported along with the SEM for each group of substrates. When significant ($P < 0.05$) differences were detected, individual means were compared using the least significant difference (LSD) method of SAS (1994).

RESULTS AND DISCUSSION

Chemical composition. The chemical composition of substrates is presented in Table 2. Chemical composition of legumes varied widely, corroborating data of Kamath et al. (1980). In our experiment, DM concentrations were similar among legumes, except for navy beans, which were lower in DM. OM concentrations were similar among substrates. CP content ranged from a low for navy beans to a high for lentils and northern beans. The CP concentration of lentils agreed with the reported range of 20.4–30.5% (Salunkhe et al. 1985). The fat concentration of legumes ranged from a low for navy beans to a high for northern beans. Concentrations of TDF were high for the entire legume group, with black beans having the highest TDF content and black-eyed peas having the lowest. The legume group contained mainly I (92.2–100% of TDF), whereas S values ranged from 0 to 7.8% of the TDF.

DM concentrations of the cereal group ranged from a low for corn to a high for sorghum. OM concentrations differed by ~3 percentage units for the cereal group. CP content varied from a low for white rice to a high for wheat. Watson (1953) and Juliano et al. (1964) reported CP values of 11.8 and 11.0% for barley and brown rice, respectively. These values agree with our values of 12.7% for barley and 10.2% for brown rice. Cereal grain fat concentrations ranged from a low for white rice to a high for oats. Total dietary fiber concentrations varied widely, with oats containing ~25 times more TDF than white rice. Cereal grains contain the husk, pericarp and/or bran in varying concentrations, thus providing components that contain fiber, albeit in generally lower concentrations compared with legumes. The majority of TDF found in the cereal group was I, although cereals contained a much greater proportion of S than did legumes.

DM concentrations were similar among the grain and potato flour group. OM concentrations ranged from 92.9% (soy) to 99.6% (sorghum). CP content was highest for soy and lowest for brown rice. Soy flour contained the highest concentration of fat in the flour group. Total dietary fiber concentrations varied from a high for barley flour to a low for sorghum flour. High concentrations of fiber in barley flour may be a result of high concentrations of β-glucans present in the grain (Liljeberg et al. 1992). I concentrations again were higher than S concentrations in the flour group, although large differences in S concentrations occurred among substrates. Overall, grain flours contained less TDF compared with their cereal grain counterparts.

DM concentrations of grain-based food products differed by only 3 percentage units. OM concentrations were similar among substrates except for rice bran, which contained more ash (>10%). CP content ranged from 7.7% (corn meal) to 16.9% (rice bran). Fat concentrations ranged from a high for rolled oats to a low for corn meal. Total dietary fiber varied widely among the prepared grain products, with rice bran being the highest, rolled oats and hominy grits being intermediate, and macaroni, spaghetti and corn meal being the lowest. I concentrations were highest for rice bran and lowest for macaroni. As a percentage of TDF, S concentrations were highest (mean 34.5%) for macaroni, spaghetti, rolled oats and hominy grits.

TABLE 2

Proximate and fiber constituents of selected food and feed ingredients

Substrate	DM ¹	OM	CP	Fat	TDF	I ²	S ²
<i>g/100 g dry matter</i>							
Legumes							
Black beans	89.0	95.5	23.6	3.3	42.6	39.4 (92.5)	3.2 (7.5)
Red kidney beans	89.1	95.6	25.4	3.0	36.8	36.3 (98.6)	0.5 (1.4)
Lentils	90.7	96.6	27.5	2.4	33.1	33.0 (99.7)	0.1 (0.3)
Navy beans	83.7	95.1	22.8	1.6	36.2	36.2 (100.0)	0.0 (0.0)
Black-eyed peas	90.6	96.5	24.4	2.7	32.6	32.4 (99.4)	0.2 (0.6)
Split peas	90.0	96.8	26.1	2.5	33.1	31.3 (94.6)	1.8 (5.4)
Northern beans	89.2	95.3	27.5	4.0	41.1	37.9 (92.2)	3.2 (7.8)
Cereal grains							
Barley	90.3	98.6	12.7	2.8	17.0	12.0 (70.6)	5.0 (29.4)
Corn	86.8	98.6	12.8	4.9	19.6	16.0 (81.6)	3.6 (18.4)
White rice	87.9	99.4	9.1	1.6	1.5	1.2 (80.0)	0.3 (20.0)
Brewer's rice	92.2	99.2	9.6	1.9	2.1	1.5 (71.4)	0.6 (28.6)
Brown rice	87.7	98.6	10.2	4.0	5.7	4.3 (75.4)	1.4 (24.6)
Wheat	94.2	97.7	18.1	3.2	17.0	14.7 (86.5)	2.3 (13.5)
Millet	88.5	98.8	11.2	4.8	5.4	3.1 (57.4)	2.3 (42.6)
Oats	90.0	96.7	14.2	6.9	37.7	33.9 (89.9)	3.8 (10.1)
Sorghum	94.6	98.6	11.1	4.3	4.6	4.2 (91.3)	0.4 (8.7)
Flours							
Corn	92.1	99.4	11.2	2.6	2.8	2.8 (100.0)	0.0 (0.0)
Wheat	91.1	98.3	17.2	3.1	12.1	8.5 (70.2)	3.6 (29.8)
Brown rice	89.1	98.8	7.6	4.2	5.1	3.4 (66.7)	1.7 (33.3)
Potato	94.4	95.3	9.8	1.5	2.1	1.1 (52.4)	1.0 (47.6)
Soy	94.5	92.9	54.5	5.2	15.4	14.7 (95.5)	0.7 (4.5)
Barley	91.0	97.9	11.4	3.8	22.9	20.1 (87.8)	2.8 (12.2)
Sorghum	91.9	99.6	10.6	2.0	1.3	1.1 (84.6)	0.2 (15.4)
Grain-based food products							
Macaroni	89.2	99.0	15.9	2.7	5.6	3.4 (60.7)	2.2 (39.3)
Spaghetti	90.4	99.2	15.5	2.6	5.6	3.7 (66.1)	1.9 (33.9)
Corn meal	89.6	99.7	7.7	1.9	4.4	4.3 (97.7)	0.1 (2.3)
Rice bran	92.1	89.4	16.9	3.6	28.0	27.6 (98.6)	0.4 (1.4)
Rolled oats	91.1	97.9	14.2	9.1	10.0	6.6 (66.0)	3.4 (34.0)
Hominy grits	88.7	99.4	8.4	2.2	11.4	7.9 (69.3)	3.5 (30.7)
Reference substrates							
Corn starch	91.2	99.8	0.6	0.9	0.0	0.0	0.0
Potato starch	90.2	99.9	0.2	0.03	0.0	0.0	0.0
Amylomaize	88.7	99.7	0.9	1.5	5.3	3.2 (60.4)	2.1 (39.6)

¹ DM = dry matter; OM = organic matter; CP = crude protein; TDF = total dietary fiber; S = soluble fiber; I = insoluble fiber.
² Numbers in parentheses are soluble (S) or insoluble (I) fiber concentrations expressed as a percentage of TDF.

DM, OM and CP concentrations were similar among the reference substrates. Corn and potato starch contained low fat concentrations. Corn starch and potato starch contained no TDF. Although 5.3% TDF was detected in the amylo maize, this is probably RS rather than fiber.

Starch fractions. Concentrations of starch fractions of substrates are presented in Table 3. FG concentrations were low for all substrates, as expected.

The concentrations of RDS, SDS and RS in the legume group varied widely. RDS concentrations were lowest for red kidney beans and highest for split peas. SDS concentrations varied more than twofold. RS concentrations generally constituted the highest proportion of the starch fractions of legumes. Ring et al. (1988) reported that leguminous starches displayed a C-type pattern of crystallinity. This type of starch is more resistant to hydrolysis than that with an A-type crystallinity pattern and helps explain why legumes have high amounts of RS.

Gee and Johnson (1985) found that there was a relationship between the "half-time starch hydrolysis" (time taken to achieve 50% hydrolysis of the original starch of the substrate) and the dietary fiber content of certain foods. Their data

indicate that legumes such as peas and red kidney beans all had higher half-time hydrolysis rates (60.0 and 58.0 min, respectively), whereas white bread and white rice had much lower values (19.5 and 2.1 min, respectively). In their study, dietary fiber content averaged 27.8% for peas and red kidney beans and only 3.1% for white bread and white rice. McBurney et al. (1988) also found that SCFA production from ileal effluent was significantly correlated with dietary fiber isolates but not whole foods. The authors concluded that dietary fiber isolates, rather than whole foods, could provide the closest estimation of colonic SCFA production. Another possible reason for the higher RS concentrations in legumes could be the relationship between starch and protein. Tovar et al. (1990) found that when red kidney beans were preincubated with pepsin, there was an increase in their susceptibility to amylolytic attack.

TS values of legumes obtained by adding FG, RDS, SDS and RS components closely paralleled those reported from the determination of starch using the method of Thivend et al. (1972), attesting to the accuracy of the Muir and O'Dea (1993) method for quantifying starch fractions. A possible explanation for the higher concentration of TS for substrates such as black beans and black-eyed peas using the Thivend et

