

---

**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** Rotstein, David; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Ceric, Olgica  
**CC:** Norris, Anne; DeLancey, Siobhan  
**Sent:** 4/13/2018 1:06:07 PM  
**Subject:** FYI-FW: Call to discuss DCM cases

I'll keep everyone posted about a time for the meeting.

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



**From:** Jones, Jennifer L  
**Sent:** Friday, April 13, 2018 9:05 AM  
**To:** 'Darcy Adin' <dbadin@ncsu.edu>  
**Subject:** Call to discuss DCM cases

Good morning Darcy,  
I hope you're well. Are you able to chat more about the DCM cases from dogs eating grain free food that the cardiology community is seeing? I'd like to schedule a call with you and some of your colleagues who are also following the issue. I'd like to gather more information about the clinical findings and your ideas on what could be the cause. Do you have any contacts with Dr. Joshua Stern or other clinical research cardiologists that could provide additional information following this issue? I can include them on the call.

Thank you in advance for your time, and 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](mailto:jennifer.jones@fda.hhs.gov)  
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** 'Darcy Adin'  
**CC:** Rotstein, David; Norris, Anne; DeLancey, Siobhan  
**Sent:** 4/16/2018 1:48:17 PM  
**Subject:** RE: Call to discuss DCM cases

Yes, I can do 2 pm.

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



**From:** Darcy Adin [mailto:dbadin@ncsu.edu]  
**Sent:** Monday, April 16, 2018 9:43 AM  
**To:** 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:** Re: Call to discuss DCM cases

Thank you Jennifer. I will reach out to them to ask them to see if they are interested. Would it be possible to meet a bit earlier on thursday (say 2pm?)

Thanks!

Darcy

On Mon, Apr 16, 2018 at 8:20 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy.

Would you be available Thursday at 3pm eastern? If Dr. Freeman or any of the other cardiologists you mentioned below are interested, they can join the call as well.

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



**From:** Darcy Adin [mailto:dbadin@ncsu.edu]  
**Sent:** Friday, April 13, 2018 12:31 PM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** Re: Call to discuss DCM cases

Hi Jennifer,

Definitely! I'd love to chat more. I have not talked with Dr. Stern in a while but I can certainly reach out to him.

**B5, B6**

**B6**

Dr. Lisa Freeman (nutritionist at Tufts) and indirectly Dr. Ryan Fries at Illinois (he has

**B5**

I am free next week to chat wed-fri. Let me know how you would like to proceed - thank you!

Darcy

On Fri, Apr 13, 2018 at 9:05 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:

Good morning Darcy,

I hope you're well. Are you able to chat more about the DCM cases from dogs eating grain free food that the cardiology community is seeing? I'd like to schedule a call with you and some of your colleagues who are also following the issue. I'd like to gather more information about the clinical findings and your ideas on what could be the cause. Do you have any contacts with Dr. Joshua Stern or other clinical research cardiologists that could provide additional information following this issue? I can include them on the call.

Thank you in advance for your time, and 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](mailto:jennifer.jones@fda.hhs.gov)  
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



--

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

--

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:** Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)>  
**To:** Jones, Jennifer L  
**Sent:** 4/18/2018 10:58:16 AM  
**Subject:** Re: hold-call with Dr. Adin re: DCM cases

Great! I will poll the group and got back to you

On Apr 18, 2018, at 6:46 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:

Good morning Darcy,  
If Friday works best for the group, we can be available between 11 to 3pm eastern.  
Jen

Jennifer Jones, DVM  
Veterinary Medical Officer  
Tel: 240-402-5421  
<[image001.png](#)> <[image002.png](#)>

**From:** Darcy Adin [<mailto:dbadin@ncsu.edu>]  
**Sent:** Tuesday, April 17, 2018 5:18 PM  
**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Subject:** Re: hold-call with Dr. Adin re: DCM cases

**B6** is free friday as well. If this works for you then I'll poll the others!

On Tue, Apr 17, 2018 at 5:16 PM, Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)> wrote:  
I will!

I haven't heard from her but Drs. Freeman and **B6** can't easily do thursday afternoon. I'm sure there is not going to be a time that is good for everyone but I would love for her to participate. She would be available earlier on thursday (before 11) but not sure if that will work for Dr. Stern on the west coast (I can ask if this is good for you) or friday except over lunch.

Would either of these options work for your team?  
Take care  
Darcy

On Tue, Apr 17, 2018 at 8:47 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:  
Thank you, Darcy.  
I hope **B6** can join. I haven't talked with her in many years. **B6**

Jennifer Jones, DVM  
Veterinary Medical Officer  
Tel: 240-402-5421  
<[image001.png](#)> <[image005.png](#)>

**From:** Darcy Adin [<mailto:dbadin@ncsu.edu>]  
**Sent:** Tuesday, April 17, 2018 8:38 AM  
**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Subject:** Re: hold-call with Dr. Adin re: DCM cases

Thank you Jennifer. I will forward this on to Drs. Freeman (nutritionist at Tufts), Fries (cardiologist at Illinois) and [redacted] B5, B6 I am still waiting to hear back from [redacted] B5, B6 and [redacted] B5, B6  
Take care  
Darcy

On Apr 17, 2018, at 7:53 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:

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

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<mime-attachment.ics>

--

Darcy B. Adin, DVM, DACVIM (Cardiology)  
Clinical Assistant Professor of Cardiology  
North Carolina State University  
NC State Veterinary Hospital  
1060 William Moore Drive  
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**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** 'Darcy Adin'; 'Freeman, Lisa'; 'Joshua A Stern'; 'Fries, Ryan C'; [REDACTED] B6  
**CC:** Rotstein, David; Norris, Anne; DeLancey, Siobhan; Ceric, Olgica  
**Sent:** 4/20/2018 7:50:20 PM  
**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 you can just email me a spreadsheet with the data.

[REDACTED] B5

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 <jstern@ucdavis.edu>; Fries, Ryan C <rfries@illinois.edu>; [REDACTED] B6  
[REDACTED] 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

[REDACTED] B5

[REDACTED] B5

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 <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. **B6** Freema **B6** Fries and Stern - the call details are in the forwarded email below.

Just a brief introduction for the FDA group:

**B6**

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

**B6**

Dr. Ryan Fries is a Clinical Assistant Professor of Cardiology at Illinois, College of Vet Med

Dr. Josh Stern is an Associate Professor of Cardiology at UC Davis, College of Vet Med

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

Sincerely,  
Darcy Adin

----- Forwarded message -----

From: **Jones, Jennifer L** <[Jennifer.Jones@fda.hhs.gov](mailto: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](mailto:David.Rotstein@fda.hhs.gov)>, "Norris, Anne" <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>, "DeLancey, Siobhan" <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>, Darcy Adin <[dbadin@ncsu.edu](mailto: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



**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** 'Freeman, Lisa'  
**Sent:** 4/23/2018 7:22:37 PM  
**Subject:** RE: hold-call with Dr. Adin re: DCM cases

Thank you, Lisa.

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



**From:** Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]  
**Sent:** Monday, April 23, 2018 8:37 AM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** RE: hold-call with Dr. Adin re: DCM cases

Dear Jennifer

**B5**

Please let me know if you need additional info  
Thanks for your work on this issue.  
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](http://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](mailto:dbadin@ncsu.edu)>; Freeman, Lisa <[Lisa.Freeman@tufts.edu](mailto:Lisa.Freeman@tufts.edu)>; Joshua A Stern <[jstern@ucdavis.edu](mailto:jstern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>; **B6**

**B6**

**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Ceric, Olgica <[Olgica.Ceric@fda.hhs.gov](mailto:Olgica.Ceric@fda.hhs.gov)>  
**Subject:** RE: hold-call with Dr. Adin re: DCM cases  
**Importance:** High

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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](mailto:dbadin@ncsu.edu)>; Freeman, Lisa <[lisa.freeman@tufts.edu](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[jstern@ucdavis.edu](mailto:jstern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>; [REDACTED] **B6**

[REDACTED] **B6**

**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>; Ceric, Olgica <[Olgica.Ceric@fda.hhs.gov](mailto: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, [REDACTED] **B5**

**B5**

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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](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[jstern@ucdavis.edu](mailto:jstern@ucdavis.edu)>; Fries, Ryan C <[rfries@illinois.edu](mailto:rfries@illinois.edu)>; [REDACTED] **B6** [REDACTED] **B6**

Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Cc:** Rotstein, David <[David.Rotstein@fda.hhs.gov](mailto:David.Rotstein@fda.hhs.gov)>; Norris, Anne <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>; DeLancey, Siobhan <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>  
**Subject:** Fwd: hold-call with Dr. Adin re: DCM cases

Dear Dr. Jones,

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

Just a brief introduction for the FDA group:

[REDACTED] **B6**

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**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](mailto: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](mailto:David.Rotstein@fda.hhs.gov)>, "Norris, Anne" <[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)>, "DeLancey, Siobhan" <[Siobhan.Delancey@fda.hhs.gov](mailto:Siobhan.Delancey@fda.hhs.gov)>, Darcy Adin <[dbadin@ncsu.edu](mailto: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

---

**From:** Darcy Adin <dbadin@ncsu.edu>  
**To:** Jones, Jennifer L  
**CC:** Freeman, Lisa; Joshua A Stern <[REDACTED]> Rotstein, David  
**Sent:** 8/16/2018 12:49:22 PM  
**Subject:** Re: a few NCSU cases

Thanks Jennifer!

On Thu, Aug 16, 2018 at 8:13 AM, Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)> wrote:

Good morning everyone,

Here's our Vet-LIRN rapid necropsy document.

Take care,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



**From:** Jones, Jennifer L  
**Sent:** Wednesday, August 15, 2018 2:49 PM  
**To:** 'Freeman, Lisa' <[Lisa.Freeman@tufts.edu](mailto:Lisa.Freeman@tufts.edu)>; Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)>

**Cc:** Joshua A Stern <[jstern@ucdavis.edu](mailto:jstern@ucdavis.edu)> <[REDACTED]> **B6**  
**Subject:** RE: a few NCSU cases

Thank you, Darcy! We'll be on the lookout for the cases.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



**From:** Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]

**Sent:** Wednesday, August 15, 2018 8:50 AM

**To:** Darcy Adin <dbadin@ncsu.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

**Cc:** Joshua A Stern <jstern@ucdavis.edu>

B6

**Subject:** RE: a few NCSU cases

That's really interesting, Darcy!

I wonder

B5

Thanks for sharing

Lisa

**From:** Darcy Adin <dbadin@ncsu.edu>

**Sent:** Tuesday, August 14, 2018 8:00 PM

**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

**Cc:** Freeman, Lisa <lisa.freeman@tufts.edu>; Joshua A Stern <jstern@ucdavis.edu>

B6

B6

**Subject:** a few NCSU cases

Hi Jennifer,

I wanted to follow up on the case where NCSU sent you necropsy samples (B6 3 yr Fs Great Dane). I've attached her whole blood and plasma taurine concentrations for your records, which were normal.

One of my residents saw a littermate pair of Dobermans back for their 3 month recheck after being diagnosed with DCM while eating Acana. Taurines were normal on these dogs back in April and I honestly didn't have a ton of hope for these dogs (B6) because they were dobermans and their genetic tests were abnormal (the female is homozygous positive for one mutation and negative for a 2nd, the male was heterozygous positive for one mutation and negative for a 2nd). But, 3 months after a diet change to Purina grain-based (and no taurine supplementation), they both have shown significant improvement (the less severely affected female has near normalized and the severely affected male (who was in heart failure) has also significantly improved.

I have asked our resident to report these dogs to the FDA using the portal (B6) so hopefully you will see these soon. She will also be submitting a taurine deficient Golden eating Acana (B6 maybe the lowest I've ever seen).

Thank you!

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

--

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:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Jones, Jennifer L; Darcy Adin  
**CC:** Joshua A Stern; [REDACTED] Rotstein, David  
**Sent:** 8/16/2018 6:17:49 PM  
**Subject:** RE: a few NCSU cases

Hi Jen

[REDACTED] **B5**

Just want to be sure we get what you're

looking for.

We appreciate your putting this together. This will be helpful

Thanks

Lisa

**From:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Sent:** Thursday, August 16, 2018 8:13 AM  
**To:** Freeman, Lisa <lisa.freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>  
**Cc:** Joshua A Stern <jstern@ucdavis.edu>; [REDACTED] Rotstein, David  
<David.Rotstein@fda.hhs.gov>  
**Subject:** RE: a few NCSU cases

Good morning everyone,  
Here's our Vet-LIRN rapid necropsy document.  
Take care,  
Jen

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



**From:** Jones, Jennifer L  
**Sent:** Wednesday, August 15, 2018 2:49 PM  
**To:** 'Freeman, Lisa' <Lisa.Freeman@tufts.edu>; Darcy Adin <dbadin@ncsu.edu>  
**Cc:** Joshua A Stern <jstern@ucdavis.edu>; [REDACTED]  
**Subject:** RE: a few NCSU cases

Thank you, Darcy! We'll be on the lookout for the cases.

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



**From:** Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]  
**Sent:** Wednesday, August 15, 2018 8:50 AM  
**To:** Darcy Adin <dbadin@ncsu.edu>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Cc:** Joshua A Stern <jstern@ucdavis.edu>; [REDACTED]  
**Subject:** RE: a few NCSU cases

That's really interesting, Darcy!

I wonder [REDACTED]

**B5**

Thanks for sharing

Lisa



**From:** Darcy Adin <[dbadin@ncsu.edu](mailto:dbadin@ncsu.edu)>

**Sent:** Tuesday, August 14, 2018 8:00 PM

**To:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>

**Cc:** Freeman, Lisa <[lisa.freeman@tufts.edu](mailto:lisa.freeman@tufts.edu)>; Joshua A Stern <[istern@ucdavis.edu](mailto:istern@ucdavis.edu)>; [REDACTED] B6

[REDACTED] B6

**Subject:** a few NCSU cases

Hi Jennifer,

I wanted to follow up on the case where NCSU sent you necropsy samples [REDACTED] B6 3 yr Fs Great Dane). I've attached her whole blood and plasma taurine concentrations for your records, which were normal.

One of my residents saw a littermate pair of Dobermans back for their 3 month recheck after being diagnosed with DCM while eating Acana. Taurines were normal on these dogs back in April and I honestly didn't have a ton of hope for these dogs [REDACTED] B6 because they were dobermans and their genetic tests were abnormal (the female is homozygous positive for one mutation and negative for a 2nd, the male was heterozygous positive for one mutation and negative for a 2nd). But, 3 months after a diet change to Purina grain-based (and no taurine supplementation), they both have shown significant improvement (the less severely affected female has near normalized and the severely affected male (who was in heart failure) has also significantly improved.

I have asked our resident to report these dogs to the FDA using the portal [REDACTED] B6 hopefully you will see these soon. She will also be submitting a taurine deficient Golden eating Acana [REDACTED] B6 maybe the lowest I've ever seen).

Thank you!  
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

Owner: **B6**

Accession Number: **B6**

Reference Number:

Case Coordinator: **B6**

Received: **B6**

Finalized: **B6**

Sampled:

To: **B6**

Phone #: **B6**

Addended Report

ANATOMIC PATHOLOGY RESULTS

SMALLANIMAL NECROPSY

ANIMAL ID **B6**

REF CASE NO 212267

SPECIES Canine

BREED Schnauzer

SEX Mc

AGE 3y

SPECIMEN DESC Body

GROSS An 8.2 kg, 2.5-year-old, castrated male miniature schnauzer dog is presented for postmortem examination. The animal was euthanized and the body is in fair postmortem condition with a euthanasia?to?necropsy interval of approximately 16 hours. **B6**

**B6**

**B6**

**B6** The heart is subjectively enlarged. **B6**

**B6**

Addended Report

Accession Number: **B6**

ANATOMIC PATHOLOGY RESULTS

**B6**

GROSS DIAGNOSIS

**B6**

2. Heart: mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation

**B6**

REPORT STATUS  
COMMENTS

PRELIMINARY REPORT-HISTOLOGY PENDING

Except for gross evidence of moderate to marked pulmonary edema and mild cardiac changes, gross examination is otherwise mostly unremarkable. The heart is mildly enlarged with mild mitral valve endocardiosis and associated mild left atrial dilation and left ventricular hypertrophy. This mild degree of cardiac changes does not fit well with the moderate to severe degree of pulmonary edema present. In addition to the mild structural changes, a functional cardiac abnormality may have been contributing to clinical disease in this patient. Samples of lung and heart were rushed and examined histologically. In addition to the pulmonary edema, there is also histologic evidence of diffuse, acute alveolar injury. These pulmonary changes can explain this patient's signs of respiratory distress. However, the heart is histologically unremarkable and the skeletal muscle was grossly unremarkable; as such, a cause for the markedly elevated CK is not yet identified. Histology of skeletal muscle is pending.

PATH RESIDENT  
SENIOR PATH  
DATE

**B6**

Final Necropsy Report  
MICROSCOPIC

**B6**

Addended Report

Accession Number: **B6**

ANATOMIC PATHOLOGY RESULTS

**B6**

Heart (slide 1), Skeletal muscle (slide 3), Kidneys (slide 3), Spleen (slide 3), Stomach (slide 4), Small intestine (slide 4), Colon (slide 4), Pancreas (slide 4), Adrenal gland (slide 4); **B6**

**B6**

FINAL DIAGNOSIS

**B6**

2. Heart: mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation

**B6**

COMMENTS

Histology reveals:

**B6**

**B6**

PATH RESIDENT  
SENIOR PATH  
FINALIZED DATE

**B6**

### NECROPSY REPORT FINAL REPORT

Animal ID: EON-361684  
 Accession Number: **B6**  
 Species: Canine  
 Date: (DON)  
 Sex, Age Class: UNK, Mature  
 Body Condition: Good  
 Condition at Investigation: Alive, Euthanized  
 Carcass Disposition/Post-Mortem Interval: ~5 minutes

#### ANCILLARY FINDINGS

| Test | Test Sample | Result | Comment |
|------|-------------|--------|---------|
|      |             |        |         |
|      |             |        |         |
|      |             |        |         |

#### TISSUES/SAMPLES RECEIVED

On 1 November 2018, cardiac measurements and sampling was conducted. Representative sections were placed in Cassettes #1-16. In addition, non-cardiac tissues were received, and representative sections were placed in Cassettes A-F. Received 7 February 2019 are 22 H&E slides. Letters or numbers in parentheses correspond to the slide number.

#### MICROSCOPIC DESCRIPTION

*Tissue Preservation:* Good

Respiratory System

**B6**

Hematolymphatic System

**B6**

Hepatobiliary System

**B6**

Integumentary System/Musculoskeletal System:

**B6**

Urogenital System:

**B6**

Digestive System:

**B6**

Cardiovascular System:

**B6**

B6

**B6**

Nervous System:

B6

Endocrine System:

B6

Sensory System:

**B6**

Body as a Whole:

Tissues with No Significant Histologic Findings:

B6

B6

**MORPHOLOGICAL DIAGNOSES**

Respiratory System

**B6**

Hematolymphatic System

**B6**

Hepatobiliary System

**B6**

Nervous System:

**B6**

Integumentary System/Musculoskeletal System:

**B6**

Urogenital System:

**B6**

Endocrine System:

**B6**

Digestive System:

**B6**

Cardiovascular System:

A. Heart:

- a. Atria and Ventricles: Cardiomyocyte attenuation (atrophy) and degeneration, diffuse, moderate with fatty infiltration, lymphocytic and histiocytic myocarditis, fibrosis (endocardial), wavy fibers, and edema.
- b. Left Atrioventricular Valve: Valvular endocardiosis, moderate.
- c. Arterial intimal cushions, multifocal, mild.

Sensory System:

**B6**

Body Cavity

**B6**



**FINAL DIAGNOSES/INTERPRETATIVE SUMMARY**

| <b>Diagnosis</b>                   |
|------------------------------------|
| Cardiomyopathy                     |
| Hepatic Chronic Passive Congestion |
| Interstitial Nephritis, MIId       |
|                                    |
|                                    |

Linked Cases: NA

Grossly, there was remarkable biventricular dilation and left atrial dilation. There was flattening of the ventricular endocardial surface as well as left atrioventricular valvular endocardiosis. Histopathologic finding were remarkable and including atrophy, degeneration, interstitial edema, inflammation, and fibrosis. These findings are consistent with a cardiomyopathy, specifically, a dilated cardiomyopathy. Though there was fatty infiltration in the right ventricle, the overall pattern of wavy fibers and degeneration are most aligned with an “attenuated wavy fiber” type of DCM.<sup>1</sup> Adin et al. (2019) proposed echocardiographic phenotypical differences based on diet type.<sup>2</sup> The role of taurine, diet, and breed are under continual and current investigation.

**RECOMMENDED TESTS**

| <b>TEST</b> | <b>PURPOSE</b> | <b>SITE</b> | <b>RESULT</b> |
|-------------|----------------|-------------|---------------|
|             |                |             |               |
|             |                |             |               |

|                   |   |
|-------------------|---|
| DATE:<br>3/1/2019 | REPORTING PATHOLOGIST:<br>David S. Rotstein, DVM, MPVM, DACVP |
|-------------------|---|

<sup>1</sup> Tidholm A and Jonsson L. 2005. Vet Pathol 42: 1-8.  
<sup>2</sup> Adin D et al. 2019. J Vet Cardiol Feb;21:1-9. doi: 10.1016/j.jvc.2018.11.002. Epub 2018 Dec 5.

**FIGURES**

No Figures

### NECROPSY REPORT FINAL REPORT

Animal ID: EON-362158  
 Accession Number: **B6**  
 Species: Canine  
 Date: **B6** (DON)  
 Sex, Age Class: M, Adult  
 Body Condition: Good  
 Condition at Investigation: Alive, Euthanized  
 Carcass Disposition/Post-Mortem Interval: ~5 minutes

#### GROSS FINDINGS/HISTORICAL FINDINGS

- DILATED CARDIOMYOPATHY (chronic congestive heart failure); heart 1.9% BW
- ABDOMINAL EFFUSION (MILD)
- GASTRITIS
- HEPATIC FIBRINOUS CAPSULITIS
- SPLENIC SIDEROCALCIFIC PLAQUES
- ABDOMINAL EFFUSION (~30.0 ML)
- UNDERWEIGHT (cachexia)

#### ANCILLARY FINDINGS

| Test | Test Sample | Result | Comment |
|------|-------------|--------|---------|
|      |             |        |         |
|      |             |        |         |
|      |             |        |         |

#### TISSUES/SAMPLES RECEIVED

On 30 November 2018, cardiac measurements and sampling was conducted. Representative sections were placed in Cassettes #1-17. In addition, non-cardiac tissues were received, and representative sections were placed in Cassettes A-F. Received 7 February 2019 are 23 H&E slides. Letters or numbers in parentheses correspond to the slide number.

#### MICROSCOPIC DESCRIPTION

*Tissue Preservation:* Good

##### Respiratory System

**B6**

**B6**

**B6**

Hematolymphatic System

**B6**

Hepatobiliary System

**B6**

Integumentary System/Musculoskeletal System:

**B6**

Urogenital System:

**B6**

Digestive System:

**B6**

Cardiovascular System:

**B6**

**B6**

Other:

**B6**

Nervous System:

**B6**

Endocrine System:

**B6**

Sensory System:

**B6**

Body as a Whole:

Tissues with No Significant Histologic Findings:

**B6**

**B6**

MORPHOLOGICAL DIAGNOSES

Respiratory System

B6

Hematolymphatic System

B6

Hepatobiliary System

B6

Nervous System:

B6

Integumentary System/Musculoskeletal System:

B6

Urogenital System:

B6

Endocrine System:

B6

Digestive System:

B6

Cardiovascular System:

A. Heart

- a. Cardiomyocyte attenuation (atrophy), multifocal, mild to moderate with Anitschkow cells, fibrosis, interstitial edema, cardiomyocyte degeneration, and perinuclear ceroid-lipofuscinosis ("wear and tear" pigment).
- b. Mitral, Tricuspid, and Pulmonic Valves: Endocardiosis, mild to moderate.

Sensory System:

B6

Body Cavity

FINAL DIAGNOSES/INTERPRETATIVE SUMMARY

| Diagnosis      |
|----------------|
| Cardiomyopathy |

|                            |
|----------------------------|
|                            |
| Pulmonary Edema            |
| Chronic Passive Congestion |
|                            |

Linked Cases: NA

Grossly, there was dilation of the heart along with hepatic changes consistent with right sided heart failure. There was atrophy of myofibers in all heart sections. The left was more severely affected. These findings are consistent with a cardiomyopathy, specifically, a dilated cardiomyopathy. The presence of wavy fibers is most consistent with an “attenuated wavy fiber” type of DCM.<sup>1</sup> There was hepatic centrilobular hepatocellular atrophy and degeneration along with centrilobular venular fibrosis consistent with chronic passive congestion further supporting the cardiac disease. Similarly, there was pulmonary edema with heart failure cells (hemosiderin-laden macrophages). Adin et al. (2019) proposed echocardiographic phenotypical differences based on diet type.<sup>2</sup> The role of taurine, diet, and breed are under continual and current investigation.

The splenic siderocalcific plaque is an age-related incidental finding and indicates a site of capsular/subcapsular hemorrhage. In the stomach, gastric vessels were congested. There was no inflammation, helical bacteria, or mucosal changes that would support a gastritis.

|                          |
|--------------------------|
| <b>RECOMMENDED TESTS</b> |
|--------------------------|

| TEST | PURPOSE | SITE | RESULT |
|------|---------|------|--------|
|      |         |      |        |
|      |         |      |        |

|                    |   |
|--------------------|---|
| DATE:<br>3/15/2019 | REPORTING PATHOLOGIST:<br>David S. Rotstein, DVM, MPVM, DACVP |
|--------------------|---|

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<sup>1</sup> Tidholm A and Jonsson L. 2005. Vet Pathol 42: 1-8.

<sup>2</sup> Adin D et al. 2019. J Vet Cardiol Feb;21:1-9. doi: 10.1016/j.jvc.2018.11.002. Epub 2018 Dec 5.