TABLE 3

Starch fractions of selected food and feed ingredients

Substrate	% FG ¹	% RDS	% SDS	% RS	TS	Thivend
<i>g/100 g dry matter</i>						
Legumes						
Black beans	0.1 (0.2)	7.5 (17.5)	8.4 (19.6)	26.9 (62.7)	42.9	46.8
Red kidney beans	0.1 (0.2)	4.3 (10.1)	13.7 (32.2)	24.6 (57.7)	42.6	42.9
Lentils	0.1 (0.2)	16.4 (30.8)	11.4 (21.4)	25.4 (47.7)	53.3	51.9
Navy beans	0.1 (0.2)	6.5 (13.2)	16.8 (34.1)	25.9 (52.5)	49.3	50.8
Black-eyed peas	0.1 (0.2)	18.5 (34.3)	18.5 (34.3)	17.7 (32.8)	53.9	57.0
Split peas	0.1 (0.2)	22.3 (34.5)	17.8 (27.5)	24.5 (37.9)	64.7	65.6
Northern beans	0.1 (0.2)	10.9 (21.8)	10.9 (21.8)	28.0 (56.1)	49.9	46.7
Cereal grains						
Barley	0.1 (0.2)	24.9 (45.1)	12.1 (21.9)	18.2 (33.0)	55.2	54.7
Corn	0.2 (0.3)	37.1 (47.6)	15.6 (20.0)	25.2 (32.3)	77.9	80.1
White rice	0.1 (0.1)	32.0 (33.6)	48.9 (51.4)	14.1 (14.8)	95.1	93.0
Brewer's rice	0.0 (0.0)	68.4 (79.4)	14.3 (16.6)	3.5 (4.1)	86.2	83.7
Brown rice	0.0 (0.0)	28.7 (32.5)	44.7 (50.7)	14.8 (16.8)	88.2	87.8
Wheat	0.1 (0.2)	29.9 (58.9)	7.3 (14.4)	13.6 (26.8)	50.8	52.9
Millet	0.1 (0.1)	35.9 (41.6)	37.7 (43.7)	12.6 (14.6)	86.2	90.9
Oats	0.2 (0.5)	35.8 (82.5)	0.3 (0.7)	7.2 (16.6)	43.4	46.5
Sorghum	0.0 (0.0)	29.2 (36.9)	13.9 (17.6)	36.1 (45.6)	79.2	77.8
Flours						
Corn	0.1 (0.1)	73.2 (86.8)	0.0 (0.0)	11.0 (13.0)	84.3	90.8
Wheat	0.0 (0.0)	38.1 (55.4)	29.0 (42.2)	1.7 (2.5)	68.8	73.4
Rice	0.0 (0.0)	57.7 (66.4)	27.6 (31.8)	1.6 (1.8)	86.9	89.3
Potato	0.1 (0.1)	75.5 (93.2)	3.8 (4.7)	1.7 (2.1)	81.0	77.9
Soy	0.1 (1.8)	2.2 (40.0)	2.7 (49.1)	0.6 (10.9)	5.5	8.2
Barley	0.0 (0.0)	37.7 (54.2)	30.6 (44.0)	1.2 (1.7)	69.5	75.6
Sorghum	0.2 (0.2)	63.5 (70.8)	24.6 (27.4)	1.6 (1.8)	89.7	84.8
Grain-based food products						
Macaroni	0.3 (0.4)	60.0 (79.9)	8.9 (11.9)	6.0 (8.0)	75.1	77.2
Spaghetti	0.0 (0.0)	48.9 (67.0)	20.9 (28.6)	3.3 (4.5)	73.0	82.7
Corn meal	0.2 (0.2)	49.3 (56.3)	33.0 (37.7)	5.0 (5.7)	87.5	95.5
Rice bran	0.0 (0.0)	0.1 (0.4)	25.1 (88.1)	3.4 (11.9)	28.5	27.5
Rolled oats	0.0 (0.0)	42.5 (75.9)	4.8 (8.6)	8.5 (15.2)	56.0	60.1
Hominy grits	0.1 (0.2)	36.8 (56.4)	20.4 (31.2)	8.0 (12.3)	65.3	70.9
Reference substrates						
Corn starch	0.0 (0.0)	71.8 (70.0)	22.6 (22.0)	8.1 (7.9)	102.5	101.5
Potato starch	0.0 (0.0)	27.2 (27.9)	3.3 (3.4)	66.9 (68.7)	97.4	99.3
Amylomaize	0.0 (0.0)	30.3 (30.1)	18.2 (18.1)	52.0 (51.7)	100.5	99.8

¹ FG = free glucose; RDS = rapidly digestible starch; SDS = slowly digestible starch; RS = resistant starch; TS = total starch = (FG × 0.9) + RDS + SDS + RS; Thivend = total starch as measured by the Thivend et al. (1972) method. Numbers in parentheses are FG, RDS, SDS and RS expressed as a percentage of the TS.

al. (1972) method may be the inclusion of sucrose in the measurement. This method enzymatically converts sucrose into monosaccharides and allows for their recovery in the supernatant. The Muir and O'Dea (1993) method does not account for this conversion, so sucrose is not part of the starch value.

Cereal grains varied widely in percentage starch found in each of the starch fractions. RDS and SDS concentrations represented the majority of the TS in the cereal group. Cereal grains have an A-type crystalline form, which is the starch structure least resistant to hydrolysis (Ring et al. 1988). This crystalline form leads to more of the starch being categorized as RDS and SDS. RDS concentrations as a percentage of TS varied from 32.5 to 82.5%. White rice contained the highest concentration of SDS (51.4%) as a percentage of TS. Raw cereals are partially inaccessible to digestion due to the physical form of the cereal itself (Englyst et al. 1992b). Structures like the pericarp and seed coat may impede the efficiency of amylase digestion of starch in cereal grains.

RS concentrations were highest for sorghum and lowest for oats. Four categories of RS have been defined (Brown 1996). The first category (RS1) includes starch granules that are

physically inaccessible and can be found in whole or partially milled grains and legumes. The second category (RS2) refers to native starch granules, whereas the third category (RS3) refers to retrograded starch that is formed during processing. The fourth category of RS (RS4) was only recently described and includes chemically modified starches resistant to enzymatic hydrolysis to some degree.

Flours also varied widely in percentage starch found in each of the starch fractions. Approximately 95% of the TS in flours is RDS and SDS combined. RS concentrations were highest for corn and soy and lowest for barley. Englyst et al. (1992a) reported that white wheat flour contained 49% RDS, 48% SDS and 3% RS as a percentage of TS. Our wheat flour contained 55.4% RDS, 42.2% SDS and 2.5% RS as a percentage of TS, agreeing closely with the values of Englyst et al. (1992a). RS concentrations were low for the flour group as a whole. Cereal flours display an A-type crystalline pattern, which is more readily hydrolyzed than raw cereals that are not as highly processed as flours. Therefore, cereal flours contain more RDS and SDS than RS.

The nutrient profile of cereal grains and their corresponding flours varied considerably. Grain flours are made up pri-

marily of two components: protein and starch. Cereal grains, in contrast, contain the pericarp, aleurone layers and germ portions of the grain that provide lipid and fiber (Hoseney 1994). Cereal grains are processed and milled to flours, thereby altering the chemical composition of the flour compared with the cereal grain. Even DM concentrations varied when cereal grains were compared with their flour counterparts. Except for barley, flours were numerically higher in OM. CP concentrations of flours were 1–3 percentage units lower than that for ground grains. Total dietary fiber concentrations of flours, except for barley, were numerically lower compared with their ground grain counterparts. This reduction in TDF points to how the processing of grains alters their fiber content through removal of the pericarp, aleurone layers and germ. Of interest is how the processing of cereals to flours affects the starch fraction profile. The combined RDS and SDS concentrations of cereal grains were ~74% of TS versus, flours, which were 95% of TS. The RS concentrations were, on average, five times higher in the cereal grains than in the flours.

For the grain-based food products, RDS concentrations, expressed as a percentage of TS, were highest for macaroni and rolled oats; intermediate for spaghetti, corn meal and hominy grits; and lowest for rice bran. SDS concentrations varied, with corn meal having the highest concentration and rolled oats having the lowest. Prepared grain products contained moderate levels of RS (mean 9.6% as a percentage of TS). Hermansen et al. (1986) postulated that starch in foods like spaghetti is more slowly digested because of the densely packed starch in the food. During pasta production, pasta is kneaded and extruded, leading to a tight, entrapped starch granule (Colonna et al. 1990). Again, food ingredients like rice bran with high TDF (28.0%) may experience a lower amount of starch hydrolysis as a result of its fiber content. Corn meal contained the highest concentration of TS, whereas rice bran contained the lowest.

The reference substrates varied widely in their starch fractions. RDS values were highest for corn starch and similar for potato starch and amylo maize. SDS values were similar for corn starch and amylo maize and lower for potato starch. As a percentage of TS, potato starch had the highest RS concentration and corn starch had the lowest. Englyst et al. (1992a) found that raw potato starch contained 75% RS as a percentage of TS. Starches from tubers such as potatoes tend to exhibit B-type crystallinity patterns that are highly resistant to digestion (Englyst et al. 1992a). Amylo maize contains mostly amylose, which has been shown to lower not only digestibility but also blood insulin and glucose values in humans (Behall et al. 1995).

A common characteristic of all foods and feeds studied is that RS is a component of each. This starch fraction is not hydrolyzed and enzymatically digested in the small intestine but rather serves as a substrate for fermentation by microflora either in the ileum and/or large bowel.

In vitro experiment 1

Ileal bacteria. Fermentative events in the nonruminant occur as a result of bacterial activity in the colon and possibly in the ileum of the small intestine. Ruseler-van Embden et al. (1992) found >25 different species of bacteria residing in the small intestine of dogs. Murray et al. (2000) found the following colony-forming units (CFU)/mL of ileal effluent after isolation and plating: 4.2×10^8 total anaerobes, 7.1×10^5 total aerobes, 1.3×10^6 *Escherichia coli*, 1.7×10^8 *Clostridium perfringens*, 1.8×10^8 *Bifidobacteria* and 3.3×10^6 *Lactobacillus*. Finegold et al. (1970) found that in the human ileostomate,

there were 10^7 – 10^8 colonies/g of ileal contents. These values confirm that there may be a substantial bacterial population residing in the small intestine of both dogs and humans. It is uncertain whether ileal microbes are indigenous to this site or whether they emanate from the cecum, finding their way via the ileocecal valve into the small intestine. The contents of the small intestine normally flow rapidly, possibly becoming static for an appreciable period only in the distal small intestine (Drasar and Hill 1974).

IDS and TDS concentrations. IDS concentrations for the legume group were statistically highest ($P < 0.05$) for black-eyed peas and split peas, next highest for lentils and navy beans and lowest for northern beans, black beans and red kidney beans (Table 4). Bjorck et al. (1992) reported that the small intestinal digestibility by rats of a cooked and canned pea product was 70%. As a percentage of TS (i.e., IDS/TS), our ileal digestibility value for split peas (45.7%) was lower and may be due to the raw, unprocessed nature and high RS content of this substrate. Key et al. (1995) also found that as the concentration of cooked haricot beans in the diet of rats increased from 0 to 450 g/kg, ileal digestibility decreased from 87 to 69% for the haricot bean-containing diet.

TDS concentrations were lowest ($P < 0.05$) for black beans, red kidney beans and northern beans and highest ($P < 0.05$) for black-eyed peas and split peas. Biliaderis et al. (1981) found that wrinkled peas contained 55.4% amylose as a percentage of TS, whereas beans contained higher amounts of amylose (mean 59.2%). Higher amylose concentrations in starches are believed to lower digestibility (Borchers 1962). This could explain why the peas displayed higher TDS concentrations and the beans displayed lower TDS concentrations. Goodlad et al. (1992) found that as the proportion of peas doubled from 250 to 500 g/kg in the diet of rats, total tract digestibility was reduced ($P < 0.05$) from 94 to 91%. The TDS concentrations were low for the bean group as a whole, with a possible explanation being the physical entrapment of the starch within fibrous, thick-walled parenchyma cells (Wursch et al. 1986). Also, antinutrients (e.g., enzyme inhibitors, lectins and tannins) have been found in legumes, and that could reduce the digestibility of legume starches. RS and TDF concentrations also were high for the legume group and could affect starch digestion in these substrates.

Starch utilized by the microflora in the large bowel (percent TDS – percent IDS) was numerically highest for split peas and lowest for northern beans.