**FIGURES**

See PowerPoint



**Report Details - EON-366756**

|                               |  |
|-------------------------------|--|
| ICSR:                         | 2055325  |
| Type Of Submission:           | Initial  |
| Report Version:               | FPSR.FDA.PETF.V.V1   |
| Type Of Report:               | Adverse Event (a symptom, reaction or disease associated with the product) |
| Reporting Type:               | Voluntary  |
| Report Submission Date:       | 2018-09-25 13:07:32 EDT  |
| Reporter is the Animal Owner: | Yes  |

**Reported Problem:** **Problem Description:** B6 has been fed grain free dog food since 2013. I acquire B6 at 9 weeks of age from a reputable breeder. She was fed Purina ProPlan for Puppies from birth - early 2013. In early 2013 B6 was diagnosed with an impacted anal gland that ruptured and the vet recommended she be fed grain-free dog food. At that time, I began feeding Fromm's Beef Firtitta Grain Free. In late 2016 B6 began to experience steady diarrhea. After much vet intervention including a 2 night stay at vet hospital on IV, I changed B6 from Fromm's to a short transition time on ground beef w/rice and then to a fresh dog food, The Farmer's Dog Beef with Lentils. Her diarrhea completely cleared and she remained on The Farmer's Dog Beef with Lentils until I began reading about the issue with Low Taurine in Golden Retrievers. Based on UC Davis and Dr Stern studies, I obtained a blood sample for testing. UC Davis completed the test and her taurine level is low at B6 while the level for a Golden Retriever is B6. I had an echocardiogram done yesterday, Sept 24, 2018. The canine cardiologist evaluation is as follows: "Mild /early dilated cardiomyopathy-suspect taurine responsive. Trace mitral valve regurgitation. Normal left atrial dimensions. High normal left ventricular dimensions with moderately decreased heart muscle function. Normal right heart size. History of eating a grain-free diet. Low taurine." "No medications are indicated at this time. Begin Taurine 1000 mg twice daily. In two weeks, begin L-carnitine 1850 mg three times daily. In four weeks, begin fish oil supplements (omega-3 fatty acids) at approximately EPA 1500 mg and DHA 925 mg total per day. Change diet from grain free, legume foods. Cardiologist recommends follow up in 6 months.

|                                    |  |
|------------------------------------|--|
| <b>Date Problem Started:</b>       | 09/24/2018   |
| <b>Concurrent Medical Problem:</b> | Yes  |
| <b>Pre Existing Conditions:</b>    | Occasional urinary tract infection due to small, hooded vulva. |
| <b>Outcome to Date:</b>            | Stable   |

|                             |   |                              |                                    |
|-----------------------------|---|------------------------------|------------------------------------|
| <b>Product Information:</b> | <b>Product Name:</b>  | The Farmer's Dog Beef Recipe |                                    |
|                             | <b>Product Type:</b>  | Pet Food                     |                                    |
|                             | <b>Lot Number:</b>  |                              |                                    |
|                             | <b>Package Type:</b>  | PACKET                       |                                    |
|                             | <b>Package Size:</b>  | 24 Ounce                     |                                    |
|                             | <b>Purchase Date:</b>                                       | 09/13/2018                   |                                    |
|                             | <b>Possess Unopened Product:</b>                            | Yes                          |                                    |
|                             | <b>Possess Opened Product:</b>                              | Yes                          |                                    |
|                             | <b>Storage Conditions:</b>                                  | Frozen and refrigerate       |                                    |
|                             | <b>Product Use Information:</b>                             | <b>Description:</b>          | Fed twice a day adding green beans |
|                             | <b>First Exposure Date:</b>                                 | 09/13/2018                   |                                    |
|                             | <b>Last Exposure Date:</b>                                  | 09/25/2018                   |                                    |
|                             | <b>Time Interval between Product Use and Adverse Event:</b> | 18 Months                    |                                    |
|                             | <b>Product Use</b>  | Yes                          |                                    |

|   |  |                                    |                                   |
|---|--|------------------------------------|-----------------------------------|
|   | <b>Stopped After the Onset of the Adverse Event:</b>   |                                    |                                   |
|   | <b>Perceived Relatedness to Adverse Event:</b>   | Probably related                   |                                   |
|   | <b>Other Foods or Products Given to the Animal During This Time Period:</b>                          | Yes                                |                                   |
| <b>Manufacturer /Distributor Information:</b> |  |                                    |                                   |
| <b>Purchase Location Information:</b>         | <b>Name:</b>   | On line purchase with manufacturer |                                   |
|   | <b>Address:</b>  | United States                      |                                   |
| <b>Product Name:</b>                          | Fromms Four Star Grain Free Beef Frittata Veg Dry Dog Food   |                                    |                                   |
| <b>Product Type:</b>                          | Pet Food   |                                    |                                   |
| <b>Lot Number:</b>                            |  |                                    |                                   |
| <b>Package Type:</b>                          | BAG  |                                    |                                   |
| <b>Package Size:</b>                          | 26 Pound   |                                    |                                   |
| <b>Purchase Date:</b>                         | 01/20/2013   |                                    |                                   |
| <b>Number Purchased:</b>                      | 1  |                                    |                                   |
| <b>Possess Unopened Product:</b>              | No   |                                    |                                   |
| <b>Possess Opened Product:</b>                | No   |                                    |                                   |
| <b>Storage Conditions:</b>                    | Store in original bag inside of a sealed plastic pet food storage container from The Container Store |                                    |                                   |
| <b>Product Use Information:</b>               | <b>Description:</b>  | Fed twice daily morning / night    |                                   |
|   | <b>First Exposure Date:</b>  | 01/20/2013                         |                                   |
|   | <b>Time Interval between Product Use and Adverse Event:</b>  | 4 Years                            |                                   |
|   | <b>Product Use Stopped After the Onset of the Adverse Event:</b>                                     | Yes                                |                                   |
|   | <b>Adverse Event Abate After Product Stop:</b>   | Unknown                            |                                   |
|   | <b>Product Use Started Again:</b>  | No                                 |                                   |
|   | <b>Perceived Relatedness to Adverse Event:</b>   | Probably related                   |                                   |
|   | <b>Other Foods or Products Given to the Animal During This Time Period:</b>                          | Yes                                |                                   |
|   | <b>Manufacturer /Distributor Information:</b>  |                                    |                                   |
|   | <b>Purchase Location Information:</b>  | <b>Name:</b>                       | Various speciality pet food store |
| <b>Address:</b>                               |  | United States                      |                                   |
| <b>Animal Information:</b>                    | <b>Name:</b>   | <b>B6</b>                          |                                   |

|  |   |
|--|---|
|  | <b>Type Of Species:</b> Dog                                     |
|  | <b>Type Of Breed:</b> Retriever - Golden                        |
|  | <b>Gender:</b> Female   |
|  | <b>Reproductive Status:</b> Neutered                            |
|  | <b>Weight:</b> 79 Pound   |
|  | <b>Age:</b> B6 Years  |
|  | <b>Assessment of Prior Health:</b> Excellent                    |
|  | <b>Number of Animals Given the Product:</b> 1                   |
|  | <b>Number of Animals Reacted:</b> 1                             |
|  | <b>Owner Information:</b>                                       |
| <b>Healthcare Professional Information:</b>      | <b>Practice Name:</b> CVCA Cardiac Care for Pets                |
|  | <b>Contact:</b> <b>Name:</b> B6                                 |
|  | <b>Phone:</b>   |
|  | <b>Email:</b>   |
|  | <b>Address:</b> B6  |
|  | United States   |
|  | <b>Type of Veterinarian:</b> Referred veterinarian              |
|  | <b>Date First Seen:</b> 09/24/2018                              |
| <b>Permission to Release Records to FDA:</b> Yes |   |
| <b>Sender Information:</b>                       | <b>Name:</b> B6   |
|  | <b>Address:</b> United States                                   |
|  | <b>Contact:</b> <b>Phone:</b> B6                                |
|  | <b>Email:</b>   |
|  | <b>Reporter Wants to Remain Anonymous:</b> No                   |
|  | <b>Permission To Contact Sender:</b> Yes                        |
|  | <b>Preferred Method Of Contact:</b> Email                       |
|  | <b>Reported to Other Parties:</b> Other Store/Place of Purchase |
| <b>Additional Documents:</b>                     |   |

**B6**

Our Services include **B6**

- Blood Bank
- Cardiology
- Critical Care
- Diagnostic Imaging
- Emergency Medicine
- Hemodialysis
- Internal Medicine
- Oncology
- Surgery

### Cardiology Report

**Client Information:**

**B6**

**Patient Information:**

**B6**

**B6**

- Neutered Male - Canine

Pomeranian

2.12 kilograms

**Primary Veterinarian:**

**B6**

**Other Partner Veterinarians:**

**Exam Date:** Tuesday, January 9, 2018

**Services provided at the **B6** hospital.**

**Diagnosis:** Dilated Cardiomyopathy (suspect taurine deficient cardiomyopathy), Congestive Heart Failure, Alopecia X

**History (from ER):**

**B6** presents for further care of possible congestive heart failure. He was noted to have an acute onset of wheezing, coughing and increased respiratory rate. He was taken to his PDVM who performed radiographs which revealed a very enlarged heart with evidence of early pulmonary infiltrates. He has no history of a heart murmur or of any cardiac disease. He did have an episode six months ago of sneezing and some coughing that responded to antibiotics, but otherwise he has been healthy, except that he has Alopecia X. Not currently taking anything other than regular flea medication. Supplements include melatonin, lignan, probiotics, and fish oils. Diet is Zignature kangaroo.

**Cardiovascular Examination (1/10/18):**

**B6**

**Diagnostics:**

**B6**

**Assessment:**

**B6** has been diagnosed with dilated cardiomyopathy (DCM), which is a primary problem with the squeezing function of the heart, leading to secondary heart enlargement. **B6** heart disease is advanced at this time, and it has caused high pressure within the left side of the heart. This high pressure has backed up into the blood vessels of the lungs, and has caused the fluid component of blood to leak out into the lung tissue (called pulmonary edema), leading to the clinical signs that you have seen at home, such as coughing/wheezing and difficulty breathing.

DCM is most commonly seen in large and giant breed dogs and would be very unexpected in a Pomeranian. Another cause that can mimic DCM includes a deficiency in taurine, a protein found in meats. Interestingly, there have been other cases of taurine deficient DCM reported in dogs eating the same diet as **B6**. For this reason, this is my top

CS Patient ID: **B6** Patient: **B6** Client: **B6**

suspicion. Taurine deficiency is reversible with supplementation and many dogs can make a full recovery and come off heart medications.

If **B6** heart disease is not due to taurine deficiency, then it will continue to progress and he will require life-long medications. In this case, his prognosis is more guarded and he may only be manageable for a period of 6-12 months.

**B6**

**Medications:**

**B6**

**Monitoring:**

- Please watch **B6** for signs of recurrent congestive heart failure such as increase in respiratory rate or effort, coughing, decreased appetite, and lethargy. Please monitor **B6** respiratory rate and keep a daily record. When asleep or resting very quietly **B6** respiratory rate should be 20-30 breaths/min or less. If you notice a respiratory rate that is trending upward or persistently elevated above 35-40 breaths/min (for 2-3 days), please call the **B6** Cardiology service or your primary care veterinarian.

**Follow-Up:**

- A recheck cardiology examination, chemistry profile, and chest x-rays are recommended in 1-2 weeks.  
- Long-term, recheck chemistry profiles are recommended every 3 months. These blood tests can be performed with your primary care veterinarian.  
- A recheck echocardiogram is recommended in 6 months to determine if **B6** heart disease has reversed and if medications may be able to be stopped.

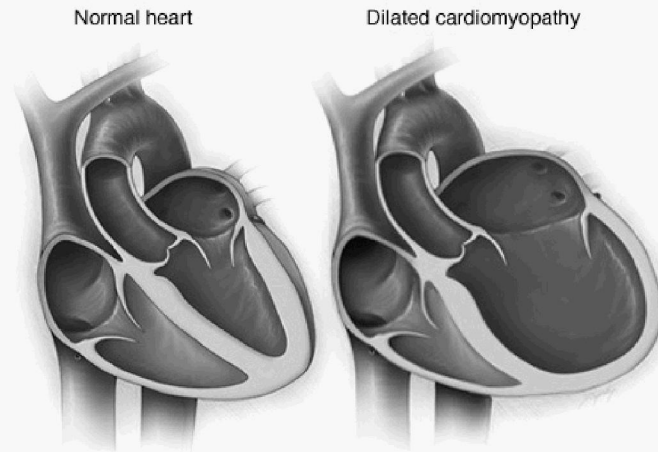
Thank you for referring **B6** to the Cardiology Service at **B6** **B6**. We appreciate the opportunity to participate in the care of your patients and thank you for entrusting our hospital with your clients and their pets; your continued confidence is greatly appreciated. Please call or email us if you have any questions or concerns.

Sincerely,

**B6**

\*\*\*For prescription refills, please call **B6** and ask for the Cardiology Prescription Refill Line. Please be aware that it can take up to 72 hours to get prescriptions refilled. This line, along with our email, will be monitored Tuesday – Friday, 8:00 am to 6:00 pm. **If you have an emergency please call the front desk immediately at **B6**** as it may take us up to 72 hours to answer emails.\*\*\*

# Dilated Cardiomyopathy (DCM)



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Dilated cardiomyopathy, or DCM, is a heart condition characterized by a decreased pumping ability of the heart. This leads to volume retention within the heart and dilation of the heart chambers. In some dogs, this may only occur on the left side, while others have all chambers affected. This predisposes to the development of congestive heart failure and arrhythmias, which can cause sudden death in affected dogs.

This condition is most common in large to giant breeds, including Doberman pinschers, Irish wolfhounds, Great Danes, and Boxers. In these breeds, it is suspected of having a genetic basis as numerous abnormalities have been described in people with this condition. In veterinary medicine, we are aware of certain genetic defects that cause DCM including PDK4 & DCM2 in Dobermans and RBM20 in standard schnauzers, among others. Not all affected dogs will have one of these mutations however, and in these dogs, the disease is typically idiopathic meaning that no definitive cause can be identified.

There are also other conditions that can mimic DCM such as chronic doxorubicin toxicity (a chemotherapy agent), chronic myocarditis (i.e., inflammation of the heart muscle), or a nutritional deficiency in taurine. Taurine is a part of proteins that are found in meat products. Animals that are fed vegetarian diets that are not supplemented with taurine, and occasionally, dogs that are fed diets where this nutrient is just unavailable for absorption, are at risk for manifesting this disease. Importantly, this form of the disease may be reversible if supplementation is initiated and some dogs are able to be weaned completely from cardiac medications.

Treatment of this disease revolves around management of the complications (heart failure, arrhythmias) as well as taurine supplementation if there is concern for a dietary cause. There are currently no surgeries that have been shown to improve the prognosis in these dogs.

Prognosis for this disease is variable depending upon the underlying cause. Dobermans with the genetic or idiopathic form of the disease are known to be at a high risk for sudden death and heart failure may only be manageable for 3-6 months. In other breeds with the idiopathic form of this disease, the prognosis is better with survivals averaging 6-12 months and, in general, lower risks for sudden death. As stated above, taurine deficiency is potentially reversible to the point that medications may be discontinued; however, resolution generally takes at least 4 months to become evident on an echocardiogram.

## Congestive heart failure (CHF)

CHF is a result of very severe heart disease. When there is severe heart disease, the normal function of the heart (left-sided, right-sided, or both) is so impaired that it cannot handle the normal flow of blood/fluid in the body and therefore, the fluid backs up. Congestion refers to this backup of fluid either into the lungs (left-sided heart failure) or body (right-sided heart failure). The most common causes of CHF include a stiff heart that does not stretch and fill appropriately, impaired heart valves that leak, or disease resulting in a poor pumping function of the heart. Complete diagnostic evaluations, including echocardiograms, allow the management of the heart disease to be tailored to the individual patient. The goal of treatment of CHF in animals is to remove the fluid and allow the patient to be able to breathe comfortably and live a good quality of life. Because severe disease will always progress, it is important to monitor for signs of worsening disease, that is, return of congestion so that treatment can be modified appropriately.

### *Monitoring left sided congestive heart failure (CHF): pulmonary edema*

Pulmonary edema is the back up of fluid into the lungs. When animals have evidence of pulmonary edema, they will have an increased rate and sometimes effort of breathing, coughing, and exercise intolerance.

**At home monitoring:**

The most sensitive means of monitoring for pulmonary edema is counting the sleeping respiratory rate at home. Keeping a log of how fast your pet is breathing during deep sleep can be helpful in determining if fluid is starting to build up in the lungs. A normal dog or cat should have a sleeping respiratory rate of 20-30 breaths per minute (bpm) or less. One breath is one excursion of the chest up and down. Panting is not excessive breathing. Panting can indicate many things and therefore, cannot be used as a determination of breathing rate. An awake animal who is managed for CHF will probably have a respiratory rate over 30 breaths/min, therefore it is important to consider the rate only while sleeping. Some animals also have underlying lung disease that might increase the breathing rate, therefore, this may need to be taken into consideration. It is most important to get a baseline when it is believed that there is no evidence of congestion (as assessed by yourself and your veterinarian). If you notice a consistent increased rate over a few days, then you should call your veterinarian as they will be able to determine if your pet is showing signs of congestion and determine the best course of action. As a general guideline, a rate between 30-45 breaths/min may indicate a small amount of fluid or could possibly be normal for a patient who has consistently had this higher breathing rate. If your pet's respiratory rate jumps up above 40-44 breaths/min when it has been consistently under 30 breaths/min, then it is likely that there is fluid in the lungs. You should call your veterinarian or consider taking your pet into the veterinarian soon.

Chest x-rays are needed to document congestive heart failure. However, if there is only a small amount of fluid, the x-rays may not always give a clear answer. Many times, the diagnosis of congestion is based on your observations at home (particularly respiratory rate), physical examination findings, as well as the x-ray results. If after x-rays and a review of your observations at home it is still difficult to determine if there is truly congestion, a trial with an increased dose of lasix can be tried. If you can determine by monitoring the breathing rate or resolution of the clinical signs that the lasix helps significantly, then congestion can be confidently identified.

**Medications**

**B6**

**B6**

CS Patient ID: **B6** Patient: **B6** Patient: **B6**



**Report Details - EON-362878**

ICSR: 2053969  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2018-08-20 16:33:06 EDT

**Reported Problem:**  
**Problem Description:** Taken to RDVM for lameness. Dilated cardiomyopathy and CHF diagnosed 8/6 /18. Started on meds [B6] We saw at Tufts 8/16 /18. Clinically improved but still has significant DCM and CHF plus arrhythmia. We added [B6] WB taurine pending. Another dog in household (also a Doberman) was eating the same food but was echoed today and has no signs of DCM.  
**Date Problem Started:** 08/06/2018  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Hypothyroid, obesity, osteoarthritis, behavioral issues  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Acana Free Run Poultry dry  
**Product Type:** Pet Food  
**Lot Number:**  
**UPC:** 6499250125  
**Package Type:** BAG  
**Package Size:** 25 Pound  
**Possess Unopened Product:** No  
**Possess Opened Product:** Yes  
**Product Use Information:**  
**Description:** Fed to 2 Dobermans in household.  
**First Exposure Date:** 09/01/2016  
**Last Exposure Date:** 08/16/2018  
**Product Use Stopped After the Onset of the Adverse Event:** Yes  
**Adverse Event Abate After Product Stop:** Unknown  
**Product Use Started Again:** No  
**Perceived Relatedness to Adverse Event:** Probably related  
**Other Foods or Products Given to the Animal During This Time Period:** Yes  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** [B6]

|                              |   |
|------------------------------|---|
|                              | <b>Type Of Species:</b> Dog   |
|                              | <b>Type Of Breed:</b> Doberman Pinscher   |
|                              | <b>Gender:</b> Male   |
|                              | <b>Reproductive Status:</b> Neutered  |
|                              | <b>Weight:</b> 45 Kilogram  |
|                              | <b>Age:</b> B6 years  |
|                              | <b>Assessment of Prior Health:</b> Excellent  |
|                              | <b>Number of Animals Given the Product:</b> 2   |
|                              | <b>Number of Animals Reacted:</b> 1   |
|                              | <b>Owner Information:</b>   |
|                              | <b>Owner Information provided:</b> Yes  |
|                              | <b>Contact:</b>   |
|                              | <b>Name:</b> B6   |
|                              | <b>Phone:</b>   |
|                              | <b>Email:</b>   |
|                              | <b>Address:</b> B6<br>United States   |
|                              | <b>Healthcare Professional Information:</b>   |
|                              | <b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine                          |
|                              | <b>Contact:</b>   |
|                              | <b>Name:</b> Lisa Freeman   |
|                              | <b>Phone:</b> (508) 887-4523  |
|                              | <b>Email:</b> lisa.freeman@tufts.edu  |
|                              | <b>Address:</b> 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |
| <b>Sender Information:</b>   | <b>Name:</b> Lisa Freeman   |
|                              | <b>Address:</b> 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |
|                              | <b>Contact:</b>   |
|                              | <b>Phone:</b> 5088874523  |
|                              | <b>Email:</b> lisa.freeman@tufts.edu  |
|                              | <b>Permission To Contact Sender:</b> Yes  |
|                              | <b>Preferred Method Of Contact:</b> Email   |
|                              | <b>Reported to Other Parties:</b> None  |
| <b>Additional Documents:</b> | <b>Attachment:</b> B6 cardio report 8-16-18.pmx.pdf   |
|                              | <b>Description:</b> Cardio report   |
|                              | <b>Type:</b> Sonogram   |
|                              | <b>Attachment:</b> B6 discharge 8-16-18.pdf   |
|                              | <b>Description:</b> Discharge report  |
|                              | <b>Type:</b> Other  |

|                     |                      |                         |
|---------------------|----------------------|-------------------------|
| <b>Attachment:</b>  | <b>B6</b>            | prnx.pdf                |
| <b>Description:</b> | Chest rads from rdvm |                         |
| <b>Type:</b>        | Radiographs          |                         |
| <b>Attachment:</b>  | <b>B6</b>            | profile 8-16-18.prx.pdf |
| <b>Description:</b> | Chemistry profile    |                         |
| <b>Type:</b>        | Laboratory Report    |                         |

**Report Details - EON-374786**

ICSR: 2060599  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2018-12-27 10:09:22 EST

**Reported Problem:**  
**Problem Description:** Housemate was diagnosed with DCM ( [B6] - previously reported) [B6] was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months WB taurine [B6]  
**Date Problem Started:** 08/20/2018  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** [B6]  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Acana Free Run Poultry dry  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:** **Description:** Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** [B6]  
**Type Of Species:** Dog  
**Type Of Breed:** Doberman Pinscher  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 38.1 Kilogram  
**Age:** 10 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 2  
**Number of Animals Reacted:** 2  
**Owner Information:** **Owner Information provided:** Yes  
**Contact:** **Name:** [B6]  
**Phone:** [B6]  
**Email:** [B6]  
**Address:** [B6]  
 United States  
**Healthcare Professional Information:** **Practice Name:** Tufts Cummings School of Veterinary Medicine  
**Contact:** **Name:** Lisa Freeman

|                                     |                                      |   |   |
|-------------------------------------|--------------------------------------|---|---|
|                                     |                                      |   | <b>Phone:</b> (508) 887-4523  |
|                                     |                                      |   | <b>Email:</b> lisa.freeman@tufts.edu  |
|                                     |                                      | <b>Address:</b>   | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |
| <b>Sender Information:</b>          | <b>Name:</b>                         | Lisa Freeman  |   |
|                                     | <b>Address:</b>                      | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |   |
|                                     | <b>Contact:</b>                      | <b>Phone:</b>   | 5088874523  |
|                                     |                                      | <b>Email:</b>   | lisa.freeman@tufts.edu  |
|                                     | <b>Permission To Contact Sender:</b> | Yes   |   |
| <b>Preferred Method Of Contact:</b> | Email                                |   |   |
| <b>Additional Documents:</b>        | <b>Attachment:</b>                   | <b>B6</b>   | medical records.pdf   |
|                                     | <b>Description:</b>                  | Medical records   |   |
|                                     | <b>Type:</b>                         | Medical Records   |   |

**Report Details - EON-383005**

|                                  |  |
|----------------------------------|--|
| ICSR:                            | 2064397  |
| Type Of Submission:              | Followup   |
| Report Version:                  | FPSR.FDA.PETF.V.V1   |
| Type Of Report:                  | Adverse Event (a symptom, reaction or disease associated with the product) |
| Reporting Type:                  | Voluntary  |
| Report Submission Date:          | 2019-03-21 17:33:50 EDT  |
| Initial Report Date:             | 12/27/2018   |
| Parent ICSR:                     | 2060599  |
| Follow-up Report to FDA Request: | Yes  |

|                   |                                    |  |
|-------------------|------------------------------------|--|
| Reported Problem: | <b>Problem Description:</b>        | Housemate was diagnosed with DCM ( [B6] - previously reported). [B6] was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months WB taurine [B6] |
|                   | <b>Date Problem Started:</b>       | 08/20/2018   |
|                   | <b>Concurrent Medical Problem:</b> | Yes  |
|                   | <b>Pre Existing Conditions:</b>    | [B6]   |
|                   | <b>Outcome to Date:</b>            | Better/Improved/Recovering   |

|                      |   |   |
|----------------------|---|---|
| Product Information: | <b>Product Name:</b>                          | Acana Free Run Poultry dry  |
|                      | <b>Product Type:</b>                          | Pet Food  |
|                      | <b>Lot Number:</b>                            |   |
|                      | <b>Package Type:</b>                          | BAG   |
|                      | <b>Product Use Information:</b>               | <b>Description:</b> Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018 |
|                      | <b>Manufacturer /Distributor Information:</b> |   |
|                      | <b>Purchase Location Information:</b>         |   |

|                     |   |  |
|---------------------|---|--|
| Animal Information: | <b>Name:</b>                                | [B6]                                   |
|                     | <b>Type Of Species:</b>                     | Dog                                    |
|                     | <b>Type Of Breed:</b>                       | Doberman Pinscher                      |
|                     | <b>Gender:</b>                              | Female                                 |
|                     | <b>Reproductive Status:</b>                 | Neutered                               |
|                     | <b>Weight:</b>                              | 38.1 Kilogram                          |
|                     | <b>Age:</b>                                 | 10 Years                               |
|                     | <b>Assessment of Prior Health:</b>          | Excellent                              |
|                     | <b>Number of Animals Given the Product:</b> | 2                                      |
|                     | <b>Number of Animals Reacted:</b>           | 2                                      |
|                     | <b>Owner Information:</b>                   | <b>Owner Information provided:</b> Yes |
|                     | <b>Contact:</b> <b>Name:</b> [B6]           |  |
|                     | <b>Phone:</b> [B6]                          |  |
|                     | <b>Email:</b> [B6]                          |  |
|                     | <b>Address:</b> [B6]                        |  |

|   |   |   |                            |  |
|---|---|---|----------------------------|--|
|   |   |   | <b>B6</b><br>United States |  |
| <b>Healthcare Professional Information:</b> | <b>Practice Name:</b>   | Tufts Cummings School of Veterinary Medicine                                |                            |  |
|   | <b>Contact:</b>   | <b>Name:</b>  | Lisa Freeman               |  |
|   |   | <b>Phone:</b>   | (508) 887-4523             |  |
|   |   | <b>Email:</b>   | lisa.freeman@tufts.edu     |  |
| <b>Address:</b>                             | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |   |                            |  |
| <b>Sender Information:</b>                  | <b>Name:</b>  | Lisa Freeman  |                            |  |
|   | <b>Address:</b>   | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |                            |  |
|   | <b>Contact:</b>   | <b>Phone:</b>   | 5088874523                 |  |
|   |   | <b>Email:</b>   | lisa.freeman@tufts.edu     |  |
|   | <b>Permission To Contact Sender:</b>  | Yes   |                            |  |
|   | <b>Preferred Method Of Contact:</b>   | Email   |                            |  |
|   | <b>Reported to Other Parties:</b>   | None  |                            |  |
| <b>Additional Documents:</b>                | <b>Attachment:</b>  | Medical Record.pdf  |                            |  |
|   | <b>Description:</b>   | Updated diet history, echo, ECG and Holter monitor                          |                            |  |
|   | <b>Type:</b>  | Medical Records   |                            |  |

**Report Details - EON-390790**

|                                  |  |
|----------------------------------|--|
| ICSR:                            | 2069328  |
| Type Of Submission:              | Followup   |
| Report Version:                  | FPSR.FDA.PETF.V.V1   |
| Type Of Report:                  | Adverse Event (a symptom, reaction or disease associated with the product) |
| Reporting Type:                  | Voluntary  |
| Report Submission Date:          | 2019-06-18 12:50:49 EDT  |
| Initial Report Date:             | 12/27/2018   |
| Parent ICSR:                     | 2060599  |
| Follow-up Report to FDA Request: | Yes  |

|                          |                                    |   |
|--------------------------|------------------------------------|---|
| <b>Reported Problem:</b> | <b>Problem Description:</b>        | Housemate was diagnosed with DCM [B6] - previously reported). [B6] was asymptomatic but eating same diet (Acana) so was screened 8/20/18 - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on 12/12/18 echo. Will recheck in 3 months WB taurine: [B6] |
|                          | <b>Date Problem Started:</b>       | 08/20/2018  |
|                          | <b>Date of Recovery:</b>           | 06/11/2019  |
|                          | <b>Concurrent Medical Problem:</b> | Yes   |
|                          | <b>Pre Existing Conditions:</b>    | [B6]  |
|                          | <b>Outcome to Date:</b>            | Recovered Completely  |

|                             |   |   |
|-----------------------------|---|---|
| <b>Product Information:</b> | <b>Product Name:</b>                          | Acana Free Run Poultry dry  |
|                             | <b>Product Type:</b>                          | Pet Food  |
|                             | <b>Lot Number:</b>                            |   |
|                             | <b>Package Type:</b>                          | BAG   |
|                             | <b>Product Use Information:</b>               | <b>Description:</b> Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018 |
|                             | <b>Manufacturer /Distributor Information:</b> |   |
|                             | <b>Purchase Location Information:</b>         |   |

|                            |   |   |
|----------------------------|---|---|
| <b>Animal Information:</b> | <b>Name:</b>                                | [B6]  |
|                            | <b>Type Of Species:</b>                     | Dog   |
|                            | <b>Type Of Breed:</b>                       | Doberman Pinscher   |
|                            | <b>Gender:</b>                              | Female  |
|                            | <b>Reproductive Status:</b>                 | Neutered  |
|                            | <b>Weight:</b>                              | 38.1 Kilogram   |
|                            | <b>Age:</b>                                 | 10 Years  |
|                            | <b>Assessment of Prior Health:</b>          | Excellent   |
|                            | <b>Number of Animals Given the Product:</b> | 2   |
|                            | <b>Number of Animals Reacted:</b>           | 2   |
|                            | <b>Owner Information:</b>                   | <b>Owner Information provided:</b> Yes  |
|                            |   | <b>Contact:</b> <b>Name:</b> [B6]<br><b>Phone:</b> [B6]<br><b>Email:</b> [B6] |
|                            |   | <b>Address:</b> [B6]  |



**B6**

United States

**Healthcare Professional Information:**

**Practice Name:** Tufts Cummings School of Veterinary Medicine

**Contact Name:** Lisa Freeman

**Phone:** (508) 887-4523

**Email:** lisa.freeman@tufts.edu

**Address:** 200 Westboro Rd  
North Grafton  
Massachusetts  
01536  
United States

**Sender Information:**

**Name:** Lisa Freeman

**Address:** 200 Westboro Rd  
North Grafton  
Massachusetts  
01536  
United States

**Contact Phone:** 5088874523

**Email:** lisa.freeman@tufts.edu

**Permission To Contact Sender:** Yes

**Preferred Method Of Contact:** Email

**Reported to Other Parties:** None

**Additional Documents:**

**Attachment:** **B6**-2019-06-12-1033.pdf

**Description:** Idexx NT pro-BNP

**Type:** Laboratory Report

**Attachment:** Diet hx 6-11-2019.pdf

**Description:** med records

**Type:** Medical Records

**Attachment:** Echo report V9.pdf

**Description:** Echo report

**Type:** Echocardiogram

---

**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** 'Freeman, Lisa'  
**Sent:** 8/23/2018 3:56:57 PM  
**Subject:** RE: updates

Hi Lisa,  
Do we have permission to contact [B6] about the 2 dobermans?  
Thank you,  
Jen

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



**From:** Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]  
**Sent:** Monday, August 20, 2018 6:18 PM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** updates

Hi Jen  
I forgot to note on the report I submitted today that I have a food sample and UPC code for the Acana food that the 2 Dobies were eating.