For the cereal grains group, IDS concentrations were highest ($P < 0.05$) for brewer's rice and lowest for oats. As a percentage of TS, starch in oats and barley was completely digested at the ileum. Englyst and Cummings (1985), using human ileostomates, found that raw oat starch hydrolysis was complete in the small intestine. Barriers to amylase digestion apparently do not impede the starch in oats. Of interest is how white rice and brown rice differ with respect to IDS values. O'Dea et al. (1981) found that relative rates of starch hydrolysis in an *in vitro* system correlated very closely with *in vivo* peak glucose responses in humans. *In vitro* rates of starch hydrolysis (percent hydrolyzed/30 min) for ground brown rice and white rice were 68.2 and 71.8%, respectively. O'Dea et al. (1981) suggest that fiber might act indirectly to slow carbohydrate absorption, restricting access of hydrolytic enzymes to starch from an unrefined source like brown rice. Our brown rice source was higher in TDF content and lower in IDS than white rice. Two other grains have been shown to have structural differences that may contribute to resistance to digestion. Hosney (1994) suggested that the protein-starch matrix of

TABLE 4

In vitro ileal digestible starch (IDS) and total digestible starch (TDS) concentrations of selected food and feed ingredients^{1,2,3}

Substrate	IDS	TDS	TDS-IDS
	%		
Legumes			
Black beans	16.4 ^c (35.0)	22.3 ^c (47.6)	5.9 ^c
Red kidney beans	15.0 ^d (35.0)	21.7 ^c (50.6)	6.7 ^{b,c}
Lentils	20.6 ^b (39.7)	32.8 ^b (63.2)	12.2 ^{a,b}
Navy beans	20.6 ^b (40.6)	33.7 ^b (66.3)	13.1 ^a
Black-eyed peas	30.0 ^a (52.6)	44.4 ^a (77.9)	14.4 ^a
Split peas	30.0 ^a (45.7)	44.5 ^a (67.8)	14.5 ^a
Northern beans	17.0 ^c (36.4)	20.3 ^c (43.5)	3.3 ^c
SEM	0.33	1.93	1.72
Cereal grains			
Barley	54.7 ^d (100.0)	52.3 ^e (95.6)	-2.4 ^h
Corn	59.4 ^c (74.2)	74.2 ^c (92.6)	14.8 ^b
White rice	69.0 ^b (74.2)	80.0 ^b (86.0)	11.0 ^d
Brewer's rice	73.2 ^a (87.5)	79.1 ^b (94.5)	5.9 ^f
Brown rice	61.3 ^c (69.8)	74.3 ^c (84.6)	13.0 ^c
Wheat	52.8 ^d (99.8)	47.1 ^f (89.0)	-5.7 ⁱ
Millet	68.9 ^b (75.8)	86.4 ^a (95.0)	17.5 ^a
Oats	46.5 ^e (100.0)	46.5 ^e (100.0)	0.0 ^g
Sorghum	52.8 ^d (67.9)	62.4 ^d (80.2)	9.6 ^e
SEM	1.07	0.71	0.92
Flours			
Corn	82.3 ^a (90.6)	90.8 ^a (100.0)	8.5 ^{a,b}
Wheat	62.7 ^d (85.4)	73.4 ^f (100.0)	10.7 ^a
Rice	78.6 ^b (88.0)	88.7 ^b (99.3)	10.1 ^a
Potato	70.7 ^c (90.8)	77.6 ^d (99.6)	6.9 ^{b,c}
Soy	2.4 ^e (29.3)	8.2 ^g (100.0)	5.8 ^{b,c}
Barley	69.9 ^c (92.5)	75.2 ^e (99.5)	5.3 ^c
Sorghum	84.8 ^a (100.0)	84.8 ^c (100.0)	0.0 ^d
SEM	0.82	0.33	0.82
Grain-based food products			
Macaroni	73.7 ^c (95.5)	76.7 ^c (99.4)	3.0 ^c
Spaghetti	75.7 ^b (91.5)	82.6 ^b (99.9)	6.9 ^b
Corn meal	83.9 ^a (87.9)	92.3 ^a (96.6)	8.4 ^a
Rice bran	27.5 ^f (100.0)	27.5 ^f (100.0)	0.0 ^d
Rolled oats	60.1 ^e (100.0)	60.1 ^e (100.0)	0.0 ^d
Hominy grits	70.9 ^d (100.0)	63.2 ^d (89.1)	-7.7 ^e
SEM	0.14	0.75	0.31
Reference substrates			
Corn starch	95.0 ^a (93.6)	101.5 ^a (100.0)	6.5 ^c
Potato starch	34.5 ^c (34.7)	64.0 ^b (64.5)	29.5 ^a
Amylomaize	42.5 ^b (42.6)	59.8 ^c (59.9)	17.3 ^b
SEM	0.74	0.38	1.00

¹ IDS determined by subtracting (free glucose \times 0.9) from (total glucose/original sample weight) present in supernate after 15 h of digestion. Numbers in parentheses are IDS concentrations expressed as a percentage of total starch as determined by the Thivend et al. (1972) method.

² TDS determined by subtracting [(total glucose/original sample weight) \times 0.9] in the remaining sample from the percent total starch as determined by the Thivend et al. (1972) method. Numbers in parentheses are TDS concentrations expressed as a percentage of total starch as determined by the Thivend et al. (1972) method.

³ Means in a column within substrate category not sharing superscript letters differ ($P < 0.05$).

sorghum and corn grains was quite strong, making hydrolysis and digestion more difficult.

TDS concentrations for cereals varied from a high ($P < 0.05$) for millet to a low ($P < 0.05$) for oats and barley. TDS concentrations were high, indicating continued digestion of

starch by the microflora once it reached the large bowel. Moore et al. (1980) fed plant-based diets containing one of three grain sources (rice, oats or corn) to dogs. Total tract starch digestibility for the uncooked oat diet (93.8%) was lowest, intermediate for the uncooked corn diet (94.3%) and highest for the uncooked rice diet (98.6%). Our values were 92.6% for corn, 86.0% for white rice and 100.0% for oats. The dog diets in the Moore et al. (1980) study were extruded; this leads to increased susceptibility to amylase and greater starch digestion.

Cereal starch utilization by microflora in the large bowel varied. Millet had the highest ($P < 0.05$) and wheat had the lowest ($P < 0.05$) digestibility values. Of interest is how fermentable each substrate is if any appreciable amount reaches the large bowel. According to Hosney (1994), millet, sorghum and corn starch granules appear to be similar. In our study, their fermentative capabilities were similar, with millet having the highest value.

IDS concentrations for flours were lowest ($P < 0.05$) for soy, which has very low starch concentrations, but higher for wheat, barley, potato and brown rice. The highest ($P < 0.05$) concentrations were noted for corn and sorghum. IDS concentrations were high for most flours. With low TDF and RS concentrations in the flours, there appears to be less of a barrier to digestion of starch. Our wheat flour had a lower IDS concentration compared with all other flours with the exception of soy. (Snow and O'Dea 1981) assayed different flours (rice, barley, rye, white [bleached wheat flour] and wheat) to determine their *in vitro* starch hydrolysis capacity. After 30 min of hydrolysis, all flours were similar in percent starch hydrolyzed (mean 16.1%) except for wheat flour. The authors postulated that an amylase inhibitor may have affected the hydrolysis rate of the wheat flour. Also, wheat starch can contain nonstarch polysaccharides (Topping et al. 1993).

The flour that had the lowest ($P < 0.05$) TDS concentration was soy, whereas corn had the highest ($P < 0.05$) TDS value. All flours were virtually completely digested when TDS concentrations were compared. The flours used were primarily composed of RDS and SDS (mean 95.1%), and as a result of processing, most barriers to digestion are overcome. Murray et al. (1999) found that the starch component of canine diets containing high-starch flours as the main source of carbohydrate was nearly completely digested (>99%).

Starch utilization by microflora (percent TDS - percent IDS) varied numerically in the flour group from a low for sorghum to a high for wheat. Microflora fermented virtually all available remaining starch. Even though the wheat flour IDS concentration was relatively low, large bowel microflora appeared to ferment the remaining starch well. The wheat amylase inhibitor mentioned by Snow and O'Dea (1981) appeared to have no effect on the microflora once the wheat starch was placed in an environment simulating the large bowel.

For the grain-based food products, IDS was lowest for rice bran and highest ($P < 0.05$) for corn meal. Expressed as a percentage of TS, rice bran, rolled oat and hominy grit starches were completely digested at or before the ileum. Macaroni and spaghetti were well digested at the ileum (95.5 and 91.5% as a percentage of TS, respectively), but certain factors can reduce their susceptibility to amylolytic attack. Colonna et al. (1990) found that high-temperature drying of pasta may result in high levels of protein cross-linking, leading to a greater encapsulation of starch and thus decreasing its susceptibility to amylase. There also can be differences ($P < 0.05$) between the digestion of macaroni and spaghetti, as noted in our study. Granfeldt and Bjorck (1991) tested mac-

aroni and spaghetti glucose responses in 10 human subjects. Spaghetti resulted in a glycemic index score of 60.5, whereas macaroni resulted in a score of 78.0. Macaroni had a lower product thickness and a greater surface area that allowed easier access to amylase. Rolled oats were completely digested at the ileum. This corroborates the results of Heaton et al. (1988), where insulin responses were measured in humans fed certain cereal products (corn, wheat or rolled oats). Rolled oats resulted in a higher peak insulin response compared with oat flour. Decreasing the particle size of both corn and wheat seemed to increase digestion rate, but this was not the case for oat products.

When grain-based food products were compared, TDS concentrations were different ($P < 0.05$) among substrates. The highest ($P < 0.05$) TDS value was found for corn meal. Rice bran, rolled oats and hominy grits were completely digested proximal to the terminal ileum. The processing and cooking of rice bran and rolled oats affect their digestion. As mentioned previously, rolling oats appeared to disrupt the structural integrity of the grain, leaving it accessible to enzymatic attack. Processing of the rice kernel through a milling machine produces rice bran and polished rice. The compositions of rice and rice bran vary greatly due to this processing. Rice bran is composed of the aleurone layer and some parts of the endosperm and germ of the rice kernel after milling.

Starch utilization by microflora (percent TDS – percent IDS) again varied for the grain-based food products. Corn meal was highest ($P < 0.05$) compared with all other substrates. A larger percentage of starch was fermented in the large bowel for spaghetti compared with macaroni. This relates to the greater amount of starch escaping digestion in the small intestine, making spaghetti more efficacious if the goal is to supply the large bowel with more starch.

Of the reference substrates, IDS concentrations were lowest ($P < 0.05$) for potato starch, intermediate for amylo maize and highest ($P < 0.05$) for corn starch. High concentrations of RS in potato starch cause its digestion to be limited in the small intestine. Mathers et al. (1997) fed either a raw potato or corn starch diet to rats and found that the digestibility of the corn starch diet was 99% at the ileum, whereas only 28% of the potato starch diet was digested at the ileum. Native potato starch granules are composed of a B-type crystalline pattern. These granules exist as a layer of large blocklets that appear to confer resistance to enzymatic hydrolysis (Gallant et al. 1992). Amylo maize was more digestible than potato starch, possibly due to its lower concentration of RS.

TDS concentrations were lowest ($P < 0.05$) for amylo maize, intermediate for potato starch and highest ($P < 0.05$) for corn starch. Total tract digestibility of potato starch fed to rats at 240 g/kg of the diet was 80%, whereas corn starch at 240 g/kg was 100% (Mathers et al. 1997).

Starch utilization by microflora in the large bowel (percent TDS – percent IDS) was greatest ($P < 0.05$) for potato starch, pointing to its high fermentative capacity. Of interest is that although potato starch was lower in IDS, it was higher in TDS compared with amylo maize. Lajvardi et al. (1993) fed rats either a cooked potato starch, arrowroot starch, high amylose corn starch or raw potato starch diet. Raw potato starch was found to be the most fermentable starch of the four tested. Only raw potato starch was found to significantly prolong gastrointestinal transit time, possibly allowing this substrate a longer time to ferment in the large bowel.