Also, for [B6], whose heart has improved significantly, I just got a sample from the owner who found some food remaining at her [B6] house – it is not fresh but I'm saving for you in case you want  
Thanks  
Lisa

Lisa M. Freeman, DVM, PhD, DACVN  
Board Certified Veterinary Nutritionist™  
Professor  
Cummings School of Veterinary Medicine  
Friedman School of Nutrition Science and Policy  
Tufts Clinical and Translational Science Institute  
Tufts University  
[www.petfoodology.org](http://www.petfoodology.org)

---

**From:** Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>  
**To:** 'Freeman, Lisa'  
**Sent:** 8/24/2018 11:29:51 AM  
**Subject:** RE: updates

Thank you, Lisa. I'll contact them.

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



**From:** Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]  
**Sent:** Thursday, August 23, 2018 12:26 PM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** Re: updates

Hi Jen. They gave permission to report so i think it would be fine til contact but I can specifically check if you'd prefer  
Lisa

Sent from my iPhone

On Aug 23, 2018, at 11:57 A Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Lisa,  
Do we have permission to contact [B6] about the 2 dobermans?  
Thank you,  
Jen

Jennifer Jones, DVM  
Veterinary Medical Officer  
Tel: 240-402-5421  
<image001.png> <image002.png>

**From:** Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]  
**Sent:** Monday, August 20, 2018 6:18 PM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** updates

Hi Jen  
I forgot to note on the report I submitted today that I have a food sample and UPC code for the Acana food that the 2 Dobies were eating.

Also, for [B6] whose heart has improved significantly, I just got a sample from the owner who found some food remaining at her [B6] house – it is not fresh but I'm saving for you in case you want  
Thanks  
Lisa

Lisa M. Freeman, DVM, PhD, DACVN  
Board Certified Veterinary Nutritionist™  
Professor  
Cummings School of Veterinary Medicine

Friedman School of Nutrition Science and Policy  
Tufts Clinical and Translational Science Institute  
Tufts University  
[www.petfoodology.org](http://www.petfoodology.org)

**Report Details - EON-383005**

|                                  |  |
|----------------------------------|--|
| ICSR:                            | 2064397  |
| Type Of Submission:              | Followup   |
| Report Version:                  | FPSR.FDA.PETF.V.V1   |
| Type Of Report:                  | Adverse Event (a symptom, reaction or disease associated with the product) |
| Reporting Type:                  | Voluntary  |
| Report Submission Date:          | 2019-03-21 17:33:50 EDT  |
| Initial Report Date:             | 12/27/2018   |
| Parent ICSR:                     | 2060599  |
| Follow-up Report to FDA Request: | Yes  |

|                          |                                    |   |
|--------------------------|------------------------------------|---|
| <b>Reported Problem:</b> | <b>Problem Description:</b>        | Housemate was diagnosed with DCM [B6] - previously reported. [B6] was asymptomatic but eating same diet (Acana) so was screened [B6] - reduced contractile function. Owner changed diet to Pro Plan Weight Management dry. No improvement on [B6] echo. Will recheck in 3 months WB taurine: [B6] |
|                          | <b>Date Problem Started:</b>       | 08/20/2018  |
|                          | <b>Concurrent Medical Problem:</b> | Yes   |
|                          | <b>Pre Existing Conditions:</b>    | [B6]  |
|                          | <b>Outcome to Date:</b>            | Better/Improved/Recovering  |

|                             |   |   |
|-----------------------------|---|---|
| <b>Product Information:</b> | <b>Product Name:</b>                          | Acana Free Run Poultry dry  |
|                             | <b>Product Type:</b>                          | Pet Food  |
|                             | <b>Lot Number:</b>                            |   |
|                             | <b>Package Type:</b>                          | BAG   |
|                             | <b>Product Use Information:</b>               | <b>Description:</b> Fed since approximately 9/2016 (see diet history form) Changed to Pro Plan Weight Management Aug 2018 |
|                             | <b>Manufacturer /Distributor Information:</b> |   |
|                             | <b>Purchase Location Information:</b>         |   |

|                            |   |  |
|----------------------------|---|--|
| <b>Animal Information:</b> | <b>Name:</b>                                | [B6]                                   |
|                            | <b>Type Of Species:</b>                     | Dog                                    |
|                            | <b>Type Of Breed:</b>                       | Doberman Pinscher                      |
|                            | <b>Gender:</b>                              | Female                                 |
|                            | <b>Reproductive Status:</b>                 | Neutered                               |
|                            | <b>Weight:</b>                              | 38.1 Kilogram                          |
|                            | <b>Age:</b>                                 | 10 Years                               |
|                            | <b>Assessment of Prior Health:</b>          | Excellent                              |
|                            | <b>Number of Animals Given the Product:</b> | 2                                      |
|                            | <b>Number of Animals Reacted:</b>           | 2                                      |
|                            | <b>Owner Information:</b>                   | <b>Owner Information provided:</b> Yes |
|                            | <b>Contact:</b> <b>Name:</b> [B6]           |  |
|                            | <b>Phone:</b> [B6]                          |  |
|                            | <b>Email:</b> [B6]                          |  |
|                            | <b>Address:</b> [B6]                        |  |

|   |   |   |                            |  |
|---|---|---|----------------------------|--|
|   |   |   | <b>B6</b><br>United States |  |
| <b>Healthcare Professional Information:</b> | <b>Practice Name:</b>   | Tufts Cummings School of Veterinary Medicine                                |                            |  |
|   | <b>Contact:</b>   | <b>Name:</b>  | Lisa Freeman               |  |
|   |   | <b>Phone:</b>   | (508) 887-4523             |  |
|   |   | <b>Email:</b>   | lisa.freeman@tufts.edu     |  |
| <b>Address:</b>                             | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |   |                            |  |
| <b>Sender Information:</b>                  | <b>Name:</b>  | Lisa Freeman  |                            |  |
|   | <b>Address:</b>   | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |                            |  |
|   | <b>Contact:</b>   | <b>Phone:</b>   | 5088874523                 |  |
|   |   | <b>Email:</b>   | lisa.freeman@tufts.edu     |  |
|   | <b>Permission To Contact Sender:</b>  | Yes   |                            |  |
|   | <b>Preferred Method Of Contact:</b>   | Email   |                            |  |
|   | <b>Reported to Other Parties:</b>   | None  |                            |  |
| <b>Additional Documents:</b>                | <b>Attachment:</b>  | Medical Record.pdf  |                            |  |
|   | <b>Description:</b>   | Updated diet history, echo, ECG and Holter monitor                          |                            |  |
|   | <b>Type:</b>  | Medical Records   |                            |  |

---

**From:** PFR Event <pfpreventcreation@fda.hhs.gov>  
**To:** Cleary, Michael \*; HQ Pet Food Report Notification; B6  
**Sent:** 2/24/2019 10:08:57 PM  
**Subject:** Acana: Lisa Freeman - EON-380708  
**Attachments:** 2063115-report.pdf; 2063115-attachments.zip

A PFR Report has been received and PFR Event [EON-380708] has been created in the EON System.

A "PDF" report by name "2063115-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2063115-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380708

**ICSR #:** 2063115

**EON Title:** PFR Event created for Acana Natural Balance Petcurean (see diet history for additional details); 2063115

|                          |   |                           |        |
|--------------------------|---|---------------------------|--------|
| <b>AE Date</b>           | 02/16/2019  | <b>Number Fed/Exposed</b> | 1      |
| <b>Best By Date</b>      |   | <b>Number Reacted</b>     | 1      |
| <b>Animal Species</b>    | Dog   | <b>Outcome to Date</b>    | Stable |
| <b>Breed</b>             | Terrier - Bull - American Pit   |                           |        |
| <b>Age</b>               | <span style="border: 1px dashed black; padding: 2px;">B6</span> Years |                           |        |
| <b>District Involved</b> | PFR-New England DO  |                           |        |

**Product information**

**Individual Case Safety Report Number:** 2063115

**Product Group:** Pet Food

**Product Name:** Acana, Natural Balance, Petcurean (see diet history for additional details)

**Description:** DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Stable

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

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

| <b>Product Name</b>   | <b>Lot Number or ID</b> | <b>Best By Date</b> |
|---|-------------------------|---------------------|
| Acana, Natural Balance, Petcurean (see diet history for additional details) |                         |                     |

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6**

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

**B6**

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

**B6**

**B6**

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| Report Details - EON-380708                 |   |  |
|---|---|--|
| ICSR:                                       | 2063115   |  |
| Type Of Submission:                         | Initial   |  |
| Report Version:                             | FPSR.FDA.PETF.V.V1  |  |
| Type Of Report:                             | Adverse Event (a symptom, reaction or disease associated with the product)  |  |
| Reporting Type:                             | Voluntary   |  |
| Report Submission Date:                     | 2019-02-24 17:00:13 EST   |  |
| Reported Problem:                           | <b>Problem Description:</b> DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that. |  |
|   | <b>Date Problem Started:</b> 02/16/2019   |  |
|   | <b>Concurrent Medical Problem:</b> Yes  |  |
|   | <b>Pre Existing Conditions:</b> Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.   |  |
|   | <b>Outcome to Date:</b> Stable  |  |
| Product Information:                        | <b>Product Name:</b> Acana, Natural Balance, Petcurean (see diet history for additional details)  |  |
|   | <b>Product Type:</b> Pet Food   |  |
|   | <b>Lot Number:</b>  |  |
|   | <b>Package Type:</b> BAG  |  |
|   | <b>Product Use Information:</b> <b>Description:</b> Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance")  |  |
|   | <b>Manufacturer /Distributor Information:</b>   |  |
|   | <b>Purchase Location Information:</b>   |  |
| Animal Information:                         | <b>Name:</b> B6   |  |
|   | <b>Type Of Species:</b> Dog   |  |
|   | <b>Type Of Breed:</b> Terrier - Bull - American Pit   |  |
|   | <b>Gender:</b> Female   |  |
|   | <b>Reproductive Status:</b> Neutered  |  |
|   | <b>Weight:</b> 18 Kilogram  |  |
|   | <b>Age:</b> B6 Years  |  |
|   | <b>Assessment of Prior Health:</b> Excellent  |  |
|   | <b>Number of Animals Given the Product:</b> 1   |  |
|   | <b>Number of Animals Reacted:</b> 1   |  |
|   | <b>Owner Information:</b>   | <b>Owner Information provided:</b> Yes |
|   |   | <b>Contact:</b>                        |
|   |   | <b>Name:</b> B6                        |
|   |   | <b>Phone:</b>                          |
|   |   | <b>Email:</b>                          |
| <b>Address:</b> B6                          |   |  |
|   | United States   |  |
| <b>Healthcare Professional Information:</b> | <b>Practice Name:</b> Tufts Cummings School of Veterinary Medicine  |  |

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

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

|                              |                     |                                |
|------------------------------|---------------------|--------------------------------|
| <b>Additional Documents:</b> | <b>Attachment:</b>  | rpt_medical_record_preview.pdf |
|                              | <b>Description:</b> | Medical records                |
|                              | <b>Type:</b>        | Medical Records                |

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**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Jones, Jennifer L  
**Sent:** 2/24/2019 11:05:45 PM  
**Subject:** ps - **B6**

Hi Jen

I forgot to mention that I have diet samples for the Natural Balance and Acana for

**B6**

Lisa

Lisa M. Freeman, DVM, PhD, DACVN  
Board Certified Veterinary Nutritionist™  
Professor  
Cummings School of Veterinary Medicine  
Friedman School of Nutrition Science and Policy  
Tufts Clinical and Translational Science Institute  
Tufts University  
[www.petfoodology.org](http://www.petfoodology.org)

---

**From:** Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>  
**To:** Carey, Lauren; Cleary, Michael \*; HQ Pet Food Report Notification;  
B6  
**Sent:** 6/10/2019 9:32:54 PM  
**Subject:** Acana: Lisa Freeman - EON-390104  
**Attachments:** 2068046-report.pdf; 2068046-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390104] has been created in the EON System.

A "PDF" report by name "2068046-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068046-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390104

**ICSR #:** 2068046

**EON Title:** Related PFR Event created for Acana Natural Balance Petcurean (see diet history for additional details); 2068046

|                          |                               |                           |                            |
|--------------------------|-------------------------------|---------------------------|----------------------------|
| <b>AE Date</b>           | 02/16/2019                    | <b>Number Fed/Exposed</b> | 1                          |
| <b>Best By Date</b>      |                               | <b>Number Reacted</b>     | 1                          |
| <b>Animal Species</b>    | Dog                           | <b>Outcome to Date</b>    | Better/Improved/Recovering |
| <b>Breed</b>             | Terrier - Bull - American Pit |                           |                            |
| <b>Age</b>               | B6 Years                      |                           |                            |
| <b>District Involved</b> | PFR-New England DO            |                           |                            |

**Product information**

**Individual Case Safety Report Number:** 2068046

**Product Group:** Pet Food

**Product Name:** Acana, Natural Balance, Petcurean (see diet history for additional details)

**Description:** DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.

**Submission Type:** Followup

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Better/Improved/Recovering

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

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

| <b>Product Name</b>   | <b>Lot Number or ID</b> | <b>Best By Date</b> |
|---|-------------------------|---------------------|
| Acana, Natural Balance, Petcurean (see diet history for additional details) |                         |                     |

This report is linked to:

**Initial EON Event Key:** EON-380708

**Initial ICSR:** 2063115

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6**

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

**B6**

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

**B6**

**B6**

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**Report Details - EON-390104**

|                                  |  |
|----------------------------------|--|
| ICSR:                            | 2068046  |
| Type Of Submission:              | Followup   |
| Report Version:                  | FPSR.FDA.PETF.V.V1   |
| Type Of Report:                  | Adverse Event (a symptom, reaction or disease associated with the product) |
| Reporting Type:                  | Voluntary  |
| Report Submission Date:          | 2019-06-10 17:24:05 EDT  |
| Initial Report Date:             | 02/24/2019   |
| Parent ICSR:                     | 2063115  |
| Follow-up Report to FDA Request: | Yes  |

|                          |                                    |   |
|--------------------------|------------------------------------|---|
| <b>Reported Problem:</b> | <b>Problem Description:</b>        | DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that. |
|                          | <b>Date Problem Started:</b>       | 02/16/2019  |
|                          | <b>Concurrent Medical Problem:</b> | Yes   |
|                          | <b>Pre Existing Conditions:</b>    | Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.   |
|                          | <b>Outcome to Date:</b>            | Better/Improved/Recovering  |

|                             |   |   |  |
|-----------------------------|---|---|--|
| <b>Product Information:</b> | <b>Product Name:</b>                          | Acana, Natural Balance, Petcurean (see diet history for additional details) |  |
|                             | <b>Product Type:</b>                          | Pet Food  |  |
|                             | <b>Lot Number:</b>                            |   |  |
|                             | <b>Package Type:</b>                          | BAG   |  |
|                             | <b>Product Use Information:</b>               | <b>Description:</b>   | Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance") |
|                             | <b>Manufacturer /Distributor Information:</b> |   |  |
|                             | <b>Purchase Location Information:</b>         |   |  |

|                            |   |                                    |               |    |
|----------------------------|---|------------------------------------|---------------|----|
| <b>Animal Information:</b> | <b>Name:</b>                                | B6                                 |               |    |
|                            | <b>Type Of Species:</b>                     | Dog                                |               |    |
|                            | <b>Type Of Breed:</b>                       | Terrier - Bull - American Pit      |               |    |
|                            | <b>Gender:</b>                              | Female                             |               |    |
|                            | <b>Reproductive Status:</b>                 | Neutered                           |               |    |
|                            | <b>Weight:</b>                              | 18 Kilogram                        |               |    |
|                            | <b>Age:</b>                                 | B6 years                           |               |    |
|                            | <b>Assessment of Prior Health:</b>          | Excellent                          |               |    |
|                            | <b>Number of Animals Given the Product:</b> | 1                                  |               |    |
|                            | <b>Number of Animals Reacted:</b>           | 1                                  |               |    |
|                            | <b>Owner Information:</b>                   | <b>Owner Information provided:</b> | Yes           |    |
|                            |   | <b>Contact:</b>                    | <b>Name:</b>  | B6 |
|                            |   |                                    | <b>Phone:</b> |    |
|                            |   | <b>Email:</b>                      |               |    |
|                            | <b>Address:</b>                             | B6                                 |               |    |



**B6**

United States

|   |   |  |                        |
|---|---|--|------------------------|
| <b>Healthcare Professional Information:</b> | <b>Practice Name:</b>   | Tufts Cummings School of Veterinary Medicine |                        |
|   | <b>Contact:</b>   | <b>Name:</b>                                 | Lisa Freeman           |
|   |   | <b>Phone:</b>                                | (508) 887-4523         |
|   |   | <b>Email:</b>                                | lisa.freeman@tufts.edu |
| <b>Address:</b>                             | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |  |                        |

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

|                              |                     |                               |  |  |
|------------------------------|---------------------|-------------------------------|--|--|
| <b>Additional Documents:</b> | <b>Attachment:</b>  | Diet hx 5-13-2019.pdf         |  |  |
|                              | <b>Description:</b> | Diet History form             |  |  |
|                              | <b>Type:</b>        | Medical Records               |  |  |
|                              | <b>Attachment:</b>  | Troponin 3-6-2019.pdf         |  |  |
|                              | <b>Description:</b> | Lab work                      |  |  |
|                              | <b>Type:</b>        | Laboratory Report             |  |  |
|                              | <b>Attachment:</b>  | Follow-up records pt 2.pdf    |  |  |
|                              | <b>Description:</b> | Medical Records               |  |  |
|                              | <b>Type:</b>        | Medical Records               |  |  |
|                              | <b>Attachment:</b>  | Follow-up records pt 1.pdf    |  |  |
|                              | <b>Description:</b> | Medical Records               |  |  |
|                              | <b>Type:</b>        | Medical Records               |  |  |
|                              | <b>Attachment:</b>  | Recheck chem 21 5-13-2019.pdf |  |  |
|                              | <b>Description:</b> | Lab work                      |  |  |
|                              | <b>Type:</b>        | Laboratory Report             |  |  |

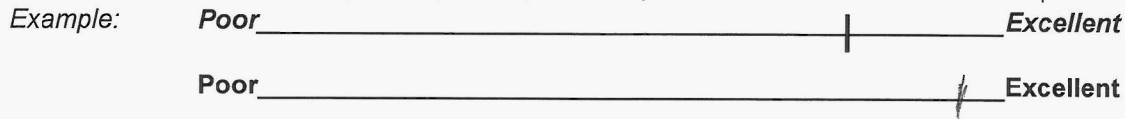
#439571

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name: B6 Today's date: 5/13/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)



2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

- Eats about the same amount as usual (checked)
Eats less than usual
Eats more than usual
Seems to prefer different foods than usual
Other

3. Over the last few weeks, has your pet (check one)

- Lost weight
Gained weight (checked)
Stayed about the same weight
Don't know

1. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats and that you have fed in the last 2 years.

Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the table

Table with 5 columns: Food (include specific product and flavor), Form, Amount, How often?, Dates fed. Rows include Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult; 85% lean hamburger; Puppperoni original beef flavor; Rawhide; and a handwritten entry for 'Quality Pro Plan Salmon' for a pet with sensitive skin and stomach.

\*Any additional diet information can be listed on the back of this sheet

2. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?

Table for dietary supplements with columns for supplement name, Yes/No, Brand/Concentration, and Amount per day. Includes handwritten entries for Taurine (NOW, 2 g/day) and Vitamin C (Nature's Bounty, 500 mg tablets - 1 per day).

3. How do you administer pills to your pet?

- I do not give any medications
I put them directly in my pet's mouth without food
I put them in my pet's dog/cat food
I put them in a Pill Pocket or similar product
I put them in foods (list foods): coconut oil

Client: **B6**  
Patient:

Chem 21 - 5/13/2019



### Tufts Cummings School Of Veterinary Medicine

200 Westboro Road  
North Grafton, MA 01536

#### DUPLICATE

|                                    |                 |   |
|------------------------------------|-----------------|---|
| Name/DOB: <b>B6</b>                | Sex: SF         | Provider: <b>B6</b>                         |
| Patient ID: 439571                 | Age: 5          | Order Location: V320559: Investigation into |
| Phone number:                      | Species: Canine | Sample ID: 1905130113                       |
| Collection Date: 5/13/2019 1:50 PM | Breed: Pit Bull |   |
| Approval date: 5/13/2019 2:51 PM   |                 |   |

#### Research Chemistry Profile - Small Animal (Cobas)

|                         |           | Ref. Range/Females |
|-------------------------|-----------|--------------------|
| SMACHUNSKI              |           |                    |
| Glucose                 |           | 67-135 mg/dL       |
| Urea                    |           | 8-30 mg/dL         |
| Creatinine              |           | 0.6-2.0 mg/dL      |
| Phosphorus              |           | 2.6-7.2 mg/dL      |
| Calcium 2               |           | 9.4-11.3 mg/dL     |
| Magnesium 2+            |           | 1.8-3.0 mEq/L      |
| Total Protein           |           | 5.5-7.8 g/dL       |
| Albumin                 |           | 2.8-4.0 g/dL       |
| Globulins               |           | 2.3-4.2 g/dL       |
| A/G Ratio               | H         | 0.7-1.6            |
| Sodium                  | H         | 140-150 mEq/L      |
| Chloride                |           | 106-116 mEq/L      |
| Potassium               | <b>B6</b> | 3.7-5.4 mEq/L      |
| tCO2(Bicarb)            |           | 14-28 mEq/L        |
| AGAP                    |           | 8.0-19.0           |
| NA/K                    |           | 29-40              |
| Total Bilirubin         |           | 0.10-0.30 mg/dL    |
| Alkaline Phosphatase    |           | 12-127 U/L         |
| GGT                     |           | 0-10 U/L           |
| ALT                     |           | 14-86 U/L          |
| AST                     |           | 9-54 U/L           |
| Creatine Kinase         |           | 22-422 U/L         |
| Cholesterol             |           | 82-355 mg/dL       |
| Triglycerides           |           | 30-338 mg/dl       |
| Amylase                 |           | 409-1250 U/L       |
| Osmolality (calculated) |           | 291-315 mmol/L     |

Sample ID: 1905130113/1  
END OF REPORT (Final)

Reviewed by: \_\_\_\_\_

Client:  
Patient:

**B6**

**B6**

-proBNP 5/13/2019

**B6**



**B6**

PET OWNER: **B6**

SPECIES: Canine

BREED: Pit Bull, American

GENDER: Female

AGE:

PATIENT ID:

Tufts University Attn: Lisa Freeman

200 Westboro Rd.

North Grafton, MA 01536

508-839-5395

ACCOUNT #: 88933

ATTENDING VET: **B6**

LAB ID: 2301800020

ORDER ID: 1A

COLLECTION DATE: 5/12/19

DATE OF RECEIPT: 5/13/19

DATE OF RESULT: 5/14/19

IDEXX Services: **Cardiopet® proBNP-Canine\***

**Chemistry**



5/13/19 (Order Received)

5/14/19 11:57 AM (Last Updated)

2/16/19

TEST

RESULT

REFERENCE VALUE

Cardiopet  
proBNP  
(Canine)

**B6**

0 - 900 pmol/L

**B6**

**B6**

Please note: Complete interpretive comments for all concentrations of  
Cardiopet proBNP are available in the online directory of services. Serum  
specimens received at room temperature may have decreased NT-proBNP  
concentrations.

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

**Troponin 5/31/2019**



**Gastrointestinal Laboratory**  
**Dr. J.M. Steiner**  
**Department of Small Animal Clinical Sciences**  
**Texas A&M University**  
**4474 TAMU**  
**College Station, TX 77843-4474**



Website User ID: lisa.freeman@tufts.edu OR **B6**@tufts.edu

GI Lab Assigned Clinic ID: 23523

**B6**  
Tufts Cummings School of Vet Med - Cardiology/Nutrition  
200 Westboro Road  
North Grafton, MA 01536  
USA

Phone: 508 887 4696  
Fax:  
Animal Name: **B6**  
Owner Name:  
Species: Canine  
Date Received: May 30, 2019

Tufts Cummings School of Vet Med -  
Cardiology/Nutrition Tracking Number:  
439571

GI Lab Accession: **B6**

| Test                               | Result    | Reference Interval | Assay Date |
|------------------------------------|-----------|--------------------|------------|
| Ultra-Sensitive Troponin I Fasting | <b>B6</b> | ≤0.06              | 05/31/19   |

**B6**

Comments:

**GI Lab Contact Information**

Phone: (979) 862-2861  
Fax: (979) 862-2864

Email: gilab@cvm.tamu.edu  
vetmed.tamu.edu/gilab

### Discharge Instructions

**Patient**

Name: B6

Species: Canine

Brown/White Female (Spayed) Pit Bull

Birthdate: B6

**Owner**

Name: B6

Address:

B6

Patient ID: 439571

**Attending Cardiologist:**

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

**Cardiology Resident:**

B6

**Cardiology Technician:**

B6

Student: B6 V20

Admit Date: B6

Discharge Date: B6

**Diagnoses:** Dilated cardiomyopathy (DCM) with congestive heart failure

**Diagnostic test results and findings:**

- **Echocardiogram findings:** The heart is smaller and has better contractile function. There is still dilation but there is marked improvement.
- **Labwork findings:** We will call you with the results

**Case summary:**

Thank you for bringing B6 for her 3 month recheck! We are glad that she is doing well at home and happy she gained weight! On her three month discharge today, her heart function has improved and her heart has decreased in size, however there is enough dilation that requires long term medication. At this point it is unclear whether her problem is a primary heart disease, secondary to diet or a combination of both. Despite there is a marked improvement in her heart, we will still keep her on her current medications and increase the B6 dose (see section below).

**Monitoring at home:**

- We would like you to monitor B6 breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 32 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- An increase in breathing rate or effort will usually mean that you should give an extra dose of B6 if

difficulty breathing is not improved by within 30-60 minutes after giving extra **B6** then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.

- o There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- o We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- o If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

#### Recommended Medications:

**B6**

**B6**

#### Diet suggestions:

**B6** can continue with her current diet.

#### Exercise Recommendations:

**B6** can continue with her walks, but should not be stimulated to go any faster than the current pacing rhythm she is on. However, if you find that **B6** is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage.

#### Recheck Visits:

You have a recheck visit scheduled for Friday, August 16th at 2 pm. Please contact our Cardiology liaison at (508)-887-4696 or email us at [cardiovet@tufts.edu](mailto:cardiovet@tufts.edu) for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

<http://vet.tufts.edu/heartsmart/>

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#### Prescription Refill Disclaimer:

*For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.*

#### Ordering Food:

*Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.*

#### Clinical Trials:

*Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: [vet.tufts.edu/cvmc/clinical-studies](http://vet.tufts.edu/cvmc/clinical-studies)*

---

Case: **B6**

Owner: **B6**

Discharge Instructions





# Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID: 439571

B6

Canine  
Years Old Female (Spayed) Pit Bull  
Brown/White

## Cardiology Appointment Report

Date: 5/13/2019

### Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

### Cardiology Resident:

B6

### Cardiology Technician:

B6

Student: B6 V20

### Presenting Complaint:

Recheck

Doing well at home, breathing rate still pretty low, short walks again (10-15min) and doing fine, does not appear lame in the hind.

O is not checking respiratory rate at home.

### Concurrent Diseases:

DCM;

### General Medical History:

- 3 months ago, came in through ER

### Diet and Supplements:

Purina Pro-Plan Sensitive

### Cardiovascular History:

Prior CHF diagnosis? Yes

Prior heart murmur? Unknown

Prior ATE? No

Prior arrhythmia? No

Monitoring respiratory rate and effort at home? Yes, high 20s-low 30s consistently, some effort; stopped monitoring in past few months, breathing better but has not been counting

Cough? No, very rarely, when drinking water

Shortness of breath or difficulty breathing? No

Syncope or collapse? No

Sudden onset lameness? No

Exercise intolerance? No, haven't been doing too much exercise, 10-15 minutes walks in past month, has been doing well on those

**Current Medications Pertinent to CV System:**

**B6**

**Cardiac Physical Examination:**

**B6**

**Muscle condition:**

- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

**Cardiovascular Physical Exam:**

**Murmur Grade:**

- None
- I/VI
- II/VI
- III/VI
- IV/VI
- V/VI
- VI/VI

**Murmur location/description: -**

**Jugular vein:**

- Bottom 1/3 of the neck
- Middle 1/3 of the neck
- 1/2 way up the neck
- Top 2/3 of the neck

**Arterial pulses:**

- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other:

**Arrhythmia:**

- None
- Sinus arrhythmia
- Premature beats
- Bradycardia
- Tachycardia

**Gallop:**

- Yes
- No
- Intermittent
- Pronounced
- Other:

**Pulmonary assessments:**

- Eupneic
- Pulmonary crackles

- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

- Wheezes
- Upper airway stridor

**Abdominal exam:**

- Normal
- Hepatomegaly
- Abdominal distension

- Mild ascites
- Marked ascites

**Problems:**

- DCM (diet induced vs. primary)
- History of CHF;
- Allergies / GI disturbances

**Diagnostic plan:**

- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure

- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests:

**B6**

**Mitral inflow:**

- Summated
- Normal
- Delayed relaxation

- Pseudonormal
- Restrictive

**B6**

**Assessment and recommendations:**

Patient improved clinically and energy level is back to normal. Echocardiogram revealed improved systolic function and LA size, however still lower than desirable. PHTN is decreased, likely due to management of CHF overall and improved systolic function. Blood work revealed normal kidney values, B6

**B6**

**Final Diagnosis:**

DCM with history of L-CHF.

**Heart Failure Classification Score:**

**ISACH Classification:**

- Ia
- Ib
- II
- IIIa
- IIIb

**ACVIM Classification:**

- A
- B1
- B2
- C
- D

**M-Mode**

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

EDV(Teich)

ESV(Teich)

EF(Teich)

%FS

SV(Teich)

Max LA

Ao Diam

LA Diam

LA/Ao

TAPSE

EPSS

**2D**

SA LA

Ao Diam

SA LA / Ao Diam

IVSd

LVIDd

LVPWd

EDV(Teich)

IVSs

LVIDs

LVPWs

ESV(Teich)

EF(Teich)

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SV(Teich)

LV Major

LV Minor

Sphericity Index

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LVEDV MOD A4C  
LVLs A4C  
LVESV MOD A4C  
LVEF MOD A4C  
SV MOD A4C

Doppler

MR Vmax  
MR maxPG  
MV E Vel  
MV DecT  
MV Dec Slope  
MV A Vel  
MV E/A Ratio  
E'  
E/E'  
A'  
IVRT  
AV Vmax  
AV maxPG  
PV Vmax  
PV maxPG  
TR Vmax  
TR maxPG

B6

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# Tufts Cummings School Of Veterinary Medicine

200 Westboro Road  
North Grafton, MA 01536

## DUPLICATE

Name/DOB: **B6**

Provider: **B6**

Patient ID: 439571

Sex: SF

Order Location: V320559: Investigation into

Phone number:

Age: 5

Sample ID: 1905130113

Collection Date: 5/13/2019 1:50 PM

Species: Canine

Approval date: 5/13/2019 2:51 PM

Breed: Pit Bull

## Research Chemistry Profile - Small Animal (Cobas)

SMACHUNSKI

Glucose

Urea

Creatinine

Phosphorus

Calcium 2

Magnesium 2+

Total Protein

Albumin

Globulins

A/G Ratio

Sodium

Chloride

Potassium

tCO2(Bicarb)

AGAP

NA/K

Total Bilirubin

Alkaline Phosphatase

GGT

ALT

AST

Creatine Kinase

Cholesterol

Triglycerides

Amylase

Osmolality (calculated)

**B6**

Ref. Range/Females

67-135 mg/dL

8-30 mg/dL

0.6-2.0 mg/dL

2.6-7.2 mg/dL

9.4-11.3 mg/dL

1.8-3.0 mEq/L

5.5-7.8 g/dL

2.8-4.0 g/dL

2.3-4.2 g/dL

0.7-1.6

140-150 mEq/L

106-116 mEq/L

3.7-5.4 mEq/L

14-28 mEq/L

8.0-19.0

29-40

0.10-0.30 mg/dL

12-127 U/L

0-10 U/L

14-86 U/L

9-54 U/L

22-422 U/L

82-355 mg/dL

30-338 mg/dl

409-1250 U/L

291-315 mmol/L

Sample ID: 1905130113/1  
END OF REPORT (Final)

Reviewed by: \_\_\_\_\_



Gastrointestinal Laboratory  
 Dr. J.M. Steiner  
 Department of Small Animal Clinical Sciences  
 Texas A&M University  
 4474 TAMU  
 College Station, TX 77843-4474



Website User ID: [Cardiovet@tufts.edu](mailto:Cardiovet@tufts.edu) OR [clinpath@tufts.edu](mailto:clinpath@tufts.edu)

GI Lab Assigned Clinic ID: 11405

|   |                |                |
|---|----------------|----------------|
| Dr. <b>B6</b>                           | Phone:         | 508 887 4669   |
| Tufts University-Clinical Pathology Lab | Fax:           | 9 508 839 7936 |
| Attn: <b>B6</b>                         | Animal Name:   | <b>B6</b>      |
| 200 Westboro Road                       | Owner Name:    |                |
| North Grafton, MA 01536                 | Species:       | Canine         |
| USA                                     | Date Received: | Mar 06, 2019   |

GI Lab Accession: **B6**

| <u>Test</u>                        | <u>Result</u> | <u>Control Range</u> | <u>Assay Date</u> |
|------------------------------------|---------------|----------------------|-------------------|
| Ultra-Sensitive Troponin I Fasting | <b>B6</b>     | ≤0.06                | 03/06/19          |

**B6**

Comments:

**Important  
Notices:**

**Internal Medicine Conference**

**Join us for a unique continuing education event in Phuket, Thailand Oct 7th - 11th, 2019. For details see <http://texasimconference.tamu.edu>**

**Ongoing studies**

**Cobalamin Supplementation Study-** Dogs and cats with cobalamin deficiency with normal PLI, and either normal or low (consistent with EPI) TLI to compare the efficacy of oral vs parenteral cobalamin supplementation. Contact Dr. Chang at [chchang@cvm.tamu.edu](mailto:chchang@cvm.tamu.edu) for further information.

**Chronic Pancreatitis with Uncontrolled Diabetes Mellitus-** Seeking dogs with chronic pancreatitis and uncontrolled diabetes mellitus for enrollment into a drug trial (medication provided at no cost). Contact Dr. Sue Yee Lim at [slim@cvm.tamu.edu](mailto:slim@cvm.tamu.edu) or Dr. Sina Marsilio at [smarsilio@cvm.tamu.edu](mailto:smarsilio@cvm.tamu.edu)

**Dogs with Primary Hyperlipidemia-** Prescription diet naïve dogs newly diagnosed with primary hyperlipidemia are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at [ylawrence@cvm.tamu.edu](mailto:ylawrence@cvm.tamu.edu) for more information.

**Dogs with Chronic Pancreatitis-** Dogs with chronic pancreatitis (cPLi >400µg/L) and hypertriglyceridemia (>300 mg/dl) are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at [ylawrence@cvm.tamu.edu](mailto:ylawrence@cvm.tamu.edu)

**Chronic enteropathies in dogs-** Please fill out this brief form <http://tinyurl.com/ibd-enroll> to see if your patient qualifies.

**Feline Chronic Pancreatitis-** Cats with chronic pancreatitis for more than 2 weeks and fPLI >10 µg/L are eligible for enrollment into a treatment trial investigating the efficacy of prednisolone or cyclosporine. Please contact Dr. Yamkate for further information at [pyamkate@cvm.tamu.edu](mailto:pyamkate@cvm.tamu.edu).

**We can not accept packages that are marked "Bill Receiver"**

**Use our preprinted shipping labels to save on shipping. Call 979-862-2861 for assistance. The GI Lab is not here to accept packages on the weekend. Samples may be compromised if you ship for arrival on Saturday or Sunday or if shipped via US Mail.**

---

**GI Lab Contact Information**

Phone: (979) 862-2861

Fax: (979) 862-2864

Email: [gilab@cvm.tamu.edu](mailto:gilab@cvm.tamu.edu)

[vetmed.tamu.edu/gilab](http://vetmed.tamu.edu/gilab)



**Report Details - EON-380708**

ICSR: 2063115  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2019-02-24 17:00:13 EST

**Reported Problem:**  
**Problem Description:** DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that.  
**Date Problem Started:** 02/16/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Acana, Natural Balance, Petcurean (see diet history for additional details)  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:** **Description:** Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance")  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Terrier - Bull - American Pit  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 18 Kilogram  
**Age:** B6 years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1  
**Owner Information:** **Owner Information provided:** Yes  
**Contact:** **Name:** B6  
**Phone:**  
**Email:**  
**Address:** B6  
 United States  
**Healthcare Professional Information:** **Practice Name:** Tufts Cummings School of Veterinary Medicine

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

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

|                              |                     |                                |
|------------------------------|---------------------|--------------------------------|
| <b>Additional Documents:</b> | <b>Attachment:</b>  | rpt_medical_record_preview.pdf |
|                              | <b>Description:</b> | Medical records                |
|                              | <b>Type:</b>        | Medical Records                |

**Report Details - EON-390104**

|   |  |
|---|--|
| <b>ICSR:</b>                            | 2068046  |
| <b>Type Of Submission:</b>              | Followup   |
| <b>Report Version:</b>                  | FPSR.FDA.PETF.V.V1   |
| <b>Type Of Report:</b>                  | Adverse Event (a symptom, reaction or disease associated with the product) |
| <b>Reporting Type:</b>                  | Voluntary  |
| <b>Report Submission Date:</b>          | 2019-06-10 17:24:05 EDT  |
| <b>Initial Report Date:</b>             | 02/24/2019   |
| <b>Parent ICSR:</b>                     | 2063115  |
| <b>Follow-up Report to FDA Request:</b> | Yes  |

|                          |                                    |   |
|--------------------------|------------------------------------|---|
| <b>Reported Problem:</b> | <b>Problem Description:</b>        | DCM and CHF diagnosed 2/16/19. Eating multiple BEG diets Taurine and troponin pending Dog changed to Purina HA vegetarian dry while in hospital and owner has continued this. Will try switching to Pro Plan Sensitive Skin and Stomach Salmon when bag of HA runs out. If she tolerates that, will stay on it. If not, will switch back to HA since she's done well on that. |
|                          | <b>Date Problem Started:</b>       | 02/16/2019  |
|                          | <b>Concurrent Medical Problem:</b> | Yes   |
|                          | <b>Pre Existing Conditions:</b>    | Diarrhea would develop 2-3 weeks after starting a new food. Owner rotated foods to try to avoid this.   |
|                          | <b>Outcome to Date:</b>            | Better/Improved/Recovering  |

|                             |   |   |  |
|-----------------------------|---|---|--|
| <b>Product Information:</b> | <b>Product Name:</b>                          | Acana, Natural Balance, Petcurean (see diet history for additional details) |  |
|                             | <b>Product Type:</b>                          | Pet Food  |  |
|                             | <b>Lot Number:</b>                            |   |  |
|                             | <b>Package Type:</b>                          | BAG   |  |
|                             | <b>Product Use Information:</b>               | <b>Description:</b>   | Please see diet history for more info ("Natural Products" written on diet history form is "Natural Balance") |
|                             | <b>Manufacturer /Distributor Information:</b> |   |  |
|                             | <b>Purchase Location Information:</b>         |   |  |

|                            |   |                                    |               |    |  |
|----------------------------|---|------------------------------------|---------------|----|--|
| <b>Animal Information:</b> | <b>Name:</b>                                | B6                                 |               |    |  |
|                            | <b>Type Of Species:</b>                     | Dog                                |               |    |  |
|                            | <b>Type Of Breed:</b>                       | Terrier - Bull - American Pit      |               |    |  |
|                            | <b>Gender:</b>                              | Female                             |               |    |  |
|                            | <b>Reproductive Status:</b>                 | Neutered                           |               |    |  |
|                            | <b>Weight:</b>                              | 18 Kilogram                        |               |    |  |
|                            | <b>Age:</b>                                 | B6 Years                           |               |    |  |
|                            | <b>Assessment of Prior Health:</b>          | Excellent                          |               |    |  |
|                            | <b>Number of Animals Given the Product:</b> | 1                                  |               |    |  |
|                            | <b>Number of Animals Reacted:</b>           | 1                                  |               |    |  |
|                            | <b>Owner Information:</b>                   | <b>Owner Information provided:</b> | Yes           |    |  |
|                            |   | <b>Contact:</b>                    | <b>Name:</b>  | B6 |  |
|                            |   |                                    | <b>Phone:</b> |    |  |
| <b>Email:</b>              |   |                                    |               |    |  |
| <b>Address:</b>            | B6  |                                    |               |    |  |

**B6**

United States

**Healthcare Professional Information:**

**Practice Name:**

Tufts Cummings School of Veterinary Medicine

**Contact:**

**Name:** Lisa Freeman

**Phone:** (508) 887-4523

**Email:** lisa.freeman@tufts.edu

**Address:**

200 Westboro Rd  
North Grafton  
Massachusetts  
01536  
United States

**Sender Information:**

**Name:**

Lisa Freeman

**Address:**

200 Westboro Rd  
North Grafton  
Massachusetts  
01536  
United States

**Contact:**

**Phone:** 5088874523

**Email:** lisa.freeman@tufts.edu

**Permission To Contact Sender:**

Yes

**Preferred Method Of Contact:**

Email

**Additional Documents:**

**Attachment:**

Diet hx 5-13-2019.pdf

**Description:**

Diet History form

**Type:**

Medical Records

**Attachment:**

Troponin 3-6-2019.pdf

**Description:**

Lab work

**Type:**

Laboratory Report

**Attachment:**

Follow-up records pt 2.pdf

**Description:**

Medical Records

**Type:**

Medical Records

**Attachment:**

Follow-up records pt 1.pdf

**Description:**

Medical Records

**Type:**

Medical Records

**Attachment:**

Recheck chem 21 5-13-2019.pdf

**Description:**

Lab work

**Type:**

Laboratory Report



Gastrointestinal Laboratory  
 Dr. J.M. Steiner  
 Department of Small Animal Clinical Sciences  
 Texas A&M University  
 4474 TAMU  
 College Station, TX 77843-4474



Website User ID: Cardiovet@tufts.edu OR clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

|   |                |                |
|---|----------------|----------------|
| <b>B6</b>                               | <b>Phone:</b>  | 508 887 4669   |
| Tufts University-Clinical Pathology Lab | <b>Fax:</b>    | 9 508 839 7936 |
| Attn: <b>B6</b>                         | Animal Name:   | <b>B6</b>      |
| 200 Westboro Road                       | Owner Name:    |                |
| North Grafton, MA 01536                 | Species:       | Canine         |
| USA                                     | Date Received: | Mar 06, 2019   |

GI Lab Accession **B6**

| <u>Test</u>                        | <u>Result</u> | <u>Control Range</u> | <u>Assay Date</u> |
|------------------------------------|---------------|----------------------|-------------------|
| Ultra-Sensitive Troponin I Fasting | <b>B6</b>     | ≤0.06                | 03/06/19          |

**B6**

Comments:

**Important  
Notices:**

**Internal Medicine Conference**

**Join us for a unique continuing education event in Phuket, Thailand Oct 7th - 11th, 2019. For details see <http://texasimconference.tamu.edu>**

**Ongoing studies**

**Cobalamin Supplementation Study-** Dogs and cats with cobalamin deficiency with normal PLI, and either normal or low (consistent with EPI) TLI to compare the efficacy of oral vs parenteral cobalamin supplementation. Contact Dr. Chang at [chchang@cvm.tamu.edu](mailto:chchang@cvm.tamu.edu) for further information.

**Chronic Pancreatitis with Uncontrolled Diabetes Mellitus-** Seeking dogs with chronic pancreatitis and uncontrolled diabetes mellitus for enrollment into a drug trial (medication provided at no cost). Contact Dr. Sue Yee Lim at [slim@cvm.tamu.edu](mailto:slim@cvm.tamu.edu) or Dr. Sina Marsilio at [smarsilio@cvm.tamu.edu](mailto:smarsilio@cvm.tamu.edu)

**Dogs with Primary Hyperlipidemia-** Prescription diet naïve dogs newly diagnosed with primary hyperlipidemia are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at [ylawrence@cvm.tamu.edu](mailto:ylawrence@cvm.tamu.edu) for more information.

**Dogs with Chronic Pancreatitis-** Dogs with chronic pancreatitis (cPLi >400µg/L) and hypertriglyceridemia (>300 mg/dl) are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at [ylawrence@cvm.tamu.edu](mailto:ylawrence@cvm.tamu.edu)

**Chronic enteropathies in dogs-** Please fill out this brief form <http://tinyurl.com/ibd-enroll> to see if your patient qualifies.

**Feline Chronic Pancreatitis-** Cats with chronic pancreatitis for more than 2 weeks and fPLI >10 µg/L are eligible for enrollment into a treatment trial investigating the efficacy of prednisolone or cyclosporine. Please contact Dr. Yamkate for further information at [pyamkate@cvm.tamu.edu](mailto:pyamkate@cvm.tamu.edu).

**We can not accept packages that are marked "Bill Receiver"**

**Use our preprinted shipping labels to save on shipping. Call 979-862-2861 for assistance. The GI Lab is not here to accept packages on the weekend. Samples may be compromised if you ship for arrival on Saturday or Sunday or if shipped via US Mail.**

---

**GI Lab Contact Information**

Phone: (979) 862-2861

Fax: (979) 862-2864

Email: [gilab@cvm.tamu.edu](mailto:gilab@cvm.tamu.edu)

[vetmed.tamu.edu/gilab](http://vetmed.tamu.edu/gilab)



Gastrointestinal Laboratory  
 Dr. J.M. Steiner  
 Department of Small Animal Clinical Sciences  
 Texas A&M University  
 4474 TAMU  
 College Station, TX 77843-4474



Website User ID: [Cardiovet@tufts.edu](mailto:Cardiovet@tufts.edu) OR [clinpath@tufts.edu](mailto:clinpath@tufts.edu)

GI Lab Assigned Clinic ID: 11405

|   |           |                |                |
|---|-----------|----------------|----------------|
| Dr:                                     | <b>B6</b> | Phone:         | 508 887 4669   |
| Tufts University-Clinical Pathology Lab |           | Fax:           | 9 508 839 7936 |
| Attn:                                   | <b>B6</b> | Animal Name:   | <b>B6</b>      |
| 200 Westboro Road                       |           | Owner Name:    |                |
| North Grafton, MA 01536                 |           | Species:       | Canine         |
| USA                                     |           | Date Received: | Mar 06, 2019   |

GI Lab Accession **B6**

| <u>Test</u>                        | <u>Result</u> | <u>Control Range</u> | <u>Assay Date</u> |
|------------------------------------|---------------|----------------------|-------------------|
| Ultra-Sensitive Troponin I Fasting | <b>B6</b>     | ≤0.06                | 03/06/19          |

**B6**

Comments:

**Important  
Notices:**

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Email: [gilab@cvm.tamu.edu](mailto:gilab@cvm.tamu.edu)

[vetmed.tamu.edu/gilab](mailto:vetmed.tamu.edu/gilab)



**From:** PFR Event <pfpreventcreation@fda.hhs.gov>  
**To:** Cleary, Michael \*; HQ Pet Food Report Notification; [B6]  
**Sent:** 11/10/2018 6:44:26 PM  
**Subject:** Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food [B6] EON-370755  
**Attachments:** 2058695-report.pdf; 2058695-attachments.zip

A PFR Report has been received and PFR Event [EON-370755] has been created in the EON System.

A "PDF" report by name "2058695-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2058695-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-370755

**ICSR #:** 2058695

**EON Title:** PFR Event created for Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food; 2058695

|                          |                    |                           |         |
|--------------------------|--------------------|---------------------------|---------|
| <b>AE Date</b>           | 08/06/2018         | <b>Number Fed/Exposed</b> | 1       |
| <b>Best By Date</b>      |                    | <b>Number Reacted</b>     | 1       |
| <b>Animal Species</b>    | Dog                | <b>Outcome to Date</b>    | Unknown |
| <b>Breed</b>             | Retriever - Golden |                           |         |
| <b>Age</b>               | [B6] years         |                           |         |
| <b>District Involved</b> | PFR [B6] DO        |                           |         |

**Product information**

**Individual Case Safety Report Number:** 2058695

**Product Group:** Pet Food

**Product Name:** Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food

**Description:** Low taurine level, eating Wellness Simple grain free for 3 months prior to testing and Wellness Core Low fat Grain Free food for 3 years before that. Taurine level was [B6] Echo showed NO DCM

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Unknown

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

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

| <b>Product Name</b>  | <b>Lot Number or ID</b> | <b>Best By Date</b> |
|--|-------------------------|---------------------|
| Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food |                         |                     |

**Sender information**

**B6**

USA

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

**B6**

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

**B6**

**B6**

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

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

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to [FDAREportableFoods@fda.hhs.gov](mailto:FDAREportableFoods@fda.hhs.gov) immediately.

**Report Details - EON-370755**

|   |  |  |              |
|---|--|--|--------------|
| <b>ICSR:</b>  | 2058695  |  |              |
| <b>Type Of Submission:</b>  | Initial  |  |              |
| <b>Report Version:</b>  | FPSR.FDA.PETF.V.V1   |  |              |
| <b>Type Of Report:</b>  | Adverse Event (a symptom, reaction or disease associated with the product) |  |              |
| <b>Reporting Type:</b>  | Voluntary  |  |              |
| <b>Report Submission Date:</b>  | 2018-11-10 13:35:47 EST  |  |              |
| <b>Reporter is the Animal Owner:</b>  | Yes  |  |              |
| <b>Reported Problem:</b>  | <b>Problem Description:</b>  | Low taurine level, eating Wellness Simple grain free for 3 months prior to testing and Wellness Core Low fat Grain Free food for 3 years before that. Taurine level was <b>B6</b> ; Echo showed NO DCM |              |
|   | <b>Date Problem Started:</b>   | 08/06/2018   |              |
|   | <b>Concurrent Medical Problem:</b>   | No   |              |
|   | <b>Outcome to Date:</b>  | Unknown  |              |
| <b>Product Information:</b>   | <b>Product Name:</b>   | Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food   |              |
|   | <b>Product Type:</b>   | Pet Food   |              |
|   | <b>Lot Number:</b>   |  |              |
|   | <b>UPC:</b>  | 7634489329   |              |
|   | <b>Package Type:</b>   | BAG  |              |
|   | <b>Package Size:</b>   | 24 Pound   |              |
|   | <b>Purchase Date:</b>  | 05/21/2018   |              |
|   | <b>Possess Unopened Product:</b>   | No   |              |
|   | <b>Possess Opened Product:</b>   | No   |              |
|   | <b>Storage Conditions:</b>   | In original bag in covered container in garage   |              |
|   | <b>Product Use Information:</b>  | <b>Description:</b>  | 4 cups a day |
|   |  | <b>First Exposure Date:</b>  | 05/21/2018   |
|   |  | <b>Last Exposure Date:</b>   | 08/31/2018   |
|   |  | <b>Time Interval between Product Use and Adverse Event:</b>  | 3 Months     |
| <b>Product Use Stopped After the Onset of the Adverse Event:</b>            |  | Yes  |              |
| <b>Adverse Event Abate After Product Stop:</b>                              |  | Unknown  |              |
| <b>Product Use Started Again:</b>   |  | No   |              |
| <b>Perceived Relatedness to Adverse Event:</b>                              |  | Definitely related   |              |
| <b>Other Foods or Products Given to the Animal During This Time Period:</b> |  | No   |              |
| <b>Manufacturer Name:</b>   | Wellpet LLC  |  |              |

|                              |   |  |   |
|------------------------------|---|--|---|
|                              | <b>/Distributor Information:</b>            |  | <b>Type(s):</b> Distributor   |
|                              |   |  | <b>Address:</b> Massachusetts<br>01876-1274<br>United States              |
|                              |   |  | <b>Contact:</b>   |
|                              |   |  | <b>Possess One or More Labels from This Product:</b> Yes                  |
|                              | <b>Purchase Location Information:</b>       |  | <b>Name:</b> Chewy.com  |
|                              |   |  | <b>Address:</b> United States   |
| <b>Animal Information:</b>   | <b>Name:</b>                                |  | <b>B6</b>   |
|                              | <b>Type Of Species:</b>                     |  | Dog   |
|                              | <b>Type Of Breed:</b>                       |  | Retriever - Golden  |
|                              | <b>Gender:</b>                              |  | Male  |
|                              | <b>Reproductive Status:</b>                 |  | Neutered  |
|                              | <b>Weight:</b>                              |  | 71 Pound  |
|                              | <b>Age:</b>                                 |  | <b>B6</b> Years   |
|                              | <b>Assessment of Prior Health:</b>          |  | Excellent   |
|                              | <b>Number of Animals Given the Product:</b> |  | 1   |
|                              | <b>Number of Animals Reacted:</b>           |  | 1   |
|                              | <b>Owner Information:</b>                   |  |   |
|                              | <b>Healthcare Professional Information:</b> |  | <b>Practice Name:</b> UC Davis  |
|                              |   |  | <b>Contact:</b> <b>Name:</b> Joshua Stern<br><b>Phone:</b> (530) 752-2475 |
|                              |   |  | <b>Address:</b> Davis<br>California<br>United States                      |
|                              |   | <b>Type of Veterinarian:</b> Referred veterinarian |   |
|                              |   | <b>Date First Seen:</b> 08/14/2018                 |   |
|                              |   | <b>Permission to Release Records to FDA:</b> No    |   |
| <b>Sender Information:</b>   | <b>Name:</b>                                |  | <b>B6</b>   |
|                              | <b>Address:</b>                             |  | <b>B6</b><br>United States  |
|                              | <b>Contact:</b>                             |  | <b>Email:</b> <b>B6</b>   |
|                              | <b>Reporter Wants to Remain Anonymous:</b>  |  | No  |
|                              | <b>Permission To Contact Sender:</b>        |  | Yes   |
|                              | <b>Preferred Method Of Contact:</b>         |  | Email   |
|                              | <b>Reported to Other Parties:</b>           |  | None  |
| <b>Additional Documents:</b> | <b>Attachment:</b>                          |  | <b>B6</b> aurine level.pdf  |
|                              | <b>Description:</b>                         |  | Taurine results from UC Davis   |
|                              | <b>Type:</b>                                |  | Laboratory Report   |

|                     |                       |          |
|---------------------|-----------------------|----------|
| <b>Attachment:</b>  | <b>B6</b>             | echo.pdf |
| <b>Description:</b> | Echocardiogram report |          |
| <b>Type:</b>        | Echocardiogram        |          |



UC VETERINARY MEDICAL CENTER-SAN DIEGO  
PHONE: (858) 875-7505

10435 SORRENTO VALLEY RD, STE 101  
SAN DIEGO, CA 92121

CARDIOLOGY  
FAX: (858) 875-7583

August 23, 2018

### Cardiology Report

Dr. **B6**

**B6** is a 6-year-old FS golden retriever belonging to **B6** who presented to the UC Veterinary Medical Center - San Diego for a cardiac evaluation.

Cardiac Diagnosis: Normal echocardiogram.

Chief Concerns/Major History: **B6** presented for an initial cardiac examination. He is part of a Golden Retriever lifetime study. Recent bloodwork showed a low normal taurine level of under 250. **B6** so it was suggested that he receive an echocardiogram. **B6** is doing well at home and not showing any clinical signs of heart disease. He is eating a low fat grain free diet. **B6** is currently receiving eye medication for corneal dystrophy.

#### Cardiology Exam:

**B6**

CV: I/VI left apical systolic heart murmur. Regular rhythm. Strong and synchronous pulses.