In vitro experiment 2

OMD. This experiment was conducted to determine whether ileal fermentation events, independent of hydrolytic digestion events, affected the disappearance of OM for a widely divergent group of substrates. Although data were collected at 0-, 2.5-, 5- and 7.5-h time periods, only those collected at 7.5 h are reported because they were judged to be most relevant from a biological perspective (i.e., data at the 5- and 7.5-h time points were similar; 7.5 h is about the length of time chyme would be available to ileal microbes).

OMD of substrates is reported in Table 5. All substrate \times time interactions were significant at $P < 0.05$. After correction for solubility, OMD was very low for the legume group as a whole. Solubilization of the substrates at the 0-h fermentation time was high (13–17%), resulting in lower corrected OMD values. Red kidney beans and black beans had the lowest ($P < 0.05$) OMD values of all legumes tested. Schweizer et al. (1990) found, using ileostomates fed a white kidney bean flake-containing diet, that ~10% of the bean starch was not absorbed from the small intestine. Tovar et al. (1992) postulated that the high amylose-to-amylopectin ratio, the physical insulation of starch by thick-walled cells and the presence of amylase inhibitors resulted in a reduction in digestibility of leguminous starches. These physicochemical characteristics of legumes act as direct inhibitors of α -amylase and, thus, starch breakdown.

Solubility of cereal grains in the *in vitro* medium generally was much lower than was the case for legumes. OMD was greatest ($P < 0.05$) for oats and lowest for corn. Again, the starch in certain cereals may be inaccessible due to the physical form of the cereal, resulting in digestion responses lower than expected (Englyst et al. 1992b). Cell walls and encapsulation of starch in a protein matrix of whole grains greatly affect digestion by reducing access of amylase to the starch itself.

Flours as a group were very digestible by ileal microbes. Potato and soy flours had extremely high solubility values. Rice and corn had the highest ($P < 0.05$) OMD values compared with other flours, and wheat flour had the lowest ($P < 0.05$). Interestingly, the two former flours had among the lowest solubility values. Wheat flour was two to three times lower in OMD than all other flours. Murray et al. (2000) also reported a low OMD at 7.5 h for wheat flour (1.9%). In this case, protein may encapsulate the starch granules, thereby reducing the digestibility of the starch (Annison and Topping 1994).

Of particular interest is how processing affects substrate disappearance. For example, barley flour was approximately five times more digestible compared with barley grain. Heaton et al. (1988) compared particle size effects of wheat, corn and oats on human *in vivo* plasma insulin responses and on *in vitro* rate of starch digestion by pancreatic amylase. Insulin responses were as follows: whole grains $<$ cracked grains $<$ coarse flour $<$ fine flour. *In vitro* starch hydrolysis by amylase was faster for grains of smaller particle size. Larger food particles have a lower surface-to-volume ratio, and this might reduce the access of enzymes to the interior of the particle as might the presence of intact cell walls. Processing affects the physical nature of cereals, causing the disruption of the cell matrix and increasing starch digestion.

Grain-based food products ranged in OMD from a low for macaroni to a high for rolled oats. Knudsen et al. (1993) stated that oat bran, a rich source of dietary fiber containing β -glucans, is an easily fermentable energy source for microflora. The

TABLE 5

Zero hour solubilities, organic matter disappearance (OMD) and total short-chain fatty acid (SCFA) and lactate concentrations at 7.5 h of *in vitro* fermentation of selected food and feed ingredients using canine ileal fluid as inoculum¹

Substrate	Solubility ²	Corrected OMD ³ at 7.5 h	Total SCFA ⁴	Lactate
	%		mmol/g OM at 7.5 h	
Legumes				
Black beans	14.2	1.8	7.24	0.04
Red kidney beans	15.2	0.2	7.28	0.05
Lentils	12.5	5.3	8.46	0.05
Navy beans	13.6	3.5	6.79	0.02
Black-eyed peas	15.4	3.4	8.35	0.06
Split peas	13.3	8.1	8.72	0.06
Northern beans	17.4	4.7	7.73	0.05
SEM	1.0	1.0	0.16	0.004
Cereal grains				
Barley	9.5	7.2	8.13	0.10
Corn	10.6	2.7	5.18	0.04
White rice	0.9	3.8	4.72	0.03
Brewer's rice	0.8	8.8	5.84	0.04
Brown rice	4.6	5.4	4.82	0.04
Wheat	2.8	8.9	6.54	0.01
Millet	2.7	15.4	5.48	0.04
Oats	9.0	19.0	7.87	0.07
Sorghum	0.0	8.4	4.70	0.02
SEM	1.1	1.1	0.17	0.01
Flours				
Corn	6.7	35.6	3.64	0.26
Wheat	18.0	11.7	4.59	0.01
Rice	5.9	37.1	2.93	0.26
Potato	58.5	21.7	10.10	0.51
Soy	30.2	25.2	6.55	0.10
Barley	13.6	33.3	4.66	0.30
Sorghum	5.9	28.0	2.45	0.17
SEM	0.9	0.9	0.12	0.01
Grain-based food products				
Macaroni	11.7	13.1	4.39	0.05
Spaghetti	9.8	18.3	4.75	0.07
Corn meal	2.3	22.4	2.27	0.14
Rice bran	13.3	22.0	3.70	0.14
Rolled oats	2.9	59.1	6.04	0.39
Hominy grits	0.0	17.6	2.08	0.07
SEM	1.1	1.1	0.11	0.01
Reference substrates				
Corn starch	0.0	32.5	3.58	0.25
Potato starch	0.0	3.9	0.64	0.02
Amylomaize	0.0	12.9	0.81	0.04
SEM	1.0	1.0	0.07	0.004

¹ The interaction of substrate × time was significant ($P < 0.05$) for OMD, total SCFA and lactate. The LSD values for separating substrate means are $2.95 \times \text{SEM}$.

² Solubility of substrates in *in vitro* medium at 0 h at 39°C.

³ Values have been corrected for solubility.

⁴ Total SCFA = acetate + propionate + butyrate.

process of rolling would make the fiber more accessible to microbial enzymes during the fermentation process.

OMD was greatest ($P < 0.05$) among reference substrates for corn starch, intermediate for amylo maize and lowest ($P < 0.05$) for potato starch. Potato starch contained the highest concentrations of RS, which influenced its digestion.

Data indicate that small intestinal bacteria ferment cereal grains and flours differently. The flour group had relatively high OMD values (mean 27.5%), whereas the cereal group had relatively low OMD values (mean 8.8%). This relates to the greater amount of processing that resulted in production of the flours. The cereal grain, as a result of this processing, loses TDF and RS components, as was found in this study. The lower concentrations of TDF and RS in flours lead to increased susceptibility to both enzymatic and microbial digestion.

Organic acid production. SCFA and lactate production data at the 7.5-h fermentation time are reported in Table 5. All substrate × time interactions were significant at $P < 0.05$.

Among leguminous substrates, the greatest ($P < 0.05$) total production of SCFA was for split peas, and the lowest was for navy beans. The high concentrations of total SCFA as a result of pea fermentation point to the ability of this substrate to be more rapidly fermented than beans. Bjorck and Siljestrom (1992) found that 90% of a pea product that reached the large bowel of a rat was fermented. The lower amylose content of peas could lead to higher fermentability by microflora, whether ileal or large bowel in origin. Tovar et al. (1992) reported that lentils contained more potentially available starch than did red kidney beans, corroborating the higher total SCFA concentration.

Lactate production was similar for all legumes. The largest amount of lactate produced was for split peas and black-eyed peas, whereas the lowest lactate production was for navy beans.

Among cereals, barley and oat fermentation resulted in the greatest ($P < 0.05$) total SCFA concentrations. The lowest ($P < 0.05$) total SCFA concentrations were for corn, white rice, brown rice and sorghum. Lactate production was greatest ($P < 0.05$) for barley compared with all other cereal grains.

Butyrate concentrations found in oats and barley (data not shown) were numerically higher compared with the cereal grains group (mean 0.66 mmol/g OM) as a whole. The presence of β -glucans, a soluble dietary fiber found in both oats and barley, may have stimulated butyrate production by ileal microflora.

Potato flour resulted in the highest ($P < 0.05$) total SCFA production compared with all other flours. Murray et al. (2000) also found that potato flour was numerically highest in total SCFA production when comparing six different flours incubated in inoculum containing ileal microorganisms. Processing was suggested as responsible for the increased susceptibility of potato flour to fermentation. The lowest ($P < 0.05$) total SCFA production was for sorghum and corn flours.

Flour fermentation resulted in generally higher lactate concentrations than for the other groups. Average lactate production for flours was 0.23 mmol/g OM. Zentek (1995) performed *in vitro* studies using canine ileal chyme to measure the fermentative capabilities of different substrates. He postulated that ileal fermentation of carbohydrates favored the growth of lactobacilli, which produce lactate as a major metabolic end-product. The high starch levels resulting from extensive processing of flours may have created a favorable environment for the selection of lactobacilli and subsequent production of lactate.

Rolled oats resulted in the highest ($P < 0.05$) total SCFA production compared with all other grain-based food products. Yiu et al. (1987) found raw oat starch to be highly digestible because of the disruption of starch granules due to oat processing. Rolling the oats leads to this disruption of the starch granules in the oat grain. Also, lactate production was highest ($P < 0.05$) for rolled oats, again relating to the high degree of processing and subsequent fermentative capacity of rolled oats.

Total SCFA production for the reference substrates was highest ($P < 0.05$) for corn starch compared with all other substrates. Zentek (1995), using canine ileal chyme, found that after 24 h of in vitro fermentation, corn starch resulted in higher concentrations of total SCFA compared with potato starch (7.11 versus 5.80 $\mu\text{mol/mL}$ of fermentation broth, respectively). This is comparable to our SCFA and lactate data, in which corn starch had the highest ($P < 0.05$) concentrations and potato starch had the lowest. Although both are composed of starch, potato starch contains a much higher concentration of RS (66.9%) than corn starch (8.1%), possibly leading to a reduction in the fermentation of potato starch.

The response criteria used in this experiment to test differences among substrates included OMD and organic acid production. Organic acid production appears to be the more accurate criterion for the determination of fermentative activity, because OMD values are obtained using a gravimetric method with its attendant difficulties. High solubility values in relation to OMD do not appear to equate to high total SCFA concentrations. For example, the average solubility value for the flour group was 19.8% and total SCFA concentrations were only 4.99 mmol/g OM. The cereal grains group, on the other hand, averaged 4.5% solubility but had a total SCFA concentration of 5.92 mmol/g OM. Likewise, there were no statistically significant correlations between OMD and total SCFA concentrations (data not shown).

Of interest to many researchers is the potential fermentation of RS. Although starch is fermentable and believed to favor butyrate production, the data are not entirely consistent (Topping and Clifton 2000). Our data do not point to increased concentrations of butyrate from the fermentation of RS. For example, legumes had high concentrations of RS (mean 24.7%), whereas butyrate concentrations averaged 0.77 mmol/g OM. Flours, low in RS concentrations (mean 2.8%), had similar butyrate concentrations (mean 0.67 mmol/g OM) as the legume group (data not shown).

What is the contribution of ileal bacteria to starch disappearance compared with that resulting from any residual digestive enzymes present in ileal chyme? Using the same ileal in vitro model, Murray et al. (2000) found that fermenting substrates in the presence of sodium azide-treated ileal bacteria resulted in no total SCFA for the first 5 h and minimal amounts at 7.5 h. This points to the minimal effect of residual digestive enzymes on starch disappearance using this in vitro model.