**B6**

#### Echocardiogram Subjective Findings:

**B6**  
**B6**

#### Echocardiogram Objective Findings:

**B6**  
**B6**

Assessment/Recommendations: There is no evidence of significant cardiomyopathy seen on this exam. There are trace insufficiencies of the mitral and tricuspid valves, which are hemodynamically insignificant at this time. No cardiac medications are warranted at this time. **B6**

**B6**

Medications: No cardiac medications warranted at this time.

Follow-up: No recheck necessary unless signs of a heart murmur is ausculted or an arrhythmia is seen or ausculted.

Thank you very much for allowing me to be of service to you and your clients. Please feel free to contact me with any questions or concerns.

**B6** DVM, DACVIM (Cardiology)

~~2020~~ 20224

### Sample Submission Form

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

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

Vet/Tech Contact: **B6**  
Company Name: **B6**  
Address: **B6**  
**B6**  
\* Please Send results to **B6**  
Email: **B6**  
Tel: **B6** Fax: **B6**

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

Patient Name: **B6**  
Species: Canine - GR  
Owner's Name: **B6**

Sample Type:  Plasma  Whole Blood  Urine  Food  Other: \_\_\_\_\_  
Test Items:  Taurine  Complete Amino Acid  Other: \_\_\_\_\_

Taurine Results (nmol/ml)  
Plasma: \_\_\_\_\_ Whole Blood: **B6** Urine: \_\_\_\_\_ Food: \_\_\_\_\_

#### Reference Ranges (nmol/ml)

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

~~2020~~ 20224

### Sample Submission Form

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

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

Vet/Tech Contact:           B6            
Company Name:                           B6                            
Address:                           B6                            
                          B6                            
\* Please Send results to:                           B6                            
Email:                           B6                            
Tel:           B6           Fax:           B6          

Billing Contact:           B6           TAX ID: \_\_\_\_\_  
Email:                           B6                           Tel:           B6          

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

Sample Type:  Plasma  Whole Blood  Urine  Food  Other: \_\_\_\_\_  
Test Items:  Taurine  Complete Amino Acid  Other: \_\_\_\_\_

Taurine Results (nmol/ml)  
Plasma: \_\_\_\_\_ Whole Blood:           B6           Urine: \_\_\_\_\_ Food: \_\_\_\_\_

#### Reference Ranges (nmol/ml)

|     | Plasma       |                                      | Whole Blood  |                                      |
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| Cat | 80-120       | >40                                  | 300-600      | >200                                 |
| Dog | 60-120       | >40                                  | 200-350      | >150                                 |



**Follow-up Case Information Uniform Data Entry Form  
Vet-LIRN**

Date (mm/dd/yy)

Aug 13, 2018

EON/CC Number:

359,970

**PATIENT INFORMATION**

Pet Name **B6**

Dog  Cat

Breed Golden Retriever

Age in years (if < 6 months, put 0.5) 4

Gender:

M  MN  F  FS

This form serves as a Uniform Data Entry Form to capture additional case specific information not clear from the Consumer Complaint or Medical Records in a standardized manner. Because each follow-up interview made with owners features questions tailored specifically to the case, each box of information contained in this Uniform Data Entry Form may not be completed.

**HISTORY-Additional Comments from Owner**

Owner's Description of What Happened:

part of Golden Retriever Lifetime study, gets a study vet appt yearly-done on **B6** he was the picture of health, including the day he died; the owner had heard for 2-3 months about diet and DCM/heart condition and brought Dr. Stern's paper to Dr. **B6** (rDVM) rDVM heard a heart murmur on PE, took to

Any Health Problems Prior to the Event (e.g. allergies, surgeries):

fed the grain free food thinking it was the best for him; always a big panter

Sensitive GI tract (e.g. stomach upset when switching foods, eats a lot of grass)  Yes

Changes to the pet's diet prior to illness  Yes

Date Diet Change:

**CLINICAL INFORMATION--Additional Comments from Owner on What Happened**

Appetite  Increased  Decreased

Water Consumption  Increased  Decreased

Vomiting  Yes

Urination  Increased  Decreased

Diarrhea  Yes

Lethargy  Yes

Duration of Diarrhea (days)

Other:

Blood in Feces  Fresh,Red  
 Coffee Ground  
 Black,Tarry

**MEDICATIONS-Taken Prior to the Event and Mentioned by Owner**

List medications mentioned by owner (e.g. NSAIDs, steroids, heartworm/flea prevention, antibiotics, etc.)

**B6**

List probiotics, vitamins, or supplements mentioned by owner:

**Follow-up Case Information Uniform Data Entry Form  
Vet-LIRN**

EON/CC Number: 359,970

Owner:

B6

Pet's Name:

B6

DIET-Any other foods the owner mentions were given to the animal during this period. (check all that apply)

Commercial Dry Product Use as Part of Diet:  Primary  Secondary  Occasional

List Product Label Name

Zignature Lamb first fed ~2.5-3 years ago (was on his puppy food ~9-12 months, then tried a few other dog foods before starting Zignature), 1-1.5 cups BID, measuring cup; last fed was the day he was

Commercial Wet-Canned Product Use as Part of Diet:  Primary  Secondary  Occasional

List Product Label Name

Commercial Wet-Pouch Product Use as Part of Diet:  Primary  Secondary  Occasional

List Product Label Name:

Commercial-Raw Product Use as Part of Diet:  Primary  Secondary  Occasional

List Product Label Name:

Homemade-Raw Product Use as Part of Diet:  Primary  Secondary  Occasional

Describe Product Type:

Homemade-Cooked Product Use as Part of Diet:  Primary  Secondary  Occasional

Describe Product Type:

diluted chicken broth, vegetables (broccoli, carrots), chicken breast

Table Scraps/Human Food (as an occasional contribution to diet) Describe Product Type(s): peanut butter in a Kong-freeze it-he'd get a Kong on a hot day, was

Pet Treat Products Product Use as Part of Diet:  Primary  Secondary  Occasional

Commercial Product Label Name/Lot: Old Mother Hubbard-Peanut butter Date first fed

How Product Administered: Date last fed was getting w

Rawhides or Pig Ears Product Label Name/Lot: previous had american made Bully sticks Date first fed

How Product Administered: hadn't had for a while Date last fed

Marrow Bones Product Label Name/Lot: Date first fed

How Product Administered: Date last fed

Chicken Jerky Product Label Name/Lot: Date first fed

How Product Administered: Date last fed

Duck Jerky Product Label Name/Lot: Date first fed

How Product Administered: Date last fed

Sweet Potato Jerky or Treats Product Label Name/Lot: Date first fed

How Product Administered: Date last fed

**Follow-up Case Information Uniform Data Entry Form  
Vet-LIRN**

EON/CC Number: 359,970

Owner:

B6

Pet's Name:

B6

DIET-continued-Any other foods the owner mentions were given to the animal during this period. (check all that apply)

Other Treats    Product Label Name/Lot:     Date first fed:   
How Product Administered:     Date last fed:

ENVIRONMENTAL EXPOSURES-Environmental Exposures Mentioned by the Owner Potentially Affecting the Animal's Overall State of Health Prior to the Event. (check all that apply)

- Indoor     Outdoor     Indoor & Outdoor     Carrion     Rodents     Grapes or Raisins     Nuts
- Plants     Trash     Hunt     Pet Shows     Sporting Events     Pet Recreation Facilities
- Livestock     Poultry     Reptiles     Pet Birds     Small Mammals     Untreated Surface Water
- Anti-freeze     Mushrooms     Heavy Metals     Ticks     Urban     Suburban     Rural

Comments:

supervised, fenced in backyard, went for walks, always on a harness walked or playing in the backyard; pavers and grass; lived w/ B6 other golden; used to pull up plants in the garden when a young dog but not as he got older

would go to a groomer or walked in the downtown area; periodically see little mushrooms but would pick them up, neither dog goes after them; they do landscape the yard and used pet safe ice melt; yes-got B6 and was treated

no trauma or hyperthermic, was always a big panter and drank a lot of water (his personality), no radiation or electric shock, no chemo or human pills, no alcohol, no japanese yew, foxglove, black locust, buttercup, lily of the valley, or gossypol

HOUSEHOLD-Signalment of Additional Animals Given the Product mentioned by the owner.

Animal 1:  B6 yr, FS Golden Retriever, related to  B6 (her sister was  B6 mother): the breeder was also feeding a grain free and taurine tested  Reacted

Animal 2:   Reacted

Animal 3:   Reacted

Comments:

Submit

---

**From:** PFR Event <pfpreventcreation@fda.hhs.gov>  
**To:** Cleary, Michael \*; HQ Pet Food Report Notification; B6  
**Sent:** 2/25/2019 1:05:02 PM  
**Subject:** Wellness CORE Grain-Free Ocean Whitefish dry-Wellness Core grain free turkey: Lisa Freeman - EON-380743  
**Attachments:** 2063134-report.pdf; 2063134-attachments.zip

A PFR Report has been received and PFR Event [EON-380743] has been created in the EON System.

A "PDF" report by name "2063134-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2063134-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380743

**ICSR #:** 2063134

**EON Title:** PFR Event created for Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey chicken liver and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe; 2063134

|                          |                    |                           |        |
|--------------------------|--------------------|---------------------------|--------|
| <b>AE Date</b>           | 02/01/2019         | <b>Number Fed/Exposed</b> | 6      |
| <b>Best By Date</b>      |                    | <b>Number Reacted</b>     | 3      |
| <b>Animal Species</b>    | Dog                | <b>Outcome to Date</b>    | Stable |
| <b>Breed</b>             | Bulldog            |                           |        |
| <b>Age</b>               | 8 Years            |                           |        |
| <b>District Involved</b> | PFR-New England DO |                           |        |

**Product information**

**Individual Case Safety Report Number:** 2063134

**Product Group:** Pet Food

**Product Name:** Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe

**Description:** Housemate (half sister; B6) - (ICSR) of 2063133) diagnosed with DCM and CHF so screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with

ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated)

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Stable

**Number of Animals Treated With Product:** 6

**Number of Animals Reacted With Product:** 3

| Product Name   | Lot Number or ID | Best By Date |
|--|------------------|--------------|
| Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe |                  |              |

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6** USA

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

**B6**

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

**B6**

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

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Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to [FDAREportableFoods@fda.hhs.gov](mailto:FDAREportableFoods@fda.hhs.gov) immediately.

**Report Details - EON-380743**

ICSR: 2063134  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2019-02-25 07:58:43 EST

**Reported Problem:**  
**Problem Description:** Housemate (half sister; [B6]) - (ICSR) of 2063133) diagnosed with DCM and CHF so screened by RDVM for BNP which was elevated. Evaluated at Tufts 2/1/19. ARVC/diet-induced DCM with ventricular arrhythmia. Diet changed to Royal Canin Early Cardiac and will re-evaluate in 3 months I have diet sample. 3 other dogs in household (1 had normal BNP, other 2 not yet evaluated)  
**Date Problem Started:** 02/01/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** [B6] puppy  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe  
**Product Type:** Pet Food  
**Lot Number:**  
**Product Use Information:** **Description:** Please see diet history for more info (and refer to [B6] diet history for more complete info - all dogs eat same diets)  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** [B6]  
**Type Of Species:** Dog  
**Type Of Breed:** Bulldog  
**Gender:** Male  
**Reproductive Status:** Neutered  
**Weight:** 22.1 Kilogram  
**Age:** 8 Years  
**Assessment of Prior Health:** Good  
**Number of Animals Given the Product:** 6  
**Number of Animals Reacted:** 3  
**Owner Information:** **Owner Information provided:** Yes  
**Contact:** **Name:** [B6]  
**Phone:** [B6]  
**Email:** [B6]  
**Address:** [B6]  
 United States  
**Healthcare Professional Practice Name:** Tufts Cummings School of Veterinary Medicine

|                                     |                                      |   |   |  |
|-------------------------------------|--------------------------------------|---|---|--|
|                                     | <b>Information:</b>                  | <b>Contact:</b>   | <b>Name:</b> Lisa Freeman   |  |
|                                     |                                      |   | <b>Phone:</b> (508) 887-4523  |  |
|                                     |                                      |   | <b>Email:</b> lisa.freeman@tufts.edu  |  |
|                                     |                                      | <b>Address:</b>   | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |  |
| <b>Sender Information:</b>          | <b>Name:</b>                         | Lisa Freeman  |   |  |
|                                     | <b>Address:</b>                      | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |   |  |
|                                     | <b>Contact:</b>                      | <b>Phone:</b>   | 5088874523  |  |
|                                     |                                      | <b>Email:</b>   | lisa.freeman@tufts.edu  |  |
|                                     | <b>Permission To Contact Sender:</b> | Yes   |   |  |
| <b>Preferred Method Of Contact:</b> | Email                                |   |   |  |
| <b>Additional Documents:</b>        | <b>Attachment:</b>                   | rpt_medical_record_preview.pdf  |   |  |
|                                     | <b>Description:</b>                  | Medical record  |   |  |
|                                     | <b>Type:</b>                         | Medical Records   |   |  |



Client:

Address:

**B6**

**All Medical Records**

Patient:

Breed:

DOB:

**B6**

English Bulldog

**B6**

Species: Canine

Sex: Male  
(Neutered)

Home Phone:  
Work Phone:  
Cell Phone:

**B6**

**Referring Information**

---

**B6**

Client:

Patient:

**B6**

**Initial Complaint:**

---

**Initial Complaint:**

---

**Initial Complaint:**

---

**Initial Complaint:**

---

Client:  
Patient:

**B6**

---

**Initial Complaint:**

Scanned Record

---

**Initial Complaint:**

Cardiology DCM study - will come fasted - u/f samples

---

SOAP Text Feb 1 2019 11:50AM -

**B6**

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**Disposition/Recommendations**

---

Client:  
Patient:

**B6**

---

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Client:  
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:       | <b>B6</b> |
| Veterinarian: |           |
| Patient ID:   | 438225    |
| Visit ID:     |           |

|          |                     |
|----------|---------------------|
| Patient: | <b>B6</b>           |
| Species: | Canine              |
| Breed:   | English Bulldog     |
| Sex:     | Male (Neutered)     |
| Age:     | <b>B6</b> Years Old |

**Lab Results Report**

| Accession ID: |         |                 |       |
|---------------|---------|-----------------|-------|
| Test          | Results | Reference Range | Units |



**B6**

Client: **B6**  
Patient:

**IDEXX Hematology 1/24/19**



|                  |           |                          |                                 |
|------------------|-----------|--------------------------|---------------------------------|
|                  | <b>B6</b> |                          |                                 |
| PET OWNER:       | <b>B6</b> | <b>B6</b>                | LAB ID: 2302815220              |
| SPECIES:         | Canine    |                          | ORDER ID: 38459535              |
| BREED:           |           |                          | COLLECTION DATE: <b>1/23/19</b> |
| GENDER:          | Male      |                          | DATE OF RECEIPT: <b>1/24/19</b> |
| AGE:             | 8 Years   |                          | DATE OF RESULT: <b>1/24/19</b>  |
| PATIENT ID: 5689 |           | ACCOUNT #: 84116         |                                 |
|                  |           | ATTENDING VET: <b>B6</b> |                                 |

IDEXX Services: Senior Profile with Fecal Dx™ Profile, Giardia, Lab 4Dx® Plus and Reflex Quant C6® and UPC Select, SAMPLE/TEST INFO NEEDED, Cardiopet® proBNP-Canine Add-on\*

**Hematology**

1/24/19 (Order Received)  
1/24/19 11:05 AM (Last Updated)

3/2/17

| TEST                    | RESULT         | REFERENCE VALUE   |
|-------------------------|----------------|-------------------|
| RBC                     | <b>B6</b>      | 5.39 - 8.7 M/μL   |
| Hematocrit              |                | 38.3 - 56.5 %     |
| Hemoglobin              |                | 13.4 - 20.7 g/dL  |
| MCV                     |                | 59 - 76 fL        |
| MCH                     |                | 21.9 - 26.1 pg    |
| MCHC                    |                | 32.6 - 39.2 g/dL  |
| % Reticulocyte          |                | %                 |
| Reticulocytes           |                | 10 - 110 K/μL     |
| Reticulocyte Hemoglobin |                | 22.3 - 29.6 pg    |
| WBC                     |                | 4.9 - 17.6 K/μL   |
| % Neutrophils           |                | %                 |
| % Lymphocytes           |                | %                 |
| % Monocytes             |                | %                 |
| % Eosinophils           |                | %                 |
| % Basophils             |                | %                 |
| Neutrophils             |                | 2.94 - 12.67 K/μL |
| Lymphocytes             |                | 1.06 - 4.95 K/μL  |
| Monocytes               |                | 0.13 - 1.15 K/μL  |
| Eosinophils             |                | 0.07 - 1.49 K/μL  |
| Basophils               |                | 0 - 0.1 K/μL      |
| Platelets               | 143 - 448 K/μL |                   |
| Remarks                 | <b>B6</b>      | SLIDE REV...      |

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

**IDEXX Hematology 1/24/19**



**B6**      PET OWNER: **B6**      DATE OF RESULT: **1/24/19**      LAB ID: 2302815220

**Chemistry**

1/24/19 (Order Received)  
1/24/19 11:06 AM (Last Updated)

3/2/17

| TEST                     | RESULT    | REFERENCE VALUE  |
|--------------------------|-----------|------------------|
| Glucose                  | <b>B6</b> | 63 - 114 mg/dL   |
| IDEXX SDMA               |           | 0 - 14 µg/dL     |
| Creatinine               |           | 0.5 - 1.5 mg/dL  |
| BUN                      |           | 9 - 31 mg/dL     |
| BUN: Creatinine Ratio    |           |                  |
| Phosphorus               |           | 2.5 - 6.1 mg/dL  |
| Calcium                  |           | 8.4 - 11.8 mg/dL |
| Sodium                   |           | 142 - 152 mmol/L |
| Potassium                |           | 4.0 - 5.4 mmol/L |
| Na: K Ratio              |           | 28 - 37          |
| Chloride                 |           | 108 - 119 mmol/L |
| TCO2 (Bicarbonate)       |           | 13 - 27 mmol/L   |
| Anion Gap                |           | 11 - 26 mmol/L   |
| Total Protein            |           | 5.5 - 7.5 g/dL   |
| Albumin                  |           | 2.7 - 3.9 g/dL   |
| Globulin                 |           | 2.4 - 4.0 g/dL   |
| Albumin: Globulin Ratio  |           | 0.7 - 1.5        |
| ALT                      |           | 18 - 121 U/L     |
| AST                      |           | 16 - 55 U/L      |
| ALP                      |           | 5 - 160 U/L      |
| GGT                      |           | 0 - 13 U/L       |
| Bilirubin - Total        |           | 0.0 - 0.3 mg/dL  |
| Bilirubin - Unconjugated |           | 0.0 - 0.2 mg/dL  |
| Bilirubin - Conjugated   |           | 0.0 - 0.1 mg/dL  |
| Cholesterol              |           | 131 - 345 mg/dL  |
| Amylase                  |           | 337 - 1,469 U/L  |
| Lipase                   |           | 138 - 755 U/L    |
| Creatine Kinase          |           | 10 - 200 U/L     |

**B6**

Client:  
Patient:

**B6**

**IDEXX Hematology 1/24/19**



**B6**

PET OWNER

**B6**

DATE OF RESULT: **1/24/19**

LAB ID: 2302815220

**Chemistry (continued)**

| TEST                      | RESULT    | REFERENCE VALUE |
|---------------------------|-----------|-----------------|
| Hemolysis Index           | <b>B6</b> | <b>B6</b>       |
| Lipemia Index             | <b>B6</b> |                 |
| Cardiopet proBNP - Canine | <b>B6</b> | 0 - 900 pmol/L  |

**B6**

**B6**

**B6**

Please note: Complete interpretive comments for all concentrations of Cardiopet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.

**Endocrinology**



1/24/19 (Order Received)  
1/24/19 11:05 AM (Last Updated)

3/2/17

| TEST     | RESULT    | REFERENCE VALUE |
|----------|-----------|-----------------|
| Total T4 | <b>B6</b> | 1 - 4 µg/dL     |

**B6**

**Serology**



1/24/19 (Order Received)  
1/24/19 11:05 AM (Last Updated)

| TEST              | RESULT    |
|-------------------|-----------|
| Heartworm Antigen | <b>B6</b> |

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

**IDEXX Hematology 1/24/19**



 **B6**      PET OWNER: **B6**      DATE OF RESULT: **1/24/19**      LAB ID: 2302815220

**Serology (continued)**

| TEST                               | RESULT      |
|------------------------------------|-------------|
| Ehrlichia canis / ewingii          | a <b>B6</b> |
| Lyme (Borrelia burgdorferi)        | b <b>B6</b> |
| Anaplasma phagocytophilum / platys |             |

a **B6**

b **B6**

For more information on the diagnosis and management of Tick/Vector-borne diseases, see [www.idexx.com/4DxGuide](http://www.idexx.com/4DxGuide).

**Other**



1/24/19 (Order Received)  
1/24/19 11:05 AM (Last Updated)

| TEST                    | RESULT    |
|-------------------------|-----------|
| More Information Needed | <b>B6</b> |



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

cbc and profile 2/1/19

**Cummings School of Veterinary Medicine**

Clinical Pathology Laboratory  
 200 Westboro Road  
 North Grafton, MA 01536

Name/DOB: **B6**      Sex: CM      Provider: **B6**  
 Patient ID: 438225      Age: 8      Order Location: V320559: Investigation into  
 Phone number:      Species: Canine      Sample ID: 1902010102  
 Collection Date: 2/1/2019 11:52 AM      Breed:  
 Approval date: 2/1/2019 12:57 PM

| TEST NAME | IN RANGE | RESULT | OUT OF RANGE | RANGE | UNITS | REFERENCE RANGE |
|-----------|----------|--------|--------------|-------|-------|-----------------|
|-----------|----------|--------|--------------|-------|-------|-----------------|

**CBC, Comprehensive, Sm Animal (Research) CSTCYR**

|                                     |           |  |           |        |        |             |            |
|-------------------------------------|-----------|--|-----------|--------|--------|-------------|------------|
| WBC (ADVIA)                         | <b>B6</b> |  |           | [ * ]  | K/uL   | 4.40-15.10  |            |
| RB C (Advia)                        |           |  |           | [ * ]  | M/uL   | 5.80-8.50   |            |
| Hemoglobin (ADVIA)                  |           |  |           | [ * ]  | g/dL   | 13.3-20.5   |            |
| Hematocrit (Advia)                  |           |  |           | [ * ]  | %      | 39-55       |            |
| MCV (ADVIA)                         |           |  |           | [ * ]  | fL     | 64.5-77.5   |            |
| MCH (ADVIA)                         |           |  |           | [ * ]  | pg     | 21.3-25.9   |            |
| CHCM                                |           |  |           |        | g/dl   |             |            |
| MCHC (ADVIA)                        |           |  |           |        | g/dL   | 31.9-34.3   |            |
| RDW (ADVIA)                         |           |  |           |        | [ * ]  | 11.9-15.2   |            |
| Platelet Count (Advia)              |           |  | <b>B6</b> |        | [ * ]* | K/uL        | 173-486    |
| Mean Platelet Volume (Advia)        |           |  |           | [ * ]  | fl     | 8.29-13.20  |            |
| 02/01/19 12:12 PM                   | <b>B6</b> |  |           |        |        |             |            |
| Platelet Crit                       |           |  | <b>B6</b> | [ * ]* | %      | 0.129-0.403 |            |
| 02/01/19 12:12 PM                   | <b>B6</b> |  |           |        |        |             |            |
| PDW                                 | <b>B6</b> |  |           |        | %      |             |            |
| Reticulocyte Count (Advia)          |           |  | <b>B6</b> | [ * ]* | %      | 0.20-1.60   |            |
| Absolute Reticulocyte Count (Advia) |           |  |           |        | [ * ]* | K/uL        | 14.7-113.7 |
| CHr                                 |           |  |           |        |        | pg          |            |
| MCVr                                |           |  |           |        |        | fl          |            |
| Comments (Hematology)               |           |  |           |        |        |             |            |

**Microscopic Exam of Blood Smear (Advia) CSTCYR**

|                             |           |  |  |       |        |       |              |
|-----------------------------|-----------|--|--|-------|--------|-------|--------------|
| Seg Neuts (%)               | <b>B6</b> |  |  | [ * ] | %      | 43-86 |              |
| Lymphocytes (%)             |           |  |  | [ * ] | %      | 7-47  |              |
| Monocytes (%)               |           |  |  | [ * ] | %      | 1-15  |              |
| Eosinophils (%)             |           |  |  | [ * ] | %      | 0-16  |              |
| Seg Neutrophils (Abs) Advia |           |  |  |       | [ * ]* | K/uL  | 2.800-11.500 |
| Lymphs (Abs) Advia          |           |  |  |       | [ * ]  | K/uL  | 1.00-4.80    |
| Mono (Abs) Advia            |           |  |  |       | [ * ]  | K/uL  | 0.10-1.50    |
| Eosinophils (Abs)           |           |  |  |       | [ * ]  | K/uL  | 0.00-1.40    |

Sample ID: 1902010102/1  
 This report continues... (Final)

Reviewed by: \_\_\_\_\_

Client: **B6**  
 Patient:

**cbc and profile 2/1/19**

**Cummings School of Veterinary Medicine**

Clinical Pathology Laboratory  
 200 Westboro Road  
 North Grafton, MA 01536

Name/DOB: **B6**      Sex: CM      Provider: **B6**  
 Patient ID: 438225      Age: 8      Order Location: V320559: Investigation into  
 Phone number:      Species: Canine      Sample ID: 1902010102  
 Collection Date: 2/1/2019 11:52 AM      Breed:  
 Approval date: 2/1/2019 12:57 PM

| TEST NAME | RESULT   | RANGE        | UNITS | REFERENCE RANGE |
|-----------|----------|--------------|-------|-----------------|
|           | IN RANGE | OUT OF RANGE |       |                 |

**Microscopic Exam of Blood Smear (Advia) (cont'd)** CSTCYR

Advia  
 WBC Morphology **B6**  
 RBC Morphology

**Research Chemistry Profile - Small Animal (Cobas)** SMACHUNSKI

|                         |       |        |           |
|-------------------------|-------|--------|-----------|
| Glucose                 | [ * ] | mg/dL  | 67-135    |
| Urea                    | [ * ] | mg/dL  | 8-30      |
| Creatinine              | [ * ] | mg/dL  | 0.6-2.0   |
| Phosphorus              | [ * ] | mg/dL  | 2.6-7.2   |
| Calcium 2               | [ * ] | mg/dL  | 9.4-11.3  |
| Magnesium 2+            | [ * ] | mEq/L  | 1.8-3.0   |
| Total Protein           | [ * ] | g/dL   | 5.5-7.8   |
| Albumin                 | [ * ] | g/dL   | 2.8-4.0   |
| Globulins               | [ * ] | g/dL   | 2.3-4.2   |
| A/G Ratio               | [ * ] |        | 0.7-1.6   |
| Sodium                  | [ * ] | mEq/L  | 140-150   |
| Chloride                | [ * ] | mEq/L  | 106-116   |
| Potassium               | [ * ] | mEq/L  | 3.7-5.4   |
| tCO2(Bicarb)            | [ * ] | mEq/L  | 14-28     |
| AGAP                    | [ * ] |        | 8.0-19.0  |
| NA/K                    | [ * ] |        | 29-40     |
| Total Bilirubin         | [ * ] | mg/dL  | 0.10-0.30 |
| Alkaline Phosphatase    | [ * ] | U/L    | 12-127    |
| GGT                     | [ * ] | U/L    | 0-10      |
| ALT                     | [ * ] | U/L    | 14-86     |
| AST                     | [ * ] | U/L    | 9-54      |
| Creatine Kinase         | [ * ] | U/L    | 22-422    |
| Cholesterol             | [ * ] | mg/dL  | 82-355    |
| Triglycerides           | [ * ] | mg/dl  | 30-338    |
| Amylase                 | [ * ] | U/L    | 409-1250  |
| Osmolality (calculated) | [ * ] | mmol/L | 291-315   |

Sample ID: 1902010102/2  
 END OF REPORT (Final)

Reviewed by: \_\_\_\_\_  
 Page 2

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

**NT-proBNP 2/1/19**

IDEXX Reference Laboratories

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

Client: **B6**  
Patient: **B6**  
Species: CANINE  
Breed: ENGLISH\_BULLDOG  
Gender: MALE NEUTERED  
Age: 8Y

Date: 02/01/2019  
Requisition #: 438225  
Accession #: **B6**  
Ordered by: **B6**

IDEXX VetConnect 1-888-433-9987  
**TUFTS UNIVERSITY**  
200 WESTBORO RD  
NORTH GRAFTON, Massachusetts 01536  
508-839-5395  
Account #88933

**CARDIOPET proBNP - CANINE**

| Test                      | Result    | Reference Range | Low  | Normal | High      |
|---------------------------|-----------|-----------------|------|--------|-----------|
| CARDIOPET proBNP - CANINE | <b>B6</b> | 0 - 900 pmol/L  | HIGH |        | <b>B6</b> |

**Comments:**

1. **B6**

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

**CBC/CHEM**



**Tufts Cummings School Of Veterinary Medicine**

200 Westboro Road  
North Grafton, MA 01536

**DUPLICATE**

Name/DOB: **B6**      Sex: CM      Provider: **B6**  
Patient ID: 438225      Age: 8      Order Location: V320539: Investigation into  
Phone number:      Species: Canine      Sample ID: 1902010102  
Collection Date: 2/1/2019 11:52 AM      Breed:  
Approval date: 2/1/2019 12:57 PM

**CBC, Comprehensive, Sm Animal (Research)**

|                                     |             | Ref. Range/Males |
|-------------------------------------|-------------|------------------|
| CSTCYR                              |             |                  |
| WBC (ADVIA)                         | <b>B6</b>   | 4.40-15.10 K/uL  |
| RBC (Advia)                         | <b>B6</b>   | 5.80-8.50 M/uL   |
| Hemoglobin (ADVIA)                  | <b>B6</b>   | 13.3-20.5 g/dL   |
| Hematocrit (Advia)                  | <b>B6</b>   | 39-55 %          |
| MCV (ADVIA)                         | <b>B6</b>   | 64.5-77.5 fL     |
| MCH (ADVIA)                         | <b>B6</b>   | 21.3-25.9 pg     |
| CHCM                                |             |                  |
| MCHC (ADVIA)                        |             | 31.9-34.3 g/dL   |
| RDW (ADVIA)                         |             | 11.9-15.2        |
| Platelet Count (Advia)              | H <b>B6</b> | 173-486 K/uL     |
| Mean Platelet Volume (Advia)        |             | 8.29-13.20 fl    |
| 02/01/19 12:12 PM                   | <b>B6</b>   |                  |
| Platelet Crit                       | H <b>B6</b> | 0.129-0.403 %    |
| 02/01/19 12:12 PM                   | <b>B6</b>   |                  |
| PDW                                 |             |                  |
| Reticulocyte Count (Advia)          | H <b>B6</b> | 0.20-1.60 %      |
| Absolute Reticulocyte Count (Advia) | H <b>B6</b> | 14.7-113.7 K/uL  |
| CHr                                 |             |                  |
| MCVr                                |             |                  |
| Comments (Hematology)               |             |                  |

**Microscopic Exam of Blood Smear (Advia)**

|                             |           | Ref. Range/Males  |
|-----------------------------|-----------|-------------------|
| CSTCYR                      |           |                   |
| Seg Neuts (%)               | <b>B6</b> | 43-86 %           |
| Lymphocytes (%)             | <b>B6</b> | 7-47 %            |
| Monocytes (%)               | <b>B6</b> | 1-15 %            |
| Eosinophils (%)             | <b>B6</b> | 0-16 %            |
| Seg Neutrophils (Abs) Advia | <b>B6</b> | 2.800-11.500 K/uL |
| Lymphs (Abs) Advia          | <b>B6</b> | 1.00-4.80 K/uL    |
| Mono (Abs) Advia            | <b>B6</b> | 0.10-1.50 K/uL    |
| Eosinophils (Abs) Advia     | <b>B6</b> | 0.00-1.40 K/uL    |
| WBC Morphology              |           |                   |
| RBC Morphology              |           |                   |

**Research Chemistry Profile - Small Animal (Cobas)**

Sample ID: 1902010102/1  
This report continues... (Final)

Reviewed by: \_\_\_\_\_

Client:  
Patient:

**B6**

**CBC/CHEM**



**Tufts Cummings School Of Veterinary Medicine**

200 Westboro Road  
North Grafton, MA 01536

**DUPLICATE**

|                                    |                 |   |
|------------------------------------|-----------------|---|
| Name/DOB: <b>B6</b>                | Sex: CM         | Provider: <b>B6</b>                         |
| Patient ID: 438225                 | Age: 8          | Order Location: V320559: Investigation into |
| Phone number:                      | Species: Canine | Sample ID: 1902010102                       |
| Collection Date: 2/1/2019 11:52 AM | Breed:          |   |
| Approval date: 2/1/2019 12:57 PM   |                 |   |

**Research Chemistry Profile - Small Animal (Cobas) (cont'd)**

|                         |                |                  |
|-------------------------|----------------|------------------|
| SMACHUNSKI              | <b>B6</b>      | Ref. Range/Males |
| Glucose                 |                | 67-135 mg/dL     |
| Urea                    |                | 8-30 mg/dL       |
| Creatinine              |                | 0.6-2.0 mg/dL    |
| Phosphorus              |                | 2.6-7.2 mg/dL    |
| Calcium 2               |                | 9.4-11.3 mg/dL   |
| Magnesium 2+            |                | 1.8-3.0 mEq/L    |
| Total Protein           |                | 5.5-7.8 g/dL     |
| Albumin                 |                | 2.8-4.0 g/dL     |
| Globulins               |                | 2.3-4.2 g/dL     |
| A/G Ratio               |                | 0.7-1.6          |
| Sodium                  |                | 140-150 mEq/L    |
| Chloride                |                | 106-116 mEq/L    |
| Potassium               |                | 3.7-5.4 mEq/L    |
| tCO2(Bicarb)            |                | 14-28 mEq/L      |
| AGAP                    |                | 8.0-19.0         |
| NA/K                    |                | 29-40            |
| Total Bilirubin         |                | 0.10-0.30 mg/dL  |
| Alkaline Phosphatase    |                | 12-127 U/L       |
| GGT                     |                | 0-10 U/L         |
| ALT                     | 14-86 U/L      |                  |
| AST                     | 9-54 U/L       |                  |
| Creatine Kinase         | 22-422 U/L     |                  |
| Cholesterol             | 82-355 mg/dL   |                  |
| Triglycerides           | 30-338 mg/dl   |                  |
| Amylase                 | 409-1250 U/L   |                  |
| Osmolality (calculated) | 291-315 mmol/L |                  |

Sample ID: 19020101022  
REPRINT: Orig. printing on 2/1/2019 (Final)

Reviewed by: \_\_\_\_\_  
Page 2

Client:  
Patient:

**B6**

**Taurine level**

27291 PLD  
WB (B)

**B6**

**Amino Acid Laboratory Sample Submission Form**

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

Veterinarian Contact: **B6**

Clinic/Company Name: Tufts Cummings School of Vet. Med. - Clinical Pathology Laboratory

Address: 200 Westboro Road, North Grafton, MA, 015369

Email: Clinpath@tufts.edu cardiovet@tufts.edu

Telephone: 508-887-4669 Fax: 508-839-7936

Billing Contact: **B6** Email: **B6**

Billing Contact Phone: **B6** Tax ID: \_\_\_\_\_

Patient Name: **B6** Species: CANINE

Breed: English Bulldog Owner's Name: **B6**

Current Diet: Wellness Core

Sample type:  Plasma  Whole Blood  Urine  Food  Other \_\_\_\_\_

Test:  Taurine  Complete Amino Acids  Other: \_\_\_\_\_

**Taurine Results (lab use only)**

Plasm **B6** Whole Blood: **B6** Urine: \_\_\_\_\_ Food: \_\_\_\_\_

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

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

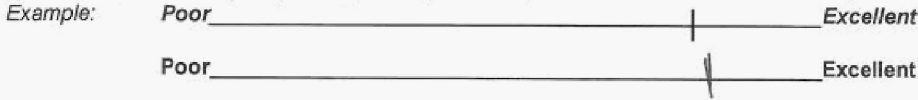
Client: **B6**  
 Patient: **B6**

**Diet history 2/1/19**

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

Pet's name: **B6** Owner's name: **B6** Today's date: **02-01-19**

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)



2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

- Eats about the same amount as usual     Eats less than usual     Eats more than usual  
 Seems to prefer different foods than usual     Other \_\_\_\_\_

3. Over the last few weeks, has your pet (check one)

- Lost weight     Gained weight     Stayed about the same weight     Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

| Food (include specific product and flavor)             | Form       | Amount       | How often? | Fed since |
|--|------------|--------------|------------|-----------|
| Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult | dry        | 1 1/2 cup    | 2x/day     | Jan 2018  |
| 85% lean hamburger                                     | microwaved | 3 oz         | 1x/week    | Jan 2015  |
| Pupperoni original beef flavor                         | treat      | 1/2          | 1x/day     | Aug 2015  |
| Rawhide  | treat      | 6 inch twist | 1x/week    | Dec 2015  |
| Wellness Core Canned chicken                           | wet        | 4 oz         | 2x/day     | Dec 2015  |
| Wellness Core fish                                     | dry        | 1/4 cup      | 2x/day     | Dec 2015  |
| Wellness Core  | treat      | 3 pcs        | 1x/day     | 11        |
| (See <b>B6</b> for exact brands/formulas)              |            |              |            |           |

\*Any additional diet information can be listed on the back of this sheet

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Yes  No If yes, please list which ones and give brands and amounts:

|  | Brand/Concentration   | Amount per day             |
|--|---|----------------------------|
| Taurine                                    | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No _____ | _____                      |
| Carnitine                                  | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No _____ | _____                      |
| Antioxidants                               | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No _____ | _____                      |
| Multivitamin                               | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No _____ | _____                      |
| Fish oil                                   | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No _____ | _____                      |
| Coenzyme Q10                               | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No _____ | _____                      |
| Other (please list):<br>Example: Vitamin C | Nature's Bounty   | 500 mg tablets – 1 per day |
| _____                                      | _____   | _____                      |
| _____                                      | _____   | _____                      |
| _____                                      | _____   | _____                      |
| _____                                      | _____   | _____                      |

6. How do you administer pills to your pet?

- I do not give any medications  
 I put them directly in my pet's mouth without food  
 I put them in my pet's dog/cat food  
 I put them in a Pill Pocket or similar product  
 I put them in foods (list foods): \_\_\_\_\_

CHANGING DIET TO  
 ROYAL CANIN EARLY  
 CARDIAC

Client: **B6**  
Patient:

**Troponin 2/1/19**



Gastrointestinal Laboratory  
Dr. J.M. Steiner  
Department of Small Animal Clinical Sciences  
Texas A&M University  
4474 TAMU  
College Station, TX 77843-4474



Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

Dr. Freeman  
Tufts University-Clinical Pathology Lab  
Attn: **B6**  
200 Westboro Road  
North Grafton, MA 01536  
USA

Phone: 508 887 4669  
Fax: 9 508 839 7936  
Animal Name:  
Owner Name: **B6**  
Species: Canine  
Date Received: Feb 12, 2019

GI Lab Accession: **B6**

| <u>Test</u>                        | <u>Result</u> | <u>Control Range</u> | <u>Assay Date</u> |
|------------------------------------|---------------|----------------------|-------------------|
| Ultra-Sensitive Troponin I Fasting | <b>B6</b>     | ≤0.06                | 02/12/19          |

**B6**

Comments:



Client:  
Patient:

**B6**

---

**Troponin 2/1/19**

---

**Important  
Notices:**

**Internal Medicine Conference**

**Join us for a unique continuing education event in Phuket, Thailand Oct 7th - 11th, 2019. For details see <http://texasimconference.tamu.edu>**

**Ongoing studies**

**Cobalamin Supplementation Study-** Dogs and cats with cobalamin deficiency with normal PLI, and either normal or low (consistent with EPI) TLI to compare the efficacy of oral vs parenteral cobalamin supplementation. Contact Dr. Chang at [chchang@cvm.tamu.edu](mailto:chchang@cvm.tamu.edu) for further information.

**Chronic Pancreatitis with Uncontrolled Diabetes Mellitus-** Seeking dogs with chronic pancreatitis and uncontrolled diabetes mellitus for enrollment into a drug trial (medication provided at no cost). Contact Dr. Sue Yee Lim at [slim@cvm.tamu.edu](mailto:slim@cvm.tamu.edu) or Dr. Sina Marsilio at [smarsilio@cvm.tamu.edu](mailto:smarsilio@cvm.tamu.edu)

**Dogs with Primary Hyperlipidemia-** Prescription diet naive dogs newly diagnosed with primary hyperlipidemia are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at [ylawrence@cvm.tamu.edu](mailto:ylawrence@cvm.tamu.edu) for more information.

**Dogs with Chronic Pancreatitis-** Dogs with chronic pancreatitis (cPLI >400µg/L) and hypertriglyceridemia (>300 mg/dl) are eligible to be enrolled in a dietary trial. Contact Dr. Lawrence at [ylawrence@cvm.tamu.edu](mailto:ylawrence@cvm.tamu.edu)

**Chronic enteropathies in dogs-** Please fill out this brief form <http://tinyurl.com/ibd-enroll> to see if your patient qualifies.

**Feline Chronic Pancreatitis-** Cats with chronic pancreatitis for more than 2 weeks and fPLI >10 µg/L are eligible for enrollment into a treatment trial investigating the efficacy of prednisolone or cyclosporine. Please contact Dr. Yamkate for further information at [pyamkate@cvm.tamu.edu](mailto:pyamkate@cvm.tamu.edu).

**We can not accept packages that are marked "Bill Receiver"**

**Use our preprinted shipping labels to save on shipping. Call 979-862-2861 for assistance. The GI Lab is not here to accept packages on the weekend. Samples may be compromised if you ship for arrival on Saturday or Sunday or if shipped via US Mail.**

---

**GI Lab Contact Information**

Phone: (979) 862-2861

Fax: (979) 862-2864

Email: [gilab@cvm.tamu.edu](mailto:gilab@cvm.tamu.edu)

[vetmed.tamu.edu/gilab](http://vetmed.tamu.edu/gilab)

Client: **B6**  
Patient:

**Vitals Results**

2/1/2019 11:00:04 AM

Weight (kg)

**B6**

**Patient History**

01/28/2019 03:52 PM

Appointment

02/01/2019 08:05 AM

UserForm

02/01/2019 08:05 AM

UserForm

02/01/2019 10:37 AM

UserForm

02/01/2019 10:38 AM

UserForm

02/01/2019 10:44 AM

Purchase

02/01/2019 11:00 AM

Vitals

02/01/2019 12:03 PM

UserForm

02/01/2019 12:50 PM

Appointment

02/01/2019 12:58 PM

Prescription

02/20/2019 12:08 PM

Patient Merge

02/21/2019 04:32 PM

Purchase

02/21/2019 04:32 PM

Purchase

**B6**



**B6**

**B6**

Male (Neutered)

Canine English Bulldog Brown/White

Patient ID: 438225

## STANDARD CONSENT FORM

---

I am the owner, or agent for the owner, of the above described animal and have the authority to execute consent. I hereby authorize the Cummings School of Veterinary Medicine at Tufts University (herein after Cummings School) to prescribe for treatment of said animal according to the following terms and conditions.

Cummings School and its officers, agents and employees will provide such veterinary medical care as they deem reasonable and appropriate under the circumstances.

Cummings School and its officers, agents, and employees will use all reasonable care in the treatment of the above mentioned animal, but will not be liable for any loss or accident that may occur or any disease that may develop as a result of the care and treatment provided.

I understand that the above identified animal may be treated by Cummings School students under the supervision and assistance of Cummings School staff members.

In executing this form, I hereby expressly acknowledge that risks, benefits and alternative forms of treatment have been explained to me. I understand said explanation, and I consent to treatment. Should any additional treatments or diagnostics be required during the continued care of my animal, I understand that I will be given the opportunity to discuss and consent to these additional procedures. I understand that further or additional treatment may be required without an opportunity for discussion and consideration by me, in the case of the development of any life-threatening emergency during the continued care of my animal and I expressly consent to all such reasonable treatment as required. I realize and understand that results cannot be guaranteed.

If any equipment is left with the animal, it will be accepted with the understanding that Cummings School assumes no responsibility for any loss of equipment that may occur.

I agree to pick up the animal when notified that it is ready for release.

In the event the animal is not picked up, and if ten (10) days have expired since a registered letter was sent to the address given above, notifying me to call for the animal, the animal may be sold or otherwise disposed of in a humane manner and the proceeds applied to the charges incurred in caring and treating the animal. Failure to remove said animal will not and does not relieve me from obligation for the costs of services rendered.

I hereby grant to the Cummings School of Veterinary Medicine at Tufts University, its officers and employees (collectively referred to herein as Cummings School), and its agents and assigns (the Grantees) the irrevocable rights to photograph / videotape the operation or procedure to be performed, including appropriate and otherwise use such photographs and images for, and in connection with, a Grantee's medical, scientific, educational, and publicity purposes, by any means, methods and media (print and electronic) now known or, in the future, developed that the Grantee deems appropriate (provided that such photographs and images may not be used in for-profit commercials, unless such commercials are publicizing educational programs at Cummings School). As medical and surgical treatment necessitates the removal of tissue, cells, fluids or body parts of my animal, I authorize the Grantees to dispose of or use these tissues, cells, fluids or body parts for scientific and educational purposes.

I understand that a FINANCE CHARGE will be applied to all accounts unpaid after 30 days. The FINANCE CHARGE is computed on a monthly rate of 1.33% per month, which is an annual percentage rate of 16% applied to the average daily balance outstanding, with a minimum fee of \$50.

I do further agree that should any payment, or the full amount of the sum stated above, become overdue more than 20 days from the above-agreed upon time of payment or payments, the entire balance shall be considered in default and become due and payable. I further agree to be responsible for any or all collection agency and/or attorney fees necessary to collect the full amount.

I do further agree to comply with hours of visitation in conjunction with our Hospital's policy.

I have read, understand, and agree to accept the terms and conditions herein.

Owner's name:  Date: 2/1/2019

Owner's address:

**B6**

Date: 01-02-19

**If the individual admitting the animal is someone other than the legal owner, please complete the portion below:**

The owner of the animal  has granted me authority to obtain medical treatment and to bind this owner to pay the veterinary medical services provided at Cummings School pursuant to the terms and conditions described above.

\_\_\_\_\_  
Authorized Agent - Please Print

\_\_\_\_\_  
Agent's Signature

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
Date

\_\_\_\_\_  
Town/City                      State                      Zip

**B6**

Patient ID: 438225

B6 Canine

B6 Years Old Male (Neutered) English

Bulldog

Body Weight: Weight (kg) 0.00

## **Brachycephalic Consent Form**

### ***Anesthesia, Sedation and Hospitalization***

Brachycephalic is a term for "short-nosed". Several dog breeds may experience difficulty breathing due to the shape of their head, muzzle and throat. Shorter nosed dogs include English Bulldogs, French Bulldogs, Pugs, Boston Terriers and many other breeds. The shorter than average nose and face in proportion to their body size can cause problems for these breeds at times. Owners with brachycephalic breeds must pay extra attention to their animals during exercise, heat and while obtaining veterinary care.

#### ***Overview***

The purpose of this form is to inform you of the risks associated with anesthesia/sedation and occasionally hospitalization, which are inherent for dogs with shorter noses (brachycephalic). Not all of these problems may apply to your dog, but these are part of the brachycephalic syndrome. Please discuss any specific concerns with your attending veterinarian.

#### ***Respiratory problems***

Brachycephalic dogs have a shortened skull, resulting in a compressed nasal passage and abnormal throat anatomy. The abnormal upper airway anatomy causes increased negative pressure while taking a breath, leading to inflammation, deformation of throat tissues, and obstruction of breathing. We encourage corrective surgery in moderate to severely affected dogs.

#### ***Cooling problems***

As dogs cool by panting, dogs with narrowed airways may have difficulty cooling themselves. This may be made worse by anxiety or stress.

#### ***Stomach and intestinal problems***

Brachycephalic dogs may swallow a lot of air which can lead to increased vomiting or regurgitation, and this could lead to pneumonia. If possible, we pre-treat brachycephalic dogs with medications to reduce stomach acids, and to promote stomach emptying.

#### ***Restraint challenges***

Due to their airway, and in some bulldogs, their intrinsic personality as "tough" dogs, it may be difficult to restrain them safely. This is a particularly significant problem with more aggressive dogs. We

occasionally need to sedate them, or ask family members to help with some routine procedures to avoid unnecessary stress on the patient.

### *Sedation and anesthesia*

While sedation and anesthesia are commonly performed in brachycephalic breeds, especially bulldogs, recovery from anesthesia may be more difficult for these patients due to a narrowed airway. We have our anesthesia team very closely involved in sedation and anesthesia of brachycephalic breeds especially bulldogs. They have found that careful monitoring is essential to a good outcome. In fact, many dog owners travel some distance in order to ensure that a Tufts board-certified anesthesiologist is present during anesthesia or sedation to minimize the risk of complications.

**We consider brachycephalic dogs a high risk population. Please be sure you talk with your doctor about the following:**

1. Any medical and/or surgical treatment alternatives for your pet
2. Sufficient details of this consent form and how they apply to your dog
3. How fully your pet might respond or recover and how long it could take
4. The most common complications and how serious they might be

I grant permission for my pet to undergo general anesthesia/sedation/hospitalization at Tufts Foster Hospital for Small Animals at the Cummings School of Veterinary Medicine.

I am aware that my pet has physical characteristics that make anesthesia and sedation more challenging and possibly more risky than for the average dog with a longer nose.

I am aware that brachycephalic breeds, such as the English and French bulldog, Boston Terrier, Pug, and Pekingese have a shortened skull, resulting in a compressed nasal passage and abnormal throat anatomy. The abnormal upper airway anatomy causes increased negative pressure while taking a breath, leading to inflammation, deformation of throat tissues, and obstruction of breathing.

I am aware that if my brachycephalic pet undergoes sedation or general anesthesia the potential complications include partial or complete airway obstruction during recovery and regurgitation/vomiting which could lead to aspiration pneumonia/respiratory distress. With airway surgery, death has been reported as a rare complication in <3% of cases.

I am aware that anesthetizing or sedating a brachycephalic animal for any reason can lead to the development of significant complications as described in this document.

**Please answer YES or NO to the following questions:**

**My pet has demonstrated difficulty breathing, exercise intolerance, and/or collapse episodes.**

YES       NO

My pet has demonstrated difficulty eating, such as gagging, vomiting, and regurgitation.

YES       NO

My pet is receiving or has recently received a non-steroidal anti-inflammatory drug (e.g., Rimadyl)

YES       NO

Your signature indicates that you have read and understand the above information and give your consent for treatment.

Owner signature \_\_\_\_\_

Date: 2/1/2019

**B6**



Cardiology Liaison: 508-887-4696

## Discharge Instructions

### Patient

Name: B6

Species: Canine

Brown/White Male (Neutered) English

Bulldog

Birthdate: B6

### Owner

Name: B6

Address: B6

Patient ID: 438225

### Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

### Cardiology Resident:

B6

### Cardiology Technician:

B6

### Veterinary Nutritionist : Dr. Lisa Freeman

Student: B6 /19

Admit Date: 2/1/2019 10:36:11 AM

Discharge Date: 2/1/2019

**Diagnoses:** Arrhythmogenic right ventricular cardiomyopathy (ARVC) with marked right heart enlargement, ventricular premature depolarizations, and left ventricular dysfunction; possible component of diet-related cardiomyopathy

**Clinical findings:** B6 has been diagnosed with a primary heart muscle disease called arrhythmogenic right ventricular cardiomyopathy (ARVC). This disease is common in bulldogs and is characterized by replacement of the normal heart muscle by fat and/or scar tissue which may result in serious ventricular arrhythmias (abnormal heart rhythms originating from the lower chamber of the heart), cardiac enlargement and congestive heart failure, or both. Dogs with ARVC may experience syncope (fainting) or sudden death as the result of ventricular arrhythmia. Though we cannot reverse the changes in the heart muscle, we can control the heart disease with medical management.

The following diagnostic test results were obtained today:

**ECG findings:** The ECG shows a number of premature ventricular contractions (VPCs) originating from the right ventricle.

**Echocardiogram findings:** The right ventricle is moderate to markedly enlarged. The left ventricle is mildly dilated with the left ventricular free wall thinned. There is reduced vigor of contraction of the left ventricle. The left atrium is mildly to moderately enlarged. The right atrium is moderately to markedly enlarged. There is some mitral and tricuspid valve regurgitation. The hepatic veins are markedly distended.

**Monitoring at home:** Please monitor for any signs of lethargy, weakness, pale gums, cough, shortness of breath, inappetence, or collapse. If a collapsing episode is noted, please check your dog's gum color and try to get a sense of whether the heart rate is slow or fast. If you have an iPhone or Android smartphone device, you may want to explore the

option of purchasing the Kardia Mobile device which will allow you to monitor the heart rate and rhythm at home ([www.alivetec.com](http://www.alivetec.com)). If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

**B6** may also benefit from wearing a Holter EKG, which is a harnessed EKG that he would wear for 24 hours. We can place that here, and send him home for the 24-hour duration. He would then return here the next day where we can remove the Holter and analyze his heart rhythm to fully assess his arrhythmia. Call if you decide to do this test.

#### Recommended Medications:

# B6

**NEXT DOSE DUE:** You can start **B6** at any time.

**Diet suggestions:** Dogs with ARVC may benefit from the addition of omega-3 fatty acids (fish oil) to the diet. Diets such as the Royal Canin Boxer or Early Cardiac diet, or Hill's j/d have ample fish oil and may not require much (or any) additional supplementation. Additional information on supplements such as fish oil or other supplements that you might have questions about may be found on the Tufts HeartSmart web site: (<http://vet.tufts.edu/heartsmart/diet/>).

- The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- We recommend switching **B6** to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- The FDA issued a statement regarding this issue (<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/uom613305.htm>) and a recent article published by Dr. Lisa Freeman on the Cummings School's Pet Foodology blog can further explain these findings (<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

#### Dry Food Options:

Royal Canin Early Cardiac (veterinary diet)

Royal Canin Boxer

Purina Pro Plan Adult Weight Management

Purina Pro Plan Bright Mind Adult Small Breed Formula

#### Canned Food Options:

Hill's Science Diet Adult Beef and Barley Entree

Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew

Royal Canin Mature 8+

We recommend slowly introducing one of the diets on the above list as follows: 25% of the new diet mixed with 75% old diet for 2-3 days, then 50:50, etc.

Hopefully you can find a diet on the list that **B6** will enjoy!

If your dog has special nutritional needs or requires a homecooked diet, we recommend you schedule an appointment with our nutritionists (508-887-4696).

**Exercise recommendations:** Generally we recommend limited activity for dogs with heart disease – Leash walk only is ideal. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are not recommended as these activities may result in worsened arrhythmia or even sudden death.

**Recheck visits:** We would like to recheck **B6** in 3 months, at which point we can discuss additional medications and

treatments as needed (such as antiarrhythmics). We will likely recommend recheck ECGs every 3 months, or you can purchase the AliveCor and send us an ECG about once a month.

Thank you for entrusting us with **B6**'s care. Please contact our Cardiology liaison at (508)-887-4696 or email us at [cardiovet@tufts.edu](mailto:cardiovet@tufts.edu) for scheduling and non-emergent questions or concerns. Please visit our HeartSmart website for more information

Please visit our HeartSmart website for more information  
<http://vet.tufts.edu/heartsmart/>

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**Prescription Refill Disclaimer:**

*For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.*

**Ordering Food:**

*Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.*

**Clinical Trials:**

*Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: [vet.tufts.edu/cvmc/clinical-studies](http://vet.tufts.edu/cvmc/clinical-studies)*

---

Case: **B6**

Owner: **B6**

Discharge Instructions

# Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

**B6**

Patient ID: 438225

**B6** Canine

**B6** Years Old Male (Neutered) English Bulldog  
Brown/White

## Cardiology Appointment Report Enrolled in DCM Study

Date: 2/1/2019

### Attending Cardiologist:

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

**B6**

### Cardiology Resident:

**B6**

### Cardiology Technician:

**B6**

Student: **B6** V19

**Presenting Complaint:** Here for possible entry to DCM study. Half-sister **B6** came in last month for CHF. **B6** had high proBNP on bloodwork **B6**

### Concurrent Diseases:

Anaplasmosis(+) on IDEXX panel.

History of **B6** trauma when young.

### General Medical History:

**B6**

Fasted today.

Had reason for concern of DCM based on diet and sister, came in based on NTproBNP level.

### Diet and Supplements:

Grain free diet- Wellness Core. Chicken and Turkey wet food 4oz BID. Fish dry food 1/4 cup BID.

No supplements or treats.