In conclusion, starch and fiber fractions in foods and feeds affect starch digestion in the gastrointestinal tract as assessed using in vitro models. It should be noted that the emphasis of this work was the effect of starch and fiber fractions on intestinal microbial digestion. Gut motility, digestive enzymes and other aspects of gut function will affect digestion in vivo. Greater knowledge of the precise chemical composition and digestive capabilities of starch fractions in foods and feeds will allow for more precise dietary formulations for both humans and companion animals, with implications in both performance and health arenas.

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Format: Abstract

J Anim Sci. 1999 Aug;77(8):2180-6.

Evaluation of selected high-starch flours as ingredients in canine diets.

Murray SM¹, Fahey GC Jr, Merchen NR, Sunvold GD, Reinhart GA.

Author information

Abstract

Cereal grains represent 30 to 60% of the DM of many companion animal diets. Once incorporated into a diet, the starch component of these grains can provide an excellent source of ME. However, crystallinity and form of starch are variable and can cause incomplete digestion within the gastrointestinal tract. Diets fed in this experiment included one of six high-starch flours as the main source of carbohydrate. The flours originated from barley, corn, potato, rice, sorghum, and wheat. The diets were extruded and kibbled. Starch fraction concentrations of flours consisted of nearly 100% rapidly digestible starch (RDS) and slowly digestible starch (SDS) combined. Starch fraction concentrations of diets paralleled concentrations in flours. Flours varied widely in concentrations of CP, fat, starch, and total dietary fiber. Ileal OM and CP digestibilities were lowest for the potato flour treatment (74 and 64%, respectively). Ileal and total tract starch digestibilities were different ($P < .05$) among treatments; however, the starch component of all diets was nearly completely digested (>99%). Total tract digestibility of DM and OM was lowest for sorghum (80 and 84%, respectively) compared to all other diets. Crude protein digestibility was highest for corn (87%). Wet fecal weights tended ($P < .08$) to be greatest for dogs fed the barley treatment (175 g/d). However, dry fecal weights (dried at 55 degrees C) were greatest for dogs consuming the sorghum diet (51 g/d). Fecal scores were consistently greater (i.e., looser stools) for the barley treatment. Any of these flours could be used without negative effects on digestion at either the ileum or in the total tract. Fecal consistency data for dogs consuming the barley treatment indicate that diets containing large amounts (>50%) of barley may not be advantageous for dog owners who house their animals indoors for most of the day.

PMID: 10461997

[Indexed for MEDLINE]

MeSH terms, Substance

LinkOut - more resources



PubMed ▼

Format: Abstract

J AOAC Int. 2004 May-Jun;87(3):787-91.

Resistant starch as related to companion animal nutrition.

Spears JK¹, Fahey GC Jr.

Author information

Abstract

Companion animal diets may contain up to 50% starch, derived from cereal grains. The amount of resistant starch (RS) in an ingredient depends on the origin and form of the ingredient and on the processing conditions to which the ingredient has been exposed. Extrusion has proven to be a means of optimizing utilization of starch by companion animals. Although the RS fraction of starch typically decreases by extrusion, retrogradation can result in increased concentrations of this fraction. Limited research exists regarding the effects of RS in companion animal nutrition and gastrointestinal health. Existing in vitro and in vivo research indicates that certain RS sources are readily fermented in the large bowel, producing short-chain fatty acids, whereas others are less fermentable, resulting in excellent laxation properties. Feeding dogs a diet high in RS may result in an increase in fecal bulk due to an increased excretion of microbial matter in those cases where RS is highly fermentable, or to indigestibility of the RS source in other cases. RS has a role to play as a potential proxy for dietary fiber, especially for those companion animals fed diets high in protein and fat and devoid of traditional dietary fiber.

PMID: 15287680

[Indexed for MEDLINE]

Publication type, MeSH terms, Substances

LinkOut - more resources

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Jones, Jennifer L; Burkholder, William; Stamper, Carmela; Rotstein, David; Queen, Jackie L; Atkinson, Krisztina Z; Palmer, Lee Anne
CC: Norris, Anne; Glover, Mark; Conway, Charlotte
Sent: 6/7/2018 8:57:01 PM
Subject: RE: Grain-Free Diet Effects
Attachments: de-Oliveira - Fibre analysis and fibre digestibility in pet foods.pdf

I agree. That's important data for us to have.

Attaching the last paper with discussion of some of these grain-free ingredient oddities. This paper has several tables that break down fiber amounts. A lot of these grain free substitutes have a lot of fiber and when you start adding them in multiples...

B5

From: Jones, Jennifer L
Sent: Thursday, June 07, 2018 2:09 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

I hope so. I thought their data was important for publishing.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Carey, Lauren
Sent: Thursday, June 07, 2018 1:55 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

He made it sound like this paper was coming in the future, so maybe a revamp?

From: Jones, Jennifer L
Sent: Thursday, June 07, 2018 1:04 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

Interesting. I reviewed a paper out of cornell that measured metals in pet foods and it wasn't well organized. Maybe they made major revisions. I wasn't concerned about any of the levels they reported.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Carey, Lauren
Sent: Thursday, June 07, 2018 12:57 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

I can only find abstracts for two. I have one other paper requested through ILL. I'll forward it once I have it. It was the one I found most interesting in regards to digestibility, etc.

B5

From: Carey, Lauren
Sent: Thursday, June 07, 2018 12:42 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

B5

B5

From: Burkholder, William

Sent: Thursday, June 07, 2018 10:49 AM

To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>

Subject: Grain-Free Diet Effects

This is from Charlotte Conway who has contacts within the pet food formulation business:

"In follow-up to Dr. Freeman's article, I got a call from [B6] this morning - so passing along his thoughts: [B6]

B6

B6

Passing along because I said I would."

Some things to think about.

Bill Burkholder

ORIGINAL ARTICLE

Fibre analysis and fibre digestibility in pet foods – a comparison of total dietary fibre, neutral and acid detergent fibre and crude fibre*L. D. de-Oliveira¹, F. S. Takakura¹, E. Kienzle², M. A. Brunetto¹, E. Teshima¹, G. T. Pereira¹, R. S. Vasconcellos¹ and A. C. Carciofi¹¹ College of Agrarian and Veterinarian Sciences, Sao Paulo State University, Jaboticabal, SP, Brazil, and² Chair of Animal Nutrition, Ludwig Maximilians University, Munich, Germany**Keywords**

carbohydrates, cat, dog, methods, nitrogen-free extract, fibre

Correspondence

Dr A. C. Carciofi, Departamento de Clínica e Cirurgia Veterinária, Universidade Estadual Paulista Júlio de Mesquita Filho (UNESP), Via de Acesso Prof. Paulo Donato Castellane, s/n, Postal code 14884-900, Jaboticabal, SP, Brazil. Tel: +55 16 3209 2626; Fax: +55 16 3203 1226; E-mail: aulus.carciofi@gmail.com

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Received: 19 June 2011;
accepted: 20 June 2011**Summary**

Six dry dog foods and six dry cat foods with different carbohydrate sources were investigated in digestion trials. Food and faecal samples were analysed for CF, TDF and starch. In dogs, also neutral detergent fibre (aNDFom) and acid detergent fibre (ADFom) were analysed. N-free extract (NfE) was calculated for CF, and similarly for all other fibre analyses. Linear regressions were calculated between fibre intake and faecal fibre excretion. True digestibility was calculated from the regression coefficients [true digestibility in % = (1 – regression coefficient)*100], with the intercept of the equation representing excretion of material of non-food origin. Crude fibre analyses gave the lowest values, and TDF the highest, while ADFom and aNDFom were in between. Variation between diets was lowest in CF and highest in TDF. Total dietary fibre, aNDFom and ADFom in food were positively correlated. Crude fibre in food did not correlate with any other method. The NfE analogue for TDF was closest to the starch content. Methods of fibre analyses in faeces did not agree very well with each other. Crude fibre had the lowest apparent digestibility, followed by ADFom, TDF and aNDFom. For all fibre analyses, there was a significant correlation between fibre intake and faecal fibre excretion. True digestibility was close to zero for CF, with a high uniformity in both species. In dogs, true digestibility of aNDFom was 53%, of ADFom 26% and of TDF 37%; in cats, true digestibility of TDF was 31%. Except for CF, the intercept of the regression equations suggest that faecal excretion of some material of non-food origin is analysed as fibre. A combination of TDF and CF analyses might give good information on the content of total (TDF), unfermentable (CF) and partially fermentable fibre (TDF-CF) in pet foods.

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B4

B4

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Norris, Anne; Carey, Lauren; Jones, Jennifer L; Burkholder, William; Stamper, Carmela; Queen, Jackie L; Atkinson, Krisztina Z; Palmer, Lee Anne
CC: Glover, Mark; Conway, Charlotte; DeLancey, Siobhan
Sent: 6/8/2018 6:03:44 PM
Subject: RE: Grain-Free Diet Effects

Thanks!

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: Friday, June 08, 2018 1:41 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

Dr. Freeman has been blogging:
<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>

And then this popped up: <https://www.mnn.com/family/pets/stories/dog-food-trends-healthy-for-pets>

From: Carey, Lauren
Sent: Thursday, June 07, 2018 4:57 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

I agree. That's important data for us to have.

Attaching the last paper with discussion of some of these grain-free ingredient oddities. This paper has several

B5

From: Jones, Jennifer L
Sent: Thursday, June 07, 2018 2:09 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

I hope so. I thought their data was important for publishing.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Carey, Lauren
Sent: Thursday, June 07, 2018 1:55 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

He made it sound like this paper was coming in the future, so maybe a revamp?

From: Jones, Jennifer L
Sent: Thursday, June 07, 2018 1:04 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

Interesting B5
Maybe they made major revisions. B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Carey, Lauren
Sent: Thursday, June 07, 2018 12:57 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

I can only find abstracts for two. I have one other paper requested through ILL. I'll forward it once I have it. It was the one I found most interesting in regards to digestibility, etc.

B5

From: Carey, Lauren
Sent: Thursday, June 07, 2018 12:42 PM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>
Subject: RE: Grain-Free Diet Effects

B5

From: Burkholder, William
Sent: Thursday, June 07, 2018 10:49 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Stamper, Carmela <Carmela.Stamper@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Norris, Anne <Anne.Norris@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Conway, Charlotte

<Charlotte.Conway@fda.hhs.gov>

Subject: Grain-Free Diet Effects

This is from Charlotte Conway who has contacts within the pet food formulation business:

"In follow-up to Dr. Freeman's article, I got a call from [REDACTED] **B6** this morning - so passing along his thoughts [REDACTED] **B6**

B6

B6

Passing along because I said I would."

Some things to think about.

Bill Burkholder

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Lisa.Freeman@tufts.edu
CC: AskOSC
Sent: 6/11/2018 8:06:59 PM
Subject: question about the FDA Safety Reporting Portal

Dr. Freeman,

Good Afternoon,

Our AskOSC team sent me over your email. It appears that what is being submitted is a RFR which is the FDA Reportable Food Registry. That's for industry to use to report any Class 1 Recalls. That's why you're seeing the fields that don't fit with what you are submitting.