### Cardiovascular History:

Prior CHF diagnosis? N

Prior heart murmur? N

Prior ATE? N

Prior arrhythmia? N

Monitoring respiratory rate and effort at home? N, but taking notice more after sister's CHF. O thinks 20-30 at rest .

Cough? N

Shortness of breath or difficulty breathing? Sounds raspy when anxious.

Syncope or collapse? N

Sudden onset lameness? N

Exercise intolerance? N- Normally low energy.

**Current Medications Pertinent to CV System:**

Medication: **B6**

Formulation:

Administration Frequency: **B6**

Need refills? N

**Cardiac Physical Examination:**

**B6**

**Muscle condition:**

- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

**Cardiovascular Physical Exam:**

**Murmur Grade:**

- None
- I/VI
- II/VI
- III/VI
- IV/VI
- V/VI
- VI/VI

**Murmur location/description:**

**Jugular vein:**

- Bottom 1/3 of the neck
- Middle 1/3 of the neck
- 1/2 way up the neck
- Top 2/3 of the neck

**Arterial pulses:**

- Weak - obese and difficult to palpate
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other:

**Arrhythmia:**

- None
- Sinus arrhythmia
- Premature beats infrequent
- Bradycardia
- Tachycardia

**Gallop:**

- Yes
- Pronounced

- No
- Intermittent

Other:

**Pulmonary assessments:**

- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary crackles
- Wheezes
- Upper airway stridor

**Abdominal exam:**

- Normal
- Hepatomegaly
- Abdominal distension mostly adipose tissue?
- Mild ascites
- Marked ascites

**Problems:**

Related dog with DCM  
Has a high NT-proBNP

**Differential Diagnoses:** DCM vs other

**Diagnostic plan:**

- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests: Study bloodwork

**Echocardiogram Findings:**

**General/2-D findings:**

B6

**B6**

**Doppler findings:**

B6

**Mitral inflow:**

- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

**ECG findings:**

B6

B6

**Assessment and recommendations:**

Findings are consistent with ARVC with concurrent LV dysfunction which is either related to ARVC or could have a component of diet-related cardiomyopathy. There was not enough arrhythmia seen today to clearly trigger antiarrhythmic therapy, but a 24 hour Holter monitor could be performed for a better assessment of arrhythmia burden, or Alivecor tracings could be evaluated serially.

B6

**B6**

# B6

## Final Diagnosis:

ARVC with LV dysfunction (possible component of diet associated cardiomyopathy)

## Heart Failure Classification Score:

### ISACHC Classification:

- |  |                               |
|--|-------------------------------|
| <input type="checkbox"/> Ia            | <input type="checkbox"/> IIIa |
| <input checked="" type="checkbox"/> Ib | <input type="checkbox"/> IIIb |
| <input type="checkbox"/> II            |                               |

### ACVIM Classification:

- |  |                            |
|--|----------------------------|
| <input type="checkbox"/> A             | <input type="checkbox"/> C |
| <input type="checkbox"/> B1            | <input type="checkbox"/> D |
| <input checked="" type="checkbox"/> B2 |                            |

### M-Mode

|            |    |
|------------|----|
| IVSd       | cm |
| LVIDd      | cm |
| LVPWd      | cm |
| IVSs       | cm |
| LVIDs      | cm |
| LVPWs      | cm |
| EDV(Teich) | ml |
| ESV(Teich) | ml |
| EF(Teich)  | %  |
| %FS        | %  |
| SV(Teich)  | ml |
| Ao Diam    | cm |
| LA Diam    | cm |
| LA/Ao      |    |
| Max LA     | cm |
| TAPSE      | cm |

# B6

### M-Mode Normalized

|           |                   |
|-----------|-------------------|
| IVSdN     | (0.290 - 0.520) ! |
| LVIDdN    | (1.350 - 1.730)   |
| LVPWdN    | (0.330 - 0.530)   |
| IVSsN     | (0.430 - 0.710)   |
| LVIDsN    | (0.790 - 1.140)   |
| LVPWsN    | (0.530 - 0.780) ! |
| Ao Diam N | (0.680 - 0.890) ! |
| LA Diam N | (0.640 - 0.900) ! |

|                  |       |
|------------------|-------|
| SALA             | cm    |
| Ao Diam          | cm    |
| SALA / Ao Diam   |       |
| IVSd             | cm    |
| LVIDd            | cm    |
| LVPWd            | cm    |
| EDV(Teich)       | ml    |
| IVSs             | cm    |
| LVIDs            | cm    |
| LVPWs            | cm    |
| ESV(Teich)       | ml    |
| EF(Teich)        | %     |
| %FS              | %     |
| SV(Teich)        | ml    |
| LV Major         | cm    |
| LV Minor         | cm    |
| Sphericity Index |       |
| LVLd LAX         | cm    |
| LVAAd LAX        | cm    |
| LVEDV A-L LAX    | ml    |
| LVEDV MOD LAX    | ml    |
| LVLs LAX         | cm    |
| LVAAs LAX        | cm    |
| LVESV A-L LAX    | ml    |
| LVESV MOD LAX    | ml    |
| HR               | BPM   |
| EF A-L LAX       | %     |
| LVEF MOD LAX     | %     |
| SV A-L LAX       | ml    |
| SV MOD LAX       | ml    |
| CO A-L LAX       | l/min |
| CO MOD LAX       | l/min |
| <u>Doppler</u>   |       |
| MR Vmax          | m/s   |
| MR maxPG         | mmHg  |
| MV E Vel         | m/s   |
| MV DecT          | ms    |
| MV Dec Slope     | m/s   |
| MV A Vel         | m/s   |
| MV E/A Ratio     |       |
| E'               | m/s   |
| E/E'             |       |
| A'               | m/s   |
| S'               | m/s   |
| AV Vmax          | m/s   |
| AV maxPG         | mmHg  |
| PV Vmax          | m/s   |
| PV maxPG         | mmHg  |
| TR Vmax          | m/s   |

**B6**



TR maxPG

**B6**

mmHg

**Cummings**  
**Veterinary Medical Center**  
AT TUFTS UNIVERSITY

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**

**B6**

Male (Neutered)

Canine English Bulldog

Brown/White

438275

2/12/2019

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), DACMECC

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**From:** PFR Event <pfpreventcreation@fda.hhs.gov>  
**To:** Cleary, Michael \*; HQ Pet Food Report Notification; B6  
**Sent:** 2/25/2019 12:52:56 PM  
**Subject:** Wellness Core grain-free ocean fish dry-Wellness core grain free turkey: Lisa Freeman - EON-380742  
**Attachments:** 2063133-report.pdf; 2063133-attachments.zip

A PFR Report has been received and PFR Event [EON-380742] has been created in the EON System.

A "PDF" report by name "2063133-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2063133-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380742

**ICSR #:** 2063133

**EON Title:** PFR Event created for Wellness Core grain-free ocean fish dry Wellness core grain free turkey chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe; 2063133

|                          |   |                           |        |
|--------------------------|---|---------------------------|--------|
| <b>AE Date</b>           | 01/15/2019  | <b>Number Fed/Exposed</b> | 6      |
| <b>Best By Date</b>      |   | <b>Number Reacted</b>     | 3      |
| <b>Animal Species</b>    | Dog   | <b>Outcome to Date</b>    | Stable |
| <b>Breed</b>             | Bulldog   |                           |        |
| <b>Age</b>               | <span style="border: 1px dashed black; padding: 2px;">B6</span> Years |                           |        |
| <b>District Involved</b> | PFR-New England DO  |                           |        |

**Product information**

**Individual Case Safety Report Number:** 2063133

**Product Group:** Pet Food

**Product Name:** Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe

**Description:** DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Stable

**Number of Animals Treated With Product:** 6

**Number of Animals Reacted With Product:** 3

| <b>Product Name</b>   | <b>Lot Number or ID</b> | <b>Best By Date</b> |
|---|-------------------------|---------------------|
| Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe |                         |                     |

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6**

USA

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

**B6**

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

**B6**

**B6**

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**Report Details - EON-380742**

ICSR: 2063133  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2019-02-25 07:43:42 EST

**Reported Problem:**  
**Problem Description:** DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food  
**Date Problem Started:** 01/15/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Anxiety - takes fluoxetine  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe  
**Product Type:** Pet Food  
**Lot Number:**  
**Product Use Information:** **Description:** Please see diet history  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Bulldog  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 19.8 Kilogram  
**Age:** B6 Years  
**Number of Animals Given the Product:** 6  
**Number of Animals Reacted:** 3  
**Owner Information:** **Owner Information provided:** Yes  
**Contact:** **Name:** B6  
**Phone:** B6  
**Email:** B6  
**Address:** B6  
 United States  
**Healthcare Professional Information:** **Practice Name:** Tufts Cummings School of Veterinary Medicine  
**Contact:** **Name:** Lisa Freeman  
**Phone:** (508) 887-4523  
**Email:** lisa.freeman@tufts.edu

|  |  |   |
|--|--|---|
|  |  | <b>Address:</b> 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |
|--|--|---|

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

|                              |                     |                                |  |
|------------------------------|---------------------|--------------------------------|--|
| <b>Additional Documents:</b> | <b>Attachment:</b>  | rpt_medical_record_preview.pdf |  |
|                              | <b>Description:</b> | Med records                    |  |
|                              | <b>Type:</b>        | Medical Records                |  |

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**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Peloquin, Sarah  
**Sent:** [REDACTED] 4:36:23 PM  
**Subject:** Re: [REDACTED]

Thanks!! Lisa

Sent from my iPhone

On [REDACTED] at 8:49 AM, Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov> wrote:

Hi Lisa,

The tissues can be collected in the same way as [REDACTED] (formalin and frozen). Then the vet should hold the tissues until next week, and we could send the boxes to him then.

I'll email him to clarify as well.

Thanks!  
Sarah

**Sarah Peloquin, DVM**  
Veterinary Medical Officer  
tel: 240-402-1218

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**Sent:** [REDACTED] 10:01 AM  
**To:** Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>  
**Cc:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Guag, Jake <Jake.Guag@fda.hhs.gov>  
**Subject:** RE: [REDACTED]

Hi Sarah  
Just to clarify – all of the tissue in the freezer or some in the freezer and some in formalin?  
Thanks  
Lisa

**From:** Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>  
**Sent:** [REDACTED] 9:56 AM  
**To:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**Cc:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Guag, Jake <Jake.Guag@fda.hhs.gov>  
**Subject:** RE: [REDACTED]

Yes, -20 degrees should be fine.

Thanks, Lisa!  
Sarah

**Sarah Peloquin, DVM**  
Veterinary Medical Officer  
tel: 240-402-1218

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**Sent:** [REDACTED] 9:54 AM  
**To:** Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>



Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Guag, Jake <Jake.Guag@fda.hhs.gov>

Subject: RE: [REDACTED] B6

Hi Sarah

Can they be frozen at -20? I'm sure the primary care vet doesn't have a -80 freezer

Thanks

Lisa

From: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>

Sent: [REDACTED] B6 9:51 AM

To: Freeman, Lisa <Lisa.Freeman@tufts.edu>

Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Guag, Jake <Jake.Guag@fda.hhs.gov>

Subject: RE: [REDACTED] B6

Hi Lisa!

I hope you've been well. Jake also forwarded your email to me—thank you for following up with us.

If possible, the body and/or samples could be held frozen until next week. I'll discuss with Jen when she gets back, since I'm unsure where we are with our post-mortem samples. I'll make sure we follow up with you.

Thanks again, and have a great weekend!

Sarah

**Sarah Peloquin, DVM**

Veterinary Medical Officer

tel: 240-402-1218

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>

Sent: [REDACTED] B6 9:26 AM

To: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>

Subject: FW: [REDACTED] B6

Dear Sarah

Got an out of office message from Jennifer so updating you so you can hopefully help to facilitate

Thanks

Lisa

From: Tufts Veterinary Clinical Nutrition Service

Sent: [REDACTED] B6 9:09 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Guag, Jake <Jake.Guag@fda.hhs.gov>

Cc: [REDACTED] B6 @tufts.edu

Subject: [REDACTED] B6

Dear Jennifer and Jake

I just heard from [REDACTED] B6 the primary care vet for [REDACTED] B6. She is the dog from the household in which at least 3 dogs were affected with diet-associated DCM. This was the first case from the household which was identified when she came in for congestive heart failure.

The owners contacted him and said they will be bringing her in today to be euthanized for worsening heart failure. He's volunteered to get heart and liver samples as he did from [REDACTED] B6 Jake – could you send him shipping materials? His email is [REDACTED]

[REDACTED] B6

Thanks very much

Lisa

Lisa M. Freeman, DVM, PhD, DACVN  
Board Certified Veterinary Nutritionist™  
Professor  
Cummings School of Veterinary Medicine  
Friedman School of Nutrition Science and Policy  
Tufts Clinical and Translational Science Institute  
Tufts University

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**From:** PFR Event <pfpreventcreation@fda.hhs.gov>  
**To:** Cleary, Michael \*; HQ Pet Food Report Notification; [REDACTED] B6  
**Sent:** 2/25/2019 1:20:54 PM  
**Subject:** Wellness CORE Grain-Free Ocean Whitefish dry-Wellness Core grain free turkey: Lisa Freeman - EON-380745  
**Attachments:** 2063135-report.pdf; 2063135-attachments.zip

A PFR Report has been received and PFR Event [EON-380745] has been created in the EON System.

A "PDF" report by name "2063135-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2063135-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380745

**ICSR #:** 2063135

**EON Title:** PFR Event created for Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey chicken liver and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe; 2063135

|                          |                     |                           |        |
|--------------------------|---------------------|---------------------------|--------|
| <b>AE Date</b>           | 02/20/2019          | <b>Number Fed/Exposed</b> | 6      |
| <b>Best By Date</b>      |                     | <b>Number Reacted</b>     | 3      |
| <b>Animal Species</b>    | Dog                 | <b>Outcome to Date</b>    | Stable |
| <b>Breed</b>             | Bulldog             |                           |        |
| <b>Age</b>               | [REDACTED] B6 Years |                           |        |
| <b>District Involved</b> | PFR-New England DO  |                           |        |

**Product information**

**Individual Case Safety Report Number:** 2063135

**Product Group:** Pet Food

**Product Name:** Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe

**Description:** Eating BEG diet - 2 other dogs in household diagnosed with DCM [REDACTED] B6 (already reported) RDVM screened this dog with NT-proBNP which was elevated so we evaluated at Tufts

2/20/19 Probable **B5** diet-associated DCM but no arrhythmia detected (enlarged right ventricle, reduced contractility) Changing diet to Royal Canin Early Cardiac and will re-evaluate in 3 months. Taurine and troponin pending

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Stable

**Number of Animals Treated With Product:** 6

**Number of Animals Reacted With Product:** 3

| Product Name   | Lot Number or ID | Best By Date |
|--|------------------|--------------|
| Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe |                  |              |

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6** USA

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

**B6**

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

**B6**

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

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**Report Details - EON-380745**

ICSR: 2063135  
Type Of Submission: Initial  
Report Version: FPSR.FDA.PETF.V.V1  
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
Reporting Type: Voluntary  
Report Submission Date: 2019-02-25 08:12:41 EST

**Reported Problem:**  
**Problem Description:** Eating BEG diet - 2 other dogs in household diagnosed with DCM ( **B6** **B6** - already reported) RDVM screened this dog with NT-proBNP which was elevated so we evaluated at Tufts 2/20/19 Probable **B5** /diet-associated DCM but no arrhythmia detected (enlarged right ventricle, reduced contractility) Changing diet to Royal Canin Early Cardiac and will re-evaluate in 3 months. Taurine and troponin pending  
**Date Problem Started:** 02/20/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** **B6**  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Wellness CORE Grain-Free Ocean Whitefish dry Wellness Core grain free turkey, chicken liver, and turkey liver formula canned Wellness Core Hearty Cuts grain-free in gravy chicken and turkey recipe  
**Product Type:** Pet Food  
**Lot Number:**  
**Product Use Description:** Please see diet history for more info (and also see **B6** diet history for exact diets)  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** **B6**  
**Type Of Species:** Dog  
**Type Of Breed:** Bulldog  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 24.2 Kilogram  
**Age:** **B6** Years  
**Assessment of Prior Health:** Good  
**Number of Animals Given the Product:** 6  
**Number of Animals Reacted:** 3  
**Owner Information:** Owner Information provided: Yes  
**Contact:** Name: **B6**  
Phone: **B6**  
Email: **B6**  
**Address:** **B6**

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

---

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Jones, Jennifer L  
**Sent:** 11/13/2018 10:12:07 PM  
**Subject:** RE: 800.267-EON-358523; [B6]  
**Attachments:** taurine [B6].pdf; taurine [B6].pdf; taurine [B6].pdf

Hi Jen

Attached are 3 taurine levels on dogs I've already reported – [B6], [B6] and [B6]

I'll try to get the rest reported this week. I got a little backed up with so many. Do I have the record for most reports? 😊

Also, Darcy Adin and I are collaborating on some studies so would love to catch up at some point if you think a conference call would be worthwhile.

Thanks!

Lisa

Lisa M. Freeman, DVM, PhD, DACVN  
Board Certified Veterinary Nutritionist™  
Professor  
Cummings School of Veterinary Medicine  
Friedman School of Nutrition Science and Policy  
Tufts Clinical and Translational Science Institute  
Tufts University  
[www.petfoodology.org](http://www.petfoodology.org)

**From:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Sent:** Tuesday, November 13, 2018 3:13 PM  
**To:** Freeman, Lisa <lisa.freeman@tufts.edu>  
**Subject:** RE: 800.267-EON-358523; [B6]

Thanks, Lisa. You can send the updates to me. I'm the primary POC for the DCM cases, and Dr. Peloquin will be handling the other cases.

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



**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**Sent:** Tuesday, November 13, 2018 3:02 PM  
**To:** Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>  
**Subject:** RE: 800.267-EON-358523; [B6]

Hi Jen,

I've noted in a few submissions that I haven't yet talked to the owners but on any others, you should be able to contact them

Should I continue to send updates on cases I've submitted to you or is it better to send to someone else on your team?

The cases are continuing to come in so I've got some additional cases to submit.

Thanks

Lisa



Lisa M. Freeman, DVM, PhD, DACVN  
Board Certified Veterinary Nutritionist™  
Professor  
Cummings School of Veterinary Medicine  
Friedman School of Nutrition Science and Policy  
Tufts Clinical and Translational Science Institute  
Tufts University  
[www.petfoodology.org](http://www.petfoodology.org)

**From:** Jones, Jennifer L <[Jennifer.Jones@fda.hhs.gov](mailto:Jennifer.Jones@fda.hhs.gov)>  
**Sent:** Tuesday, November 13, 2018 2:45 PM  
**To:** Freeman, Lisa <[lisa.freeman@tufts.edu](mailto:lisa.freeman@tufts.edu)>  
**Subject:** 800.267-EON-358523- B6

Hi Lisa,  
Should I assume that it's ok to contact the owners for an interview when you submit the complaints?  
Hope you're well. Just want to check,  
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](mailto:jennifer.jones@fda.hhs.gov)  
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



24576 PL  
24577 WB

**B6**  
SHIP w ICE PACKS, TAURINE  
PANEL  
Lithium Heparin

### Amino Acid Laboratory Sample Submission Form

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

Veterinarian Contact: **B6**

Clinic/Company Name: Tufts Cummings School of Vet. Med. - Clinical Pathology Laboratory

Address: 200 Westboro Road, North Grafton MA 015369

Email: Clinpath@tufts.edu & Cardiovet@tufts.edu

Telephone: **B6**

Fax: **B6**

Billing Contact: **B6**

Email: **B6**

Billing Contact Phone: **B6**

Tax ID: \_\_\_\_\_

Patient Name: **B6**

Species: Canine

Breed: Doberman

Owner's Name: **B6**

Current Diet: Earthborn grain free / wellness

Sample type: Plasma Whole Blood Urine Food Other \_\_\_\_\_

Test: Taurine Complete Amino Acids Other: \_\_\_\_\_

#### Taurine Results (lab use only)

Plasma: **B6** Whole Blood: **B6** Urine: \_\_\_\_\_ Food: \_\_\_\_\_  
*yellow*

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

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

PL ~~24~~ 24345

WB 24346

### Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 95616

Telephone: 530-752-5058, Fax: 530-752-4698

Email: [ucd.aminoacid.lab@ucdavis.edu](mailto:ucd.aminoacid.lab@ucdavis.edu)

[www.vetmed.ucdavis.edu/labs/amino-acid-laboratory](http://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory)



Veterinarian Contact: **B6**

Clinic/Company Name: Tufts Cummings School of Vet. Med. - Clinical Pathology Laboratory

Address: 200 Westboro Road, North Grafton MA 015369

Email: Clinpath@tufts.edu / cardiovet@tufts.edu

Telephone: **B6**

Fax: **B6**

Billing Contact: **B6**

Email: **B6**

Billing Contact Phone: **B6**

Tax ID: \_\_\_\_\_

Patient Name: **B6**

Species: canine

Breed: Boxer

Owner's Name: **B6**

Current Diet: Rachel Ray super premium dry chicken/vegs redry, Purina and chicken rice canned, Newman's own chicken rice

Sample type:  Plasma  Whole Blood  Urine  Food  Other \_\_\_\_\_

Test:  Taurine  Complete Amino Acids  Other: \_\_\_\_\_

#### Taurine Results (lab use only)

Plasma: **B6** Whole Blood: **B6** Urine: \_\_\_\_\_ Food: \_\_\_\_\_

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

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

PL: 24421  
WB: 24422

### Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 95616

Telephone: 530-752-5058, Fax: 530-752-4698

Email: [ucd.aminoacid.lab@ucdavis.edu](mailto:ucd.aminoacid.lab@ucdavis.edu)

[www.vetmed.ucdavis.edu/labs/amino-acid-laboratory](http://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory)

Veterinarian Contact: B6

Clinic/Company Name: Tufts Cummings School of Vet. Med. - Clinical Pathology Laboratory

Address: 200 Westboro Road, North Grafton MA 015369

Email: Clinpath@tufts.edu / *cardiovet@tufts.edu*

Telephone: B6 Fax: B6

Billing Contact: B6 Email: B6

Billing Contact Phone: B6 Tax ID: \_\_\_\_\_

Patient Name: B6 Species: Golden

Breed: Golden Owner's Name: B6

Current Diet: Beneful - was on grain free taste of food and

Sample type: Plasma Whole Blood Urine Food Other \_\_\_\_\_ *Natures Balance*

Test: Taurine Complete Amino Acids Other: \_\_\_\_\_

#### Taurine Results (lab use only)

Plasma: B6 Whole Blood: B6 Urine: \_\_\_\_\_ Food: \_\_\_\_\_

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

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

---

**From:** Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>  
**To:** Rotstein, David; Cleary, Michael \*; HQ Pet Food Report Notification;  
B6  
**Sent:** 6/11/2019 7:17:00 PM  
**Subject:** Earthborn grain free weight management dry: Lisa Freeman - EON-390207  
**Attachments:** 2068098-report.pdf; 2068098-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390207] has been created in the EON System.

A "PDF" report by name "2068098-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2068098-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390207

**ICSR #:** 2068098

**EON Title:** Related PFR Event created for Earthborn grain free weight management dry; 2068098

|                          |                    |                           |                 |
|--------------------------|--------------------|---------------------------|-----------------|
| <b>AE Date</b>           | 11/05/2018         | <b>Number Fed/Exposed</b> | 1               |
| <b>Best By Date</b>      |                    | <b>Number Reacted</b>     | 1               |
| <b>Animal Species</b>    | Dog                | <b>Outcome to Date</b>    | Died Euthanized |
| <b>Breed</b>             | Doberman Pinscher  |                           |                 |
| <b>Age</b>               | B6 Years           |                           |                 |
| <b>District Involved</b> | PFR-New England DO |                           |                 |

**Product information**

**Individual Case Safety Report Number:** 2068098

**Product Group:** Pet Food

**Product Name:** Earthborn grain free weight management dry

**Description:** Diagnosed with DCM, CHF, and atrial fibrillation 11/5/18. Currently hospitalized. Taurine submitted to UC Davis. Unclear if related to diet, given breed but eating boutique, grain-free diet. Only prior history is traumatic injury in 2015. Genetic testing - negative for DCM1 & DCM2 Normal taurine levels - plasma B6 whole blood B6 Patient was humanely euthanized B6 due to worsening CHF. Specimens were not collected for evaluation per owner.

**Submission Type:** Followup

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Died Euthanized

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

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

| Product Name                               | Lot Number or ID | Best By Date |
|--|------------------|--------------|
| Earthborn grain free weight management dry |                  |              |

This report is linked to:

**Initial EON Event Key:** EON-370708

**Initial ICSR:** 2058678

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6** USA

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

**B6**

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

**B6**

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**Report Details - EON-390207**

|                                  |  |
|----------------------------------|--|
| ICSR:                            | 2068098  |
| Type Of Submission:              | Followup   |
| Report Version:                  | FPSR.FDA.PETF.V.V1   |
| Type Of Report:                  | Adverse Event (a symptom, reaction or disease associated with the product) |
| Reporting Type:                  | Voluntary  |
| Report Submission Date:          | 2019-06-11 15:06:46 EDT  |
| Initial Report Date:             | 11/09/2018   |
| Parent ICSR:                     | 2058678  |
| Follow-up Report to FDA Request: | Yes  |

|                          |                                    |  |
|--------------------------|------------------------------------|--|
| <b>Reported Problem:</b> | <b>Problem Description:</b>        | Diagnosed with DCM, CHF, and atrial fibrillation 11/5/18. Currently hospitalized. Taurine submitted to UC Davis. Unclear if related to diet, given breed but eating boutique, grain-free diet. Only prior history is traumatic injury in 2015. Genetic testing - negative for DCM1 & DCM2 Normal taurine levels - plasma B6 whole blood B6 Patient was humanely euthanized B6 due to worsening CHF. Specimens were not collected for evaluation per owner. |
|                          | <b>Date Problem Started:</b>       | 11/05/2018   |
|                          | <b>Concurrent Medical Problem:</b> | No   |
|                          | <b>Outcome to Date:</b>            | Died Euthanized  |
|                          | <b>Date of Death:</b>              | B6   |

|                             |   |  |
|-----------------------------|---|--|
| <b>Product Information:</b> | <b>Product Name:</b>                          | Earthborn grain free weight management dry |
|                             | <b>Product Type:</b>                          | Pet Food                                   |
|                             | <b>Lot Number:</b>                            |  |
|                             | <b>Package Type:</b>                          | BAG  |
|                             | <b>Product Use Information:</b>               |  |
|                             | <b>Manufacturer /Distributor Information:</b> |  |
|                             | <b>Purchase Location Information:</b>         |  |

|                            |   |  |
|----------------------------|---|--|
| <b>Animal Information:</b> | <b>Name:</b>                                | B6                                     |
|                            | <b>Type Of Species:</b>                     | Dog                                    |
|                            | <b>Type Of Breed:</b>                       | Doberman Pinscher                      |
|                            | <b>Gender:</b>                              | Male                                   |
|                            | <b>Reproductive Status:</b>                 | Neutered                               |
|                            | <b>Weight:</b>                              | 45.2 Kilogram                          |
|                            | <b>Age:</b>                                 | B6 Years                               |
|                            | <b>Assessment of Prior Health:</b>          | Excellent                              |
|                            | <b>Number of Animals Given the Product:</b> | 1                                      |
|                            | <b>Number of Animals Reacted:</b>           | 1                                      |
|                            | <b>Owner Information:</b>                   | <b>Owner Information provided:</b> Yes |
|                            |   | <b>Contact:</b>                        |
|                            |   | <b>Name:</b> B6                        |
|                            | <b>Phone:</b> B6                            |  |
|                            | <b>Email:</b> B6                            |  |
|                            | <b>Address:</b> B6                          |  |



**B6**

United States

|   |   |  |                        |
|---|---|--|------------------------|
| <b>Healthcare Professional Information:</b> | <b>Practice Name:</b>   | Tufts Cummings School of Veterinary Medicine |                        |
|   | <b>Contact:</b>   | <b>Name:</b>                                 | Lisa Freeman           |
|   |   | <b>Phone:</b>                                | (508) 887-4523         |
|   |   | <b>Email:</b>                                | lisa.freeman@tufts.edu |
| <b>Address:</b>                             | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |  |                        |

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

|                              |                     |                                |  |
|------------------------------|---------------------|--------------------------------|--|
| <b>Additional Documents:</b> | <b>Attachment:</b>  | Follow-up med records pt 4.pdf |  |
|                              | <b>Description:</b> | Med records                    |  |
|                              | <b>Type:</b>        | Medical Records                |  |
|                              | <b>Attachment:</b>  | Follow-up med records pt 2.pdf |  |
|                              | <b>Description:</b> | Med records                    |  |
|                              | <b>Type:</b>        | Medical Records                |  |
|                              | <b>Attachment:</b>  | Follow-up med records pt 3.pdf |  |
|                              | <b>Description:</b> | Med records                    |  |
|                              | <b>Type:</b>        | Medical Records                |  |
|                              | <b>Attachment:</b>  | Follow-up med records pt 1.pdf |  |
|                              | <b>Description:</b> | Med records                    |  |
|                              | <b>Type:</b>        | Medical Records                |  |

Client: **B6**  
Patient:

---

**ECG from Cardio**

---

**B6**

3/14/2019 3:34:06 PM

Page 1 of 2

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

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**B6**

Client: **B6**  
Patient:

---

**ECG from Cardio**

---

**B6**

3/14/2019 3:34:06 PM

Page 2 of 2

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

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**B6**

Client:  
Patient:

**B6**

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**ECG from Cardio**

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**B6**

3/14/2019 3:34:20 PM

Page 1 of 2

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

---

**B6**

Client: **B6**  
Patient:

---

**ECG from Cardio**

---

**B6**

3/14/2019 3:34:20 PM

Page 2 of 2

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

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**B6**

Client: **B6**  
Patient:

---

**ECG from Cardio**

---

**B6**

3/14/2019 3:34:39 PM

Page 1 of 2

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

---

**B6**

Client: **B6**  
Patient:

---

**ECG from Cardio**

---

**B6**

3/14/2019 3:34:39 PM

Page 2 of 2

Tufts University  
Tufts Cummings School of Vet Med  
Cardiology

---

**B6**

---

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Jones, Jennifer L  
**Sent:** 12/27/2018 1:55:26 PM  
**Subject:** updates

Hi Jen

I'm finally digging out from other deadlines so am back to reporting cases to you. I'll submit a bunch online but wanted to let you know that [B6] died [B6]

Hope you get some time off to enjoy the holidays!