Here are some suggestions:

For the page on the new report-

Select: Start a New Report

Select: A private citizen/business submitting a voluntary report

Select: Pet Food or Pet Treat for the cause of the issue

Select: Pet Food Report (a veterinarian or veterinary staff member) for the next field: Select a Report to begin

From there, it should be pretty straightforward. You can upload any documents.

Please let me know if this helps or if I can provide any other assistance.

Dave Rotstein

Safety Reporting Portal X

https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=b1c84606-0305-4...

New Guest Report

***Required Field**

You have chosen to use this portal as a Guest reporter.

Reports submitted as a Guest cannot be saved. Therefore, please plan to complete your report in full during this session. If you prefer to save your report and complete it at a later time, please return to the home page and create an account.

***Select the option that best describes what you want to do:**

- Start a new report
- Follow-up on a report previously submitted as a guest portal user.
- Follow-up on a report previously submitted as a logged in user.
- None of the above

***Who are You?**

- A private citizen/business submitting a voluntary report
- A federal, state or local public health official submitting a reportable food report about human and/or animal food
- A healthcare professional or researcher reporting a tobacco product problem
- A manufacturer reporting a tobacco product problem
- A manufacturer, sponsor or applicant of a drug product
- A manufacturer, packer or distributor of a human dietary supplement
- A food facility or responsible party that manufactures, processes, packs or holds food submitting a reportable food report

***What do you think caused the issue?** Pet Food or Pet Treat

***Select the report to begin** Pet Food Report (a veterinarian or veterinary staff member)

You have selected: Pet Food Report (a veterinarian or veterinary staff member)

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



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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Norris, Anne; Palmer, Lee Anne; Rotstein, David; Carey, Lauren; Hartogensis, Martine; DeLancey, Siobhan
Sent: 6/11/2018 4:00:58 PM
Subject: RE: Call with FDA to discuss recent findings
Attachments: 800.267-DCM-Grainfree analysis-UPDATED-PFI-redacted.pptx

Here is a version we could share. I can cut/add info as necessary.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Norris, Anne
Sent: Monday, June 11, 2018 10:34 AM
To: Jones, Jennifer L <Jennifer.Jones@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>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Call with FDA to discuss recent findings

If you use Chrome or Mozilla, you should be able to log in. Internet Explorer gave me trouble.

-----Original Appointment-----

From: Tabor, Peter [<mailto:peter@petfoodinstitute.org>]
Sent: Tuesday, June 05, 2018 7:17 PM
To: Tabor, Peter; Jones, Jennifer L; Palmer, Lee Anne; Rotstein, David; Carey, Lauren; Norris, Anne; Dana Brooks; Mary Emma Young; Tovey, Pat; Hartogensis, Martine
Subject: FW: Call with FDA to discuss recent findings
When: Monday, June 11, 2018 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: GoToMeeting - details below

Hope this works for everyone!

-----Original Appointment-----

From: Tabor, Peter [<mailto:peter@petfoodinstitute.org>]
Sent: Tuesday, June 05, 2018 5:47 PM
To: Tabor, Peter; Dana Brooks; Mary Emma Young; Tovey, Pat; Hartogensis, Martine
Subject: Call with FDA to discuss recent findings
When: Monday, June 11, 2018 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: GoToMeeting - details below

Many thanks for the call today, Martine. Per our conversation, I have set up a GoToMeeting for us. I hope the proposed time (an hour later) than discussed) works for you and your colleagues – we have a conflict at 9:30am I was unaware of when we spoke. Please forward the invite to all you think should attend.

Peter

Call with FDA to discuss recent findings

Mon, Jun 11, 2018 10:30 PM - 11:30 PM EDT

Please join my meeting from your computer, tablet or smartphone.

<https://global.gotomeeting.com/join>

B6

You can also dial in using your phone.

United States: +1 **B6**

Access Code: **B6**

Joining from a video-conferencing room or system?

Dial: 67.217.95 **B6**

Cisco devices **B6**

First GoToMeeting? Let's do a quick system check: <https://link.gotomeeting.com/system-check>

800.267
Grain free
versus
Non Grain Free Foods

Jones
Vet-LIRN

Grain Free products w/ reported DCM

Product	Grain Free?	Tau (%)
Product A	Yes	0.26
Product A	Yes	0.11
Product A	Yes	0.14
Product B	Yes	0.12
Product C	Yes	0.2
Product D	Yes	0.051
Product E	Yes	0.25

- 6/7 GF products with sufficient Taurine levels
- Only 1 product was low in Taurine
 - Feline AAFCO minimum Tau is 0.1% for extruded foods
 - No AAFCO minimum for dogs
 - Dog in this case had low Whole blood Tau
- Taurine is conditionally essential in dogs, because they can synthesize it from Cystine and Methionine.

Grain Free products w/ reported DCM

Product	Grain Free?	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Product A	Yes	0.26	0.26	0.64	0.9
Product A	Yes	0.11	0.26	0.61	0.87
Product A	Yes	0.14	0.28	0.86	1.14
Product B	Yes	0.12	0.36	0.69	1.05
Product C	Yes	0.2	0.34	0.51	0.85
Product D	Yes	0.051	0.33	0.4	0.73
Product E	Yes	0.25	0.38	0.7	1.08

AAFCO min: 0.33 to 0.35 % 0.65 to 0.7%

- All Grain Free Products contain Methionine and Methionine-Cystine % within the AAFCO requirements.
 - There is no AAFCO requirement for Cystine %
- The low Tau product had the lowest Met and Met-Cys content, but it was still above AAFCO requirements (highlighted)
- One product had the lowest Cys content (highlighted).

Non Grain Free Products w/o reported DCM

Product	Grain Free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Product F	No	Canine	0.22	0.32	0.66	0.98
Product G	No	Canine	0.11	0.3	0.57	0.87
Product G	No	Canine	0.11	0.3	0.6	0.9
Product H	No	Canine	0.11	0.31	0.58	0.89
Product I	No	Canine	0.12	0.32	0.65	0.97
Product J	No	Both	0.19	0.46	0.6	1.06
Product K	No	Feline	0.24	0.42	0.78	1.2
Product L	No	Feline	0.24	0.5	0.94	1.44

- In non-GF foods, the Taurine, Met, and Met-Cys levels were above AAFCO minimums.
 - Similar to Grain free foods.

Grain Free vs. Non Grain Free

Product Name	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Avg All GF foods	0.16	0.32	0.63	0.95
Avg All Non-GF Dog foods	0.14	0.34	0.61	0.95
Avg All Non-GF Cat Foods	0.22	0.46	0.77	1.23

- Average Tau, Cys, Met, and Met-Cys content in Grain Free dog foods is similar to the non-GF dog foods.
- The *non-GF cat foods* tend to have higher average levels, because they have greater minimum AAFCO requirements.

Overall Comparison

Product	Grain Free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)
Product A	Yes	Canine	0.26	0.26	0.64	0.9
Product A	Yes	Canine	0.11	0.26	0.61	0.87
Product A	Yes	Canine	0.14	0.28	0.86	1.14
Product B	Yes	Canine	0.12	0.36	0.69	1.05
Product C	Yes	Canine	0.2	0.34	0.51	0.85
Product D	Yes	Canine	0.051	0.33	0.4	0.73
Product E	Yes	Canine	0.25	0.38	0.7	1.08
Product F	No	Canine	0.22	0.32	0.66	0.98
Product G	No	Canine	0.11	0.3	0.57	0.87
Product G	No	Canine	0.11	0.3	0.6	0.9
Product H	No	Canine	0.11	0.31	0.58	0.89
Product I	No	Canine	0.12	0.32	0.65	0.97
Product J	No	Both	0.19	0.46	0.6	1.06
Product K	No	Feline	0.24	0.42	0.78	1.2
Product L	No	Feline	0.24	0.5	0.94	1.44

- Because the Grain free and Non-GF foods have a similar Tau, Cys, Met, and Met-Cys content, we can look closely at one product.
- It has adequate Met and Met-Cys levels, which should enable a dog to make adequate Tau, without needing Tau in the food.
- However, the dog eating this diet had low Whole blood Tau.

Ingredient comparison

Product	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
Product A	Yes	Canine	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.14	0.26	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product B	Yes	Canine	0.12	0.36	0.69	1.05	unknown	No	No	0	
Product C	Yes	Canine	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
Product D	Yes	Canine	0.25	0.38	0.7	1.08	unknown	Yes	No	1	peas (4)
Product E	Yes	Canine	0.051	0.33	0.4	0.73	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11)
Product F	No	Canine	0.22	0.32	0.66	0.98		Yes	No	1	pea fiber (10)
Product G	No	Canine	0.11	0.3	0.57	0.87		No	Met	0	
Product G	No	Canine	0.11	0.3	0.6	0.9		No	Met	0	
Product H	No	Canine	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
Product I	No	Canine	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
Product J	No	Both	0.19	0.46	0.6	1.06		Yes	No	2	pea protein (5), peas (9)
Product K	No	Feline	0.24	0.42	0.78	1.2		Yes	No	1	dried ground peas (12)
Product L	No	Feline	0.24	0.5	0.94	1.44		Yes	No	0	

- Other products (stars) with normal Met and Met-Cys % and are not supplemented with Met in the ingredients, like the low Tau product (red box). The non GF diet had a comparable # legume sources, but its only legume source was low on the ingredient list and contained less legume sources than the other starred GF products, respectively.
- The first starred product contains Brown Rice and Rice, so isn't grain free. But the dog in this case had DCM. Not much is known about the case.
- If the Met-Cys and Met % are normal, then something is causing the red box dog's low blood Tau. Are there problems with nutrient uptake b/c of the amount and/or number of legumes in the product?

Ingredient comparison

Product	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
Product A	Yes	Canine	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.14	0.28	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product B	Yes	Canine	0.12	0.36	0.69	1.05	unknown	No	★ No	0	
Product C	Yes	Canine	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
Product D	Yes	Canine	0.25	0.38	0.7	1.08	unknown	Yes	★ No	1	peas (4)
Product E	Yes	Canine	0.051	0.33	0.4	0.73	Low	No	★ No	6	peas (3), chickpeas (4), pea flour (5), red lentils (8), green lentils (9), pea protein (11)
Product F	No	Canine	0.22	0.32	0.66	0.98		Yes	★ No	1	pea fiber (10)
Product G	No	Canine	0.11	0.3	0.57	0.87		No	Met	0	
Product G	No	Canine	0.11	0.3	0.6	0.9		No	Met	0	
Product H	No	Canine	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
Product I	No	Canine	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
Product J	No	Both	0.19	0.46	0.6	1.06		Yes	No	2	pea protein (5), peas (9)
Product K	No	Feline	0.24	0.42	0.78	1.2		Yes	No	1	dried ground peas (12)
Product L	No	Feline	0.24	0.5	0.94	1.44		Yes	No	0	

The low Tau product may be a red herring/separate issue or a clue about how the legume may affect the product

NCSU ACVIM Abstract-Dr. Adin

Methods: *retrospective evaluation* of dogs diagnosed with DCM who had diet recorded in the last 2 years. Dogs were lumped into Grain-free (further subdivided into Brand XXXX and other) and Non-Grain free diets

Results: *-22 dogs ate grain free* (10 Brand XXXX, 7 of these were Kangaroo and Lentil). *Taurine testing in 11 of these dogs did not show deficiency* - carnitine testing in 4 did not show deficiency. Two sets of unrelated housemates were in this group.

-27 dogs ate non-grain free. Taurine testing in 11 of these and *5 were deficient (3 ate vegetarian diets)*

- Dogs eating Brand XXXX weighed less than the other groups (I interpret this to mean they are not the typical large breed DCM dog- 23 vs 35 kg P=0.03).

- Dogs eating Brand XXXX had bigger hearts in diastole and systole and a more spherical heart than 1) dogs eating other grain free diets and 2) dogs eating nongrain free diets (all statistically significant).

- Dogs eating Grain free diets as a group had bigger hearts in diastole and systole and more spherical hearts on echo than dogs eating nongrain free diets (all statistically significant)

- presence of CHF was not different between groups

Call with Cardiologists

Since the abstract:

- Dr. Adin has seen 36 DCM dogs on Grain Free diets.
- Taurine in 18 dogs was WNL.
 - The majority were supplemented.
- 7 were rechecked and *all* showed some improvement with *diet change*.
 - 1/7 not supplemented, only diet change:
 - not much echo change at 3 months but at 9 months had improved echo parameters.
 - 1/7 was changed to a Large Manufacturer Grain Free diet and had similar improvement to the dogs with diet change and Taurine supplementation at 3 months.

Call with Cardiologists

Since the abstract:

- Dr. Adin has seen 36 DCM dogs on Grain Free diets.
- Taurine levels were checked, but they may improve faster with Tau supplementation and diet change.
- 7 weeks with diet change had improved echo parameters.
- 1/7 was changed to a Large Manufacturer Grain Free diet and had similar improvement to the dogs with diet change and Taurine supplementation at 3 months.

GF Diet Ingredient comparison

Product	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
Product A	Yes	Canine	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.14	0.28	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product B	Yes	Canine	0.12	0.36	0.69	1.05	unknown	No	No	0	
Product C	Yes	Canine	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
Product D	Yes	Canine	0.25	0.38	0.7	1.08	unknown	Yes	No	1	peas (4)
Product E	Yes	Canine	0.051	0.33	0.4	0.73	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (3), green lentils (9), pea protein (11)
Product F	No	Canine	0.22	0.32	0.66	0.98		Yes	No	1	pea fiber (10)
Product G	No	Canine	0.11	0.3	0.57	0.87		No	Met	0	
Product G	No	Canine	0.11	0.3	0.5	0.9		No	Met	0	
Product H	No	Canine	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
Product I	No	Canine	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
Product J	No	Both	0.19	0.46	0.5	1.06		Yes	No	2	pea protein (5), peas (9)
Product K	No	Feline	0.24	0.42	0.78	1.2		Yes	No	1	dried ground peas (12)
Product L	No	Feline	0.24	0.5	0.94	1.44		Yes	No	0	

- Should we be looking at other dietary causes of DCM, whose GI uptake may be affected by these legume sources?
 - *Untested*: Thiamine, choline, erucic acid, vitamin E*, Polyunsaturated fatty acids*
 - Tested: Ca, Mg, P, Fe, Co, Cu, Zn, Se, Tau, Cys, Met, Iodine

*Courtesy Randall Lovell

GF Diet Ingredient comparison

Product	Grain free?	Species	Tau (%)	Cys (%)	Met (%)	Met-Cys (%)	Dog Tau level	Tau added to product?	Cys or Met added to product?	# Legume Sources	Names (place in ingredient list)
Product A	Yes	Canine	0.26	0.26	0.64	0.9	wnl (2)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.11	0.26	0.61	0.87	storebought	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product A	Yes	Canine	0.14	0.28	0.86	1.14	292 (wnl)	No	Met	4	red lentils (2), green lentils (3), peas (4), pea fiber (7)
Product B	Yes	Canine	0.12	0.36	0.69	1.05	unknown	No	No	0	
Product C	Yes	Canine	0.2	0.34	0.51	0.85	unknown	Yes	Met	4	peas (3), lentils (4), chickpeas (5), pea flour (14)
Product D	Yes	Canine	0.25	0.38	0.7	1.08	unknown	Yes	No	1	peas (4)
Product E	Yes	Canine	0.051	0.33	0.4	0.73	Low	No	No	6	peas (3), chickpeas (4), pea flour (5), red lentils (3), green lentils (9), pea protein (11)
Product F	No	Canine	0.22	0.32	0.66	0.98		Yes	No	1	pea fiber (10)
Product G	No	Canine	0.11	0.3	0.57	0.87		No	Met	0	
Product G	No	Canine	0.11	0.3	0.5	0.9		No	Met	0	
Product H	No	Canine	0.11	0.31	0.58	0.89		No	Met	1	green peas (22)
Product I	No	Canine	0.12	0.32	0.65	0.97		No	Met	1	green peas (20)
Product J	No	Both	0.19	0.46	0.5	1.06		Yes	No	2	pea protein (5), peas (9)
Product K	No	Feline	0.24	0.42	0.78	1.2		Yes	No	1	dried ground peas (12)
Product L	No	Feline	0.24	0.5	0.94	1.44		Yes	No	0	

B4 Grain Free diets have many more legume species and legume sources closer to the beginning of the ingredient list than Non-GF diets.

Questions

- Are there properties to these legumes affecting Cys or Met uptake or Tau synthesis in dogs causing DCM?

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Carey, Lauren; Palmer, Lee Anne; Queen, Jackie L
CC: Ceric, Olgica; Reimschuessel, Renate; Nemser, Sarah
Sent: 5/3/2018 4:34:39 PM
Subject: RE: 800.267-EON-345858-DCM Cluster

Thanks, everyone. We will do that!

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Thursday, May 03, 2018 12:34 PM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-EON-345858-DCM Cluster

Agreed!

From: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Date: May 3, 2018 at 12:26:29 PM EDT
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-EON-345858-DCM Cluster

Hi Jen,

I think: B5

Thanks,
Lauren

From: Jones, Jennifer L
Sent: Tuesday, May 01, 2018 9:06 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: 800.267-EON-345858-DCM Cluster

B4 I wonder about either B5
B5

B5

Thoughts?

Dave previously sent an email about lentils being deficient in Cystine and Methionine. I found the same information about peas (attached).

B5

B5

In chickens (Sarwar article), a Cys/Met ratio of 0.2 : 1 in low protein diets causes lower 2 wk weight gain, food intake, BUN, and taurine-conjugated bile acids in weanling rats.

B5

B5

In pigs, there is absolute methionine and cystine values but also the met : met+cys ratio is important. For pigs the ratio is between 30-70% but the Qiao says 54.15%. I wonder

B5

B5

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: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Jones, Jennifer L; Palmer, Lee Anne
Sent: 5/8/2018 3:03:27 PM
Subject: RE: DCM

Thank you Martine!!!!

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

B6

BB)



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!
Boorstin:

B6

https://www.cvcavets.com/doctor_directory/

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

B5

B5

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

B5

Looping in Jen.

Thanks for the update!

dave

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

B6



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the sender immediately at david.rotstein@fda.hhs.gov.

From: Hartogenesis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

B5

Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM

To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Subject: Re: DCM

Martine

Lee Anne

B6

B6

Vet-LIRN is looking into:

B6

B6

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Date: May 7, 2018 at 1:03:13 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogensis, Martine; Jones, Jennifer L; Palmer, Lee Anne
CC: Burkholder, William; Carey, Lauren; Norris, Anne; DeLancey, Siobhan
Sent: 5/9/2018 6:05:49 PM
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with [B4, B5] Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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

[B5]



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you, Len and Dave! Very interesting and sounds like you all are on it!

[B6]

[B6]

https://www.cvcavets.com/doctor_directory/

[B6]

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

B5

Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place

B5



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

Dave

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

Report Details - EON-303741

ICSR:	1063738
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Product Problem (an observed or detected product issue or defect that has the potential to cause harm)
Reporting Type:	Voluntary
Report Submission Date:	2017-03-02 09:54:35 EST

Reported Problem:	Problem Description:	A 3 year old spayed female whippet developed congestive heart failure in September 2015 and was treated with medications for congestive heart failure. She was evaluated by a veterinary cardiologist on 5/18/16 and findings consistent with dilated cardiomyopathy. Her housemate, a 4 year old castrated male whippet, developed congestive heart failure in April 2016 and was also evaluated on 5/18/16, and found to have dilated cardiomyopathy. Both dogs underwent blood testing for a heavy metal screen and were found to have increased total blood iron concentrations. Both dogs underwent MRI evaluation for heart and liver iron and were negative. The male dog died on [redacted] and his heart was evaluated by a pathologist at the [redacted] B6 School of Veterinary Medicine. The findings were typical of idiopathic dilated cardiomyopathy, and results of special stains for iron were negative. Both dogs had been fed the same dry food (Earthborn Primitive Natural) as their only diet since January, 2015 (9 months prior to the female developing congestive heart failure and [redacted] B4 months prior to the male developing congestive heart failure. A sample of the food was submitted for analysis for iron content through a commercial laboratory [redacted] B4 [redacted] B4 . The sample, taken from a bag of food purchased at a pet food center in [redacted] B6 in April 2016, showed an iron content of B6 mg/kg, which appears to be high, according to a veterinary nutritionist contacted.
	Date Problem Started:	09/01/2015

Product Information:	Product Name:	Earthborn Holistic Primitive Natural	
	Product Type:	Pet Food	
	Lot Number:	Lot Number:	M-2 L-1 B-11 N.W. 71452 Reg. No. II. PFO-0003 1830
		Expiration Date:	08/18/2017
	UPC:	3484671452	
	Package Type:	BAG	
	Package Size:	12.7 kilogram	
	Purchase Date:	04/01/2016	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Product Use Information:		
	Manufacturer /Distributor Information:	Name:	Midwestern Pet Foods, Inc.
		Type(s):	Manufacturer
		Address:	Evansville Indiana 47725 United States
Contact:		Phone:	(800) 474-4163
		Web Address:	earthbornholisticpetfood.com
Possess One or More Labels from This Product:	Yes		
Purchase Location Information:	Name:	a "pet food center"	

		Address: United States	
Animal Information:	Name:		
	Owner Information:	Owner Information provided: Yes	
	Contact:	Name: B6	
		Phone: B6	
Email: B6			
	Address: B6		
	Healthcare Professional Information:		
Sender Information:	Name:	B6	
	Address:	B6	
	Contact:	Phone:	B6
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	Other		
Additional Documents:	Attachment:	EarthbornPrimitive Analysis 2016.pdf	
	Description:	"as Fed" food analysis for iron	
	Type:	Analysis	

Report Details - EON-303743

ICSR:	1063739
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Product Problem (an observed or detected product issue or defect that has the potential to cause harm)
Reporting Type:	Voluntary
Report Submission Date:	2017-03-02 09:58:27 EST
Initial Report Date:	03/02/2017
Parent ICSR:	1063738
Follow-up Report to FDA Request:	Yes