Lisa

Lisa M. Freeman, DVM, PhD, DACVN  
Board Certified Veterinary Nutritionist™  
Professor  
Cummings School of Veterinary Medicine  
Friedman School of Nutrition Science and Policy  
Tufts Clinical and Translational Science Institute  
Tufts University  
[www.petfoodology.org](http://www.petfoodology.org)



---

**From:** Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>  
**To:** Rotstein, David; Cleary, Michael \*; HQ Pet Food Report Notification;  
B6  
**Sent:** 6/10/2019 2:56:47 PM  
**Subject:** PureVita Venison & Red Lentils Grain-Free Dry Dog Food B6  
EON-390031  
**Attachments:** 2067992-report.pdf; 2067992-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390031] has been created in the EON System.

A "PDF" report by name "2067992-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2067992-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390031

**ICSR #:** 2067992

**EON Title:** Related PFR Event created for PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula; 2067992

|                          |                           |                           |                            |
|--------------------------|---------------------------|---------------------------|----------------------------|
| <b>AE Date</b>           | 03/01/2019                | <b>Number Fed/Exposed</b> | 1                          |
| <b>Best By Date</b>      |                           | <b>Number Reacted</b>     | 1                          |
| <b>Animal Species</b>    | Dog                       | <b>Outcome to Date</b>    | Better/Improved/Recovering |
| <b>Breed</b>             | American Pit Bull Terrier |                           |                            |
| <b>Age</b>               | B6 Years                  |                           |                            |
| <b>District Involved</b> | PFR-New England DO        |                           |                            |

**Product information**

**Individual Case Safety Report Number:** 2067992

**Product Group:** Pet Food

**Product Name:** PureVita Venison & Red Lentils Grain-Free Dry Dog Food, NutriSource Adult Chicken and Rice formula

**Description:** Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related.

Patient was placed on **B6** and taurine. Taurine levels prior to supplementation was WNL.

**Submission Type:** Followup

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Better/Improved/Recovering

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

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

| Product Name   | Lot Number or ID | Best By Date |
|--|------------------|--------------|
| NutriSource Adult Chicken and Rice formula             |                  |              |
| PureVita Venison & Red Lentils Grain-Free Dry Dog Food |                  |              |

This report is linked to:

**Initial EON Event Key:** EON-386301

**Initial ICSR:** 2066404

**Sender information**

**B6**

200 Westboro Road  
North Grafton, MA 01536  
USA

**Owner information**

**B6**

USA

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

**B6**

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

**B6**

---

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**Report Details - EON-390031**

|   |  |
|---|--|
| <b>ICSR:</b>                            | 2067992  |
| <b>Type Of Submission:</b>              | Followup   |
| <b>Report Version:</b>                  | FPSR.FDA.PETF.V.V1   |
| <b>Type Of Report:</b>                  | Adverse Event (a symptom, reaction or disease associated with the product) |
| <b>Reporting Type:</b>                  | Voluntary  |
| <b>Report Submission Date:</b>          | 2019-06-10 10:48:40 EDT  |
| <b>Initial Report Date:</b>             | 04/29/2019   |
| <b>Parent ICSR:</b>                     | 2066404  |
| <b>Follow-up Report to FDA Request:</b> | Yes  |

|                          |                                    |  |
|--------------------------|------------------------------------|--|
| <b>Reported Problem:</b> | <b>Problem Description:</b>        | Patient presented to rDVM in March of 2019 for acute onset of a non-productive cough, exercise intolerance and decreased appetite. Patient was diagnosed in CHF secondary to DCM - suspect diet-related. Patient was placed on <b>B6</b> and taurine. Taurine levels prior to supplementation was WNL. |
|                          | <b>Date Problem Started:</b>       | 03/01/2019   |
|                          | <b>Concurrent Medical Problem:</b> | No   |
|                          | <b>Outcome to Date:</b>            | Better/Improved/Recovering   |

|                             |   |  |
|-----------------------------|---|--|
| <b>Product Information:</b> | <b>Product Name:</b>                          | NutriSource Adult Chicken and Rice formula             |
|                             | <b>Product Type:</b>                          | Pet Food   |
|                             | <b>Lot Number:</b>                            |  |
|                             | <b>UPC:</b>                                   | 9B15P 18581  |
|                             | <b>Package Type:</b>                          | BAG  |
|                             | <b>Package Size:</b>                          | 30 Pound   |
|                             | <b>Possess Opened Product:</b>                | Yes  |
|                             | <b>Product Use Information:</b>               |  |
|                             | <b>Manufacturer /Distributor Information:</b> |  |
|                             | <b>Purchase Location Information:</b>         |  |
|                             | <b>Product Name:</b>                          | PureVita Venison & Red Lentils Grain-Free Dry Dog Food |
|                             | <b>Product Type:</b>                          | Pet Food   |
|                             | <b>Lot Number:</b>                            |  |
|                             | <b>Package Type:</b>                          | BAG  |

|                                    |                             |                           |
|------------------------------------|-----------------------------|---------------------------|
| <b>Animal Information:</b>         | <b>Name:</b>                | <b>B6</b>                 |
|                                    | <b>Type Of Species:</b>     | Dog                       |
|                                    | <b>Type Of Breed:</b>       | American Pit Bull Terrier |
|                                    | <b>Gender:</b>              | Male                      |
|                                    | <b>Reproductive Status:</b> | Neutered                  |
|                                    | <b>Weight:</b>              | 32 Kilogram               |
|                                    | <b>Age:</b>                 | <b>B6</b> years           |
| <b>Assessment of Prior Health:</b> | Excellent                   |                           |

|  |  |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|--|--|--|------------------------------------|--|-----------------|--|------------------------|----|---------------|----|---------------|----|-----------------|---|-----------------------|------------------|-----------------|--|--------------|--------------|---------------|----------------|---------------|------------------------|------------------------------|-----------------------|--|-----|
|  | <b>Number of Animals Given the Product:</b>  | 1  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Number of Animals Reacted:</b>  | 1  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Owner Information:</b>  | <table border="1"> <tr> <td><b>Owner Information provided:</b></td> <td>Yes</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>   | <b>Owner Information provided:</b> | Yes  | <b>Contact:</b> | <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> | <b>Name:</b>           | B6 | <b>Phone:</b> | B6 | <b>Email:</b> | B6 | <b>Address:</b> | <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> | <b>B6</b>             | United States    |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Owner Information provided:</b>           | Yes  |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Contact:</b>                              | <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>   | <b>Name:</b>   | B6                                 | <b>Phone:</b>                                | B6              | <b>Email:</b>  | B6                     |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
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| <b>Phone:</b>                                | B6   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Email:</b>                                | B6   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
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| <b>B6</b>                                    |  |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| United States                                |  |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Healthcare Professional Information:</b>  | <table border="1"> <tr> <td><b>Practice Name:</b></td> <td>Tufts Cummings School of Veterinary Medicine</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td>200 Westboro Road<br/>North Grafton<br/>Massachusetts<br/>01536<br/>United States</td> </tr> <tr> <td><b>Practice Name:</b></td> <td>Tufts University</td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>Lisa Freeman</td> </tr> <tr> <td><b>Phone:</b></td> <td>(508) 887-4523</td> </tr> <tr> <td><b>Email:</b></td> <td>lisa.freeman@tufts.edu</td> </tr> </table> </td> </tr> <tr> <td><b>Type of Veterinarian:</b></td> <td>Referred veterinarian</td> </tr> <tr> <td><b>Permission to Release Records to FDA:</b></td> <td>Yes</td> </tr> </table> | <b>Practice Name:</b>              | Tufts Cummings School of Veterinary Medicine | <b>Contact:</b> | <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> | <b>Name:</b>           | B6 | <b>Phone:</b> | B6 | <b>Email:</b> | B6 | <b>Address:</b> | 200 Westboro Road<br>North Grafton<br>Massachusetts<br>01536<br>United States               | <b>Practice Name:</b> | Tufts University | <b>Contact:</b> | <table border="1"> <tr> <td><b>Name:</b></td> <td>Lisa Freeman</td> </tr> <tr> <td><b>Phone:</b></td> <td>(508) 887-4523</td> </tr> <tr> <td><b>Email:</b></td> <td>lisa.freeman@tufts.edu</td> </tr> </table> | <b>Name:</b> | Lisa Freeman | <b>Phone:</b> | (508) 887-4523 | <b>Email:</b> | lisa.freeman@tufts.edu | <b>Type of Veterinarian:</b> | Referred veterinarian | <b>Permission to Release Records to FDA:</b> | Yes |
| <b>Practice Name:</b>                        | Tufts Cummings School of Veterinary Medicine   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Contact:</b>                              | <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>   | <b>Name:</b>   | B6                                 | <b>Phone:</b>                                | B6              | <b>Email:</b>  | B6                     |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Name:</b>                                 | B6   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Phone:</b>                                | B6   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Email:</b>                                | B6   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Address:</b>                              | 200 Westboro Road<br>North Grafton<br>Massachusetts<br>01536<br>United States  |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Practice Name:</b>                        | Tufts University   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
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| <b>Name:</b>                                 | Lisa Freeman   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Phone:</b>                                | (508) 887-4523   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Email:</b>                                | lisa.freeman@tufts.edu   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Type of Veterinarian:</b>                 | Referred veterinarian  |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Permission to Release Records to FDA:</b> | Yes  |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Sender Information:</b>                   | <b>Name:</b>   | B6   |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
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| <b>Email:</b>                                | B6   |  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Permission To Contact Sender:</b>   | Yes  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Preferred Method Of Contact:</b>  | Email  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Reported to Other Parties:</b>  | None   |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
| <b>Additional Documents:</b>                 | <b>Attachment:</b>   | Diet Hx 5-3-2019.pdf   |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Description:</b>  | Med records  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Type:</b>   | Medical Records  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Attachment:</b>   | Recheck chem 21 5-3-2019.pdf   |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Description:</b>  | Lab work   |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |
|  | <b>Type:</b>   | Laboratory Report  |                                    |  |                 |  |                        |    |               |    |               |    |                 |   |                       |                  |                 |  |              |              |               |                |               |                        |                              |                       |  |     |

|                     |                   |                        |
|---------------------|-------------------|------------------------|
| <b>Attachment:</b>  | <b>B6</b>         | troponin 5-30-2019.pdf |
| <b>Description:</b> | Lab work          |                        |
| <b>Type:</b>        | Laboratory Report |                        |



Gastrointestinal Laboratory  
 Dr. J.M. Steiner  
 Department of Small Animal Clinical Sciences  
 Texas A&M University  
 4474 TAMU  
 College Station, TX 77843-4474



Website User ID **B6** @tufts.edu

GI Lab Assigned Clinic ID: 23523

|   |  |           |
|---|--|-----------|
| <b>B6</b><br>Tufts Cummings School of Vet Med - Cardiology/Nutrition<br>200 Westboro Road<br>North Grafton, MA 01536<br>USA | Phone: 508 887 4696<br>Fax:<br>Animal Name:<br>Owner Name:<br>Species: Canine<br>Date Received: May 30, 2019 | <b>B6</b> |
|---|--|-----------|

Tufts Cummings School of Vet Med - Cardiology/Nutrition Tracking Number: 444116  
 GI Lab Accession: **B6**

| <u>Test</u>                        | <u>Result</u>   | <u>Reference Interval</u> | <u>Assay Date</u> |
|------------------------------------|-----------------|---------------------------|-------------------|
| Ultra-Sensitive Troponin I Fasting | <b>B6</b> ng/mL | ≤0.06                     | 05/31/19          |

**B6**

Comments:

**GI Lab Contact Information**

Phone: (979) 862-2861  
 Fax: (979) 862-2864

Email: gilab@cvm.tamu.edu  
 vetmed.tamu.edu/gilab

444116

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

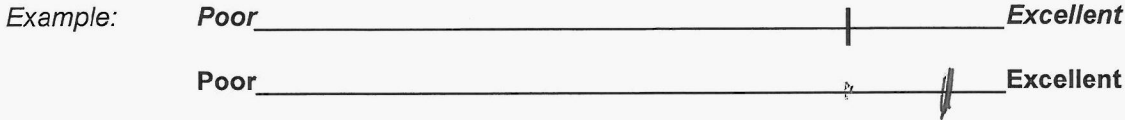
B6

B6

5/3/19

Pet's name: B6 Owner's name: B6 Today's date: 5/3/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)



2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

- Eats about the same amount as usual  Eats less than usual  Eats more than usual  Seems to prefer different foods than usual  Other

3. Over the last few weeks, has your pet (check one)

- Lost weight  Gained weight  Stayed about the same weight  Don't know

1. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats and that you have fed in the last 2 years.

Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the table

Table with 5 columns: Food (include specific product and flavor), Form, Amount, How often?, Dates fed. Rows include: Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult; 85% lean hamburger; Puppperoni original beef flavor; Rawhide; Royal Canin Boxer; Science Diet 7+ Beef + Barley; Hills Science Diet Soft Savories Peanut + Banana; ALPO Variety Snaps Big Bites.

\*Any additional diet information can be listed on the back of this sheet

2. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Yes  No If yes, please list which ones and give brands and amounts:

Table for dietary supplements with columns: Supplement Name, Yes/No, Brand/Concentration, Amount per day. Includes entries for Taurine (GNC, 2000 mg) and Nature's Bounty (500 mg tablets - 1 per day).

3. How do you administer pills to your pet?

- I do not give any medications  I put them directly in my pet's mouth without food  I put them in my pet's dog/cat food  I put them in a Pill Pocket or similar product  I put them in foods (list foods):





# Tufts Cummings School Of Veterinary Medicine

200 Westboro Road  
North Grafton, MA 01536

Name/DOB: **B6**

Patient ID: **B6**

Phone number:

Collection Date: 5/3/2019 11:51 AM

Approval date: 5/3/2019 12:55 PM

Sex: CM

Age: 2

Species: Canine

Breed: Pit Bull

Provider: **B6**

Order Location: Foster Hospital for Small Animals

Sample ID: **B6**

## Research Chemistry Profile - Small Animal (Cobas)

|                         |                                | Ref. Range/Males |
|-------------------------|--------------------------------|------------------|
| DNOYES                  |                                |                  |
| Glucose                 |                                | 67-135 mg/dL     |
| Urea                    |                                | 8-30 mg/dL       |
| Creatinine              |                                | 0.6-2.0 mg/dL    |
| Phosphorus              |                                | 2.6-7.2 mg/dL    |
| Calcium 2               |                                | 9.4-11.3 mg/dL   |
| Magnesium 2+            |                                | 1.8-3.0 mEq/L    |
| Total Protein           |                                | 5.5-7.8 g/dL     |
| Albumin                 |                                | 2.8-4.0 g/dL     |
| Globulins               | <b>B6</b>                      | 2.3-4.2 g/dL     |
| A/G Ratio               |                                | 0.7-1.6          |
| Sodium                  |                                | 140-150 mEq/L    |
| Chloride                |                                | 106-116 mEq/L    |
| Potassium               |                                | 3.7-5.4 mEq/L    |
| tCO2(Bicarb)            |                                | 14-28 mEq/L      |
| AGAP                    |                                | 8.0-19.0         |
| NA/K                    |                                | 29-40            |
| Total Bilirubin         |                                | 0.10-0.30 mg/dL  |
| Alkaline Phosphatase    | Hemolysis may affect result(s) | 12-127 U/L       |
| GGT                     | <b>B6</b>                      | 0-10 U/L         |
| ALT                     |                                | 14-86 U/L        |
| AST                     |                                | 9-54 U/L         |
| Creatine Kinase         | Hemolysis may affect result(s) | 22-422 U/L       |
| Cholesterol             |                                | 82-355 mg/dL     |
| Triglycerides           | <b>B6</b>                      | 30-338 mg/dl     |
| Amylase                 |                                | 409-1250 U/L     |
| Osmolality (calculated) |                                | 291-315 mmol/L   |
| Comments (Chemistry)    | <b>B6</b> hemolysis            |                  |

---

**From:** PFR Event <pfpreventcreation@fda.hhs.gov>  
**To:** Cleary, Michael \*; HQ Pet Food Report Notification; B6  
**Sent:** 11/9/2018 10:52:44 PM  
**Subject:** Zignature trout & salmon dry: Lisa Freeman - EON-370715  
**Attachments:** 2058683-report.pdf; 2058683-attachments.zip

A PFR Report has been received and PFR Event [EON-370715] has been created in the EON System.

A "PDF" report by name "2058683-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2058683-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-370715

**ICSR #:** 2058683

**EON Title:** PFR Event created for Zignature trout & salmon dry; 2058683

|                          |                      |                           |        |
|--------------------------|----------------------|---------------------------|--------|
| <b>AE Date</b>           | 11/07/2018           | <b>Number Fed/Exposed</b> | 3      |
| <b>Best By Date</b>      |                      | <b>Number Reacted</b>     | 2      |
| <b>Animal Species</b>    | Dog                  | <b>Outcome to Date</b>    | Stable |
| <b>Breed</b>             | Retriever - Labrador |                           |        |
| <b>Age</b>               | 3 Years              |                           |        |
| <b>District Involved</b> | PFR-New England DO   |                           |        |

**Product information**

**Individual Case Safety Report Number:** 2058683

**Product Group:** Pet Food

**Product Name:** Zignature trout & salmon dry

**Description:** Older housemate diagnosed with DCM and CHF. Screening: B6 because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner has changed diet and started taurine supplementation

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Stable

**Number of Animals Treated With Product: 3**

**Number of Animals Reacted With Product: 2**

| <b>Product Name</b>          | <b>Lot Number or ID</b> | <b>Best By Date</b> |
|------------------------------|-------------------------|---------------------|
| Zignature trout & salmon dry |                         |                     |

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6**

**B6** USA

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

**B6**

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

**B6**

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**Report Details - EON-370715**

ICSR: 2058683  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2018-11-09 17:46:50 EST

**Reported Problem:**  
**Problem Description:** Older housemate diagnosed with DCM and CHF. Screening [B6] because he has been eating the same diet. Does not have clearcut DCM on echo but has reduced cardiac contractility. Taurine pending and owner has changed diet and started taurine supplementation  
**Date Problem Started:** 11/07/2018  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Zignature trout & salmon dry  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:** **Description:** [B6] is four and was born on [B6] He ate Zignature trout & salmon from 09/30/15-10/01/18. 1.25 cups twice daily of Zignature. The primary cookies he ate was Earthborn Holistic Grain-Free, all varieties, and he might have had 3-4 cookies per day. The only other cookies he would have eaten were misc. varieties brought by misc. delivery people (propane, UPS, etc.) and not regularly. If we ever had to give medication, we always used the Greenies Pill Pockets.  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** [B6]  
**Type Of Species:** Dog  
**Type Of Breed:** Retriever - Labrador  
**Gender:** Male  
**Reproductive Status:** Neutered  
**Weight:** 25.9 Kilogram  
**Age:** 3 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 3  
**Number of Animals Reacted:** 2  
**Owner Information:** **Owner Information provided:** Yes  
**Contact:** **Name:** [B6]  
**Phone:** [B6]  
**Email:** [B6]  
**Address:** [B6]

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

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

Diet Hx 1/24/19

**CARDIOLOGY DIET HISTORY FORM**

Please answer the following

Pet's name: **B6** Owner's name: **B6** Today's date: 1/24/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)  
 Example: Poor \_\_\_\_\_ | \_\_\_\_\_ Excellent  
 Poor \_\_\_\_\_ | \_\_\_\_\_ **Excellent**

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)  
 Eats about the same amount as usual     Eats less than usual     Eats more than usual  
 Seems to prefer different foods than usual     Other \_\_\_\_\_

3. Over the last few weeks, has your pet (check one)  
 Lost weight     Gained weight     Stayed about the same weight     Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

**Food (include specific product and flavor)    Form    Amount    How often?    Fed since**  
 Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

| Food (include specific product and flavor)             | Form       | Amount       | How often?   | Fed since    |
|--|------------|--------------|--------------|--------------|
| Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult | dry        | 1 1/2 cup    | 2x/day       | Jan 2018     |
| 85% lean hamburger                                     | microwaved | 3 oz         | 1x/week      | Jan 2015     |
| Pupperoni original beef flavor                         | treat      | 1/2          | 1x/day       | Aug 2015     |
| Rawhide  | treat      | 6 inch twist | 1x/week      | Dec 2015     |
| <u>YORKINA Pils - Pure SPORT 30/20</u>                 | <u>DRY</u> | <u>1 pc</u>  | <u>2/day</u> | <u>10/18</u> |
| <u>YORKINA COOKIES - HARD MEN</u>                      |            | <u>5/day</u> |              | <u>10/18</u> |
| <u>5x200 SQUARES, RED BOX IN GROCERY STORE</u>         |            |              |              |              |
|  |            |              |              |              |
|  |            |              |              |              |
|  |            |              |              |              |

\*Any additional diet information can be listed on the back of this sheet

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Yes  No. If yes, please list which ones and give brands and amounts:

|  | Brand/Concentration                | Amount per day                    |
|--|------------------------------------|-----------------------------------|
| Taurine                                    | <u>TOP TIPS RECOMMENDED BRAND?</u> | <u>2000/day</u>                   |
| Carnitine                                  | <u>TWIN LABS</u>                   |                                   |
| Antioxidants                               |                                    |                                   |
| Multivitamin                               |                                    |                                   |
| Fish oil                                   |                                    |                                   |
| Coenzyme Q10                               |                                    |                                   |
| Other (please list):<br>Example: Vitamin C | <u>Nature's Bounty</u>             | <u>500 mg tablets - 1 per day</u> |
|  |                                    |                                   |
|  |                                    |                                   |
|  |                                    |                                   |

6. How do you administer pills to your pet?  
 I do not give any medications  
 I put them directly in my pet's mouth without food  
 I put them in my pet's dog/cat food  
 I put them in a Pill Pocket or similar product  
 I put them in foods (list foods): \_\_\_\_\_

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

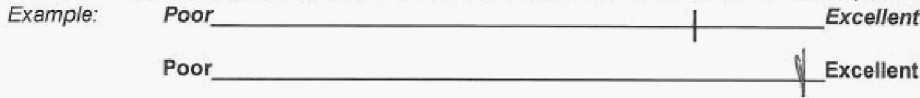
Diet Hx 5/1/2019

432033

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

Pet's name **B6** Owner's name **B6** Today's date: 5/1/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)



2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

- Eats about the same amount as usual     Eats less than usual     Eats more than usual  
 Seems to prefer different foods than usual     Other \_\_\_\_\_

3. Over the last few weeks, has your pet (check one)

- Lost weight     Gained weight     Stayed about the same weight     Don't know

1. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats and that you have fed in the last 2 years.

Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the table

| Food (include specific product and flavor)             | Form       | Amount       | How often? | Dates fed         |
|--|------------|--------------|------------|-------------------|
| Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult | dry        | 1 1/2 cup    | 2x/day     | Jan 2016-present  |
| 85% lean hamburger                                     | microwaved | 3 oz         | 1x/week    | June -Aug 2016    |
| Pupperoni original beef flavor                         | treat      | 1/2          | 1x/day     | Sept 2016-present |
| Rawhide  | treat      | 6 inch twist | 1x/week    | Dec 2018-present  |
| KIRINA PRO PLAN SAVOR STRENGTHENED BEEF + RICE         | Dry        | 1 1/2 c      | 2x/day     | 10/18 - present   |
| Porion Appo Variety Snaps Little Bites                 | TREAT      | 2-4          | per day    | 1/19 - present    |
| Crazy Dog Train - Red Training Reward - Bacon          | treat      | 3-6          | per day    | 1/19 - present    |
|  |            |              |            |                   |
|  |            |              |            |                   |

\*Any additional diet information can be listed on the back of this sheet

2. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Yes  No If yes, please list which ones and give brands and amounts:

|  | Brand/Concentration    | Amount per day                    |
|--|------------------------|-----------------------------------|
| Taurine                                    | <u>NDW 1000 mg</u>     | <u>2/day</u>                      |
| Carnitine                                  | _____                  | _____                             |
| Antioxidants                               | _____                  | _____                             |
| Multivitamin                               | _____                  | _____                             |
| Fish oil                                   | _____                  | _____                             |
| Coenzyme Q10                               | _____                  | _____                             |
| Other (please list):<br>Example: Vitamin C | <u>Nature's Bounty</u> | <u>500 mg tablets - 1 per day</u> |
| _____                                      | _____                  | _____                             |
| _____                                      | _____                  | _____                             |
| _____                                      | _____                  | _____                             |

3. How do you administer pills to your pet?

- I do not give any medications  
 I put them directly in my pet's mouth without food  
 I put them in my pet's dog/cat food  
 I put them in a Pill Pocket or similar product  
 I put them in foods (list foods): \_\_\_\_\_

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

**Idexx NT-proBNP 5/1/2019**

IDEXX Reference Laboratories

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

Client: **B6**  
Patient: **B6**  
Species: CANINE  
Breed: GOLDEN\_RETRIEVE  
Gender: MALE NEUTERED  
Age: 3Y

Date: 05/01/2019  
Requisition #: LA  
Accession #: **B6**  
Ordered by: **B6**

IDEXX VetConnect 1-888-433-9967  
**TUFTS UNIVERSITY**  
200 WESTBORO RD  
NORTH GRAFTON, Massachusetts 01536  
508-839-5395  
Account #88933

**CARDIOPET proBNP- CANINE**

| Test                     | Result    | Reference Range | Low | Normal    | High |
|--------------------------|-----------|-----------------|-----|-----------|------|
| CARDIOPET proBNP- CANINE | <b>B6</b> | 0 - 900 pmol/L  |     | <b>B6</b> |      |

**B6**

Please note: Complete interpretive comments for all concentrations of Cardiotet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT-proBNP concentrations.



Client: **B6**  
Patient:

**Troponin 5/31/2019**



**Gastrointestinal Laboratory**  
Dr. J.M. Steiner  
Department of Small Animal Clinical Sciences  
Texas A&M University  
4474 TAMU  
College Station, TX 77843-4474



Website User ID: lisa.freeman@tufts.edu OR **B6**@tufts.edu

GI Lab Assigned Clinic ID: 23523

**B6**  
Tufts Cummings School of Vet Med - Cardiology/Nutrition  
200 Westboro Road  
North Grafton, MA 01536  
USA

Phone: 508 887 4696

Fax:  
Animal Name: **B6**  
Owner Name:  
Species: Canine  
Date Received: May 30, 2019

Tufts Cummings School of Vet Med -  
Cardiology/Nutrition Tracking Number:  
432033

GI Lab Accession: **B6**

| Test                               | Result          | Reference Interval | Assay Date |
|------------------------------------|-----------------|--------------------|------------|
| Ultra-Sensitive Troponin I Fasting | <b>B6</b> ng/mL | ≤0.06              | 05/31/19   |

**B6**

Comments:

**GI Lab Contact Information