Reported Problem:	<p>Problem Description: A 3 year old spayed female whippet developed congestive heart failure in September 2015 and was treated with medications for congestive heart failure. She was evaluated by a veterinary cardiologist on 5/18/16 and findings consistent with dilated cardiomyopathy. Her housemate, a 4 year old castrated male whippet, developed congestive heart failure in April 2016 and was also evaluated on 5/18/16, and found to have dilated cardiomyopathy. Both dogs underwent blood testing for a heavy metal screen and were found to have increased total blood iron concentrations. Both dogs underwent MRI evaluation for heart and liver iron and were negative. The male dog died on B6 and his heart was evaluated by a pathologist at the B6 School of Veterinary Medicine. The findings were typical of idiopathic dilated cardiomyopathy, and results of special stains for iron were negative. Both dogs had been fed the same dry food (Earthborn Primitive Natural) as their only diet since January, 2015 (9 months prior to the female developing congestive heart failure and 15 months prior to the male developing congestive heart failure. A sample of the food was submitted for analysis for iron content through a commercial laboratory B4. B4 The sample, taken from a bag of food purchased at a pet food center in B6 showed an iron content of B6 mg/kg, which appears to be high, according to a veterinary nutritionist contacted.</p> <p>Date Problem Started: 09/01/2015</p>
--------------------------	--

Product Information:	<p>Product Name: Earthborn Holistic Primitive Natural</p> <p>Product Type: Pet Food</p> <p>Lot Number: Lot Number: M-2 L-1 B-11 N.W. 71452 Reg. No. II. PFO-0003 1830 Expiration Date: 08/18/2017</p> <p>UPC: 3484671452</p> <p>Package Type: BAG</p> <p>Package Size: 12.7 kilogram</p> <p>Purchase Date: 04/01/2016</p> <p>Number Purchased: 1</p> <p>Possess Unopened Product: No</p> <p>Possess Opened Product: Yes</p> <p>Product Use Information:</p> <p>Manufacturer /Distributor Information: Name: Midwestern Pet Foods, Inc. Type(s): Manufacturer Address: Evansville Indiana 47725 United States Contact: Phone: (800) 474-4163 Web Address: earthbornholisticpetfood.com</p>
-----------------------------	---

		Possess One or More Labels from This Product:	Yes
	Purchase Location Information:	Name:	a "pet food center"
		Address:	United States
Animal Information:	Name:		
	Owner Information:	Owner Information provided:	Yes
		Contact: Name:	B6
		Phone:	
		Email:	
		Address:	B6
	Healthcare Professional Information:		
Sender Information:	Name:		
	Address:	B6	
	Contact: Phone:	B6	
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	
Additional Documents:			

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Palmer, Lee Anne; Jones, Jennifer L; Queen, Jackie L; Carey, Lauren
CC: Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah
Sent: 5/4/2018 3:58:42 PM
Subject: RE: DCM cases-food-Iodine screening results

Lee Anne

This is excellent. Based on what is found moving forward, do you think

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 4, 2018 at 11:15:20 AM EDT

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: DCM cases-food-Iodine screening results

Grain-free does seem to be a problem. I'm going to attach 2 reports from earlier 2017 (illnesses back in 2015) which kind of pre-date this issue a bit. 2 Whippets from the same household seen at B6. You probably recall these, but at the time, they didn't get further f/u. Earthborn Holistic Primitive Naturals is a grain-free food. Iron levels were elevated in this set of 2 cases, same household. DCM cases, young dogs.

I am pulling all the cases (the added ones) into one spreadsheet

B5

B5

I am ready to go with some other analyses – I feel like I work like molasses some days. Have this afternoon, so still working on some stats for these cases.

B6

From: Jones, Jennifer L

Sent: Friday, May 4, 2018 10:35 AM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: DCM cases-food-Iodine screening results

Yes. I'm going to test some non grain free foods to see how their met/cys ratios compare to these GF foods.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Palmer, Lee Anne

Sent: Friday, May 04, 2018 10:21 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

B5

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 10:04 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

There is no minimum for dogs...it is apparently a conditionally essential amino acid because dogs can make it from methione and cystine.

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Palmer, Lee Anne
Sent: Friday, May 04, 2018 10:01 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

Interesting... so the AAFCO minimum for cats is 0.1% DMB, is there a DMB for dogs? (If not, maybe there should be...)

From: Jones, Jennifer L
Sent: Friday, May 4, 2018 9:46 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: DCM cases-food-Iodine screening results

One more nutritional deficiency-Taurine low based on AAFCO's Feline Minimum for Extruded foods. The dog consuming the product had a low whole blood Taurine level.

- Taurine = 45.5 mg/100g = 0.0455g/100g = 0.046% As Is Basis
If we assume a max of 10% moisture per the label (= 90% DMB),
then $0.0455 / 0.90 = 0.05\%$ DMB, which is less than the AAFCO minimum for cats eating extruded foods (0.1% DMB.)
- Cystine = 293 mg/100g = 0.293 g/100g = 0.29% As Is Basis
If we assume a max of 10% moisture per the label (= 90% DMB), then $0.293 / 0.90 = 0.33\%$ DMB
- Methionine = 358mg/100g = 0.358 g/100g = 0.36% As Is Basis

If we assume

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Jones, Jennifer L
Sent: Monday, April 23, 2018 10:32 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: DCM cases-food-Iodine screening results

FYI-

B5

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: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Rotstein, David; Palmer, Lee Anne; Hartogensis, Martine; Jones, Jennifer L
CC: Burkholder, William; Norris, Anne; DeLancey, Siobhan
Sent: 5/11/2018 10:12:19 AM
Subject: RE: DCM and meetign with Cardiac Care for Pets
Attachments: Infographic novel pet food proteins _ PetfoodIndustry.com - 5-11-2018.pdf

Thought this was interesting in the wake of our discussions.

B5

B5

From: Rotstein, David
Sent: Wednesday, May 09, 2018 4:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
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Subject: RE: DCM and meetign with Cardiac Care for Pets

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I want to confirm it, then will send it along – could be Friday before I get this in shape to send... not to leave you hanging, but wanted to be more sure. Definitely, not done today as I'd thought. Thanks!

From: Hartogensis, Martine
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Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L

<Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with **B5, B6** Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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

B5 (BB)



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From: Hartogenesis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!

B6

B6

https://www.cvcavets.com/doctor_directory/

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

B5

Looping in Jen.

Thanks for the update!

dave

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

B5



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Subject: RE: DCM

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Palmer, Lee Anne; Hartogensis, Martine; Jones, Jennifer L
CC: Burkholder, William; Carey, Lauren; Norris, Anne; DeLancey, Siobhan; Lovell, Randall A
Sent: 5/11/2018 8:14:20 PM
Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic

B5

B5

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Hi there –

B5

B5

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

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Subject: RE: DCM and meetign with Cardiac Care for Pets

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To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
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Martine

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Good Afternoon,

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Just some basic information:

[B5]

As a side note, there is a facebook page dedicated to this issue:

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

[B6]



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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>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was [B6]

https://www.cvcavets.com/doctor_directory/b [B6]

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
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Subject: RE: DCM

Martine,

B5

Looping in Jen.

Thanks for the update!

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
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7519 Standish Place

B6



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Dave

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To: Palmer, Lee Anne; Hartogensis, Martine; Jones, Jennifer L
CC: Burkholder, William; Carey, Lauren; Norris, Anne; DeLancey, Siobhan; Lovell, Randall A
Sent: 5/11/2018 9:41:19 PM
Subject: RE: DCM and meetign with Cardiac Care for Pets

I'll be sending out the invite shortly. Feel free to forward it on.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 11, 2018 at 4:30:16 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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>
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Martine

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David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison

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B6



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Subject: RE: DCM

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https://www.cvcavets.com/doctor_directory

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Keep us posted!

Thanks again!

Martine

Hi Martine,

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Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



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Subject: RE: DCM

Martine,

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Looping in Jen.

Thanks for the update!

dave

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

B6



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From: Hartogensis, Martine

Sent: Tuesday, May 08, 2018 9:00 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

B5

Martine

From: Rotstein, David

Sent: Monday, May 07, 2018 1:13 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Re: DCM

Martine

Lee Anne will likely [redacted B5] But it does [redacted B5]
[redacted B5]

Vet-LIRN is looking into [redacted B5]
[redacted B5]

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Palmer, Lee Anne; Rotstein, David; Jones, Jennifer L
CC: Burkholder, William; Carey, Lauren; Norris, Anne; DeLancey, Siobhan; Lovell, Randall A
Sent: 5/14/2018 1:09:15 PM
Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting.

B5

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Martine

From: Palmer, Lee Anne
Sent: Friday, May 11, 2018 4:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David
Sent: Friday, May 11, 2018 4:14 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic.

B5

I think this

B5

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@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: RE: DCM and meetign with Cardiac Care for Pets

Hi there

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B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

B5 I want to confirm it, then will send it along – could be Friday before I get this in shape to send...not to leave you hanging, but wanted to be more sure. Definitely, not done today as I'd thought. Thanks!

From: Hartogensis, Martine

Sent: Wednesday, May 9, 2018 2:17 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>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David

Sent: Wednesday, May 09, 2018 2:06 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with **B6** @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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

7519 Standish Place

B6



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From: Hartogenesis, Martine

Sent: Tuesday, May 08, 2018 10:58 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was

B6

https://www.cvcavets.com/doctor_directory

B6

Keep us posted!

Thanks again!

Martine

Hi Martine.

B5

I'm happy to share more info as needed.

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

B5

Looping in Jen.

Thanks for the update!

dave

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

B6



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From: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

B5

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>
Date: May 7, 2018 at 1:03:13 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Putnam, Juli; Hartogensis, Martine; Palmer, Lee Anne; DeLancey, Siobhan; Norris, Anne; Forfa, Tracey; Rotstein, David; Jones, Jennifer L
Sent: 7/18/2018 7:41:18 PM
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi Juli,

Sorry, so many emails that things are getting buried.

B5

B5

Thanks,
Lauren

From: Putnam, Juli
Sent: Wednesday, July 18, 2018 2:54 PM
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

Hi all, can you please confirm

B5

B5

Thanks!

Best,
Juli

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

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

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.

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

Proposed response:

B5

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>

Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Hi,

B5

Thanks,
Lauren

From: Putnam, Juli

Sent: Friday, July 13, 2018 9:04 AM

To: Hartogenesis, Martine <Martine.Hartogenesis@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>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Bloomberg News inquiry re: Dog Food causing canine heart disease - Deadline: ASAP

Thanks, everyone [redacted] B5
[redacted] B5 See the draft proposed response below for your review.

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?

Proposed response:

B5

From: Hartogenesis, 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! [redacted] B6

From: Palmer, Lee Anne
Sent: Thursday, July 12, 2018 6:20 PM
To: Hartogenesis, Martine <Martine.Hartogenesis@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

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: July 12, 2018 at 6:16:01 PM EDT
To: Hartogenesis, Martine <Martine.Hartogenesis@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 [redacted] B5 to date . Can't see whole steam - will send them read all

From: Hartogenesis, Martine <Martine.Hartogenesis@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 ab

B5

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>, Hartogenesis, Martine <Martine.Hartogenesis@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>; Hartogenesis, Martine <Martine.Hartogenesis@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

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

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:

- Were the foods from several brands or from one brand of dog food? Can you name the companies that produced the foods linked to the reports, and which foods exactly the dogs ate? Was there one particular food brand that was heavily linked to the unusual reports?

B5

- How many of those unusual reports have you received so far? Can you give us a number of the dogs affected, to FDA knowledge?
CVM, please advise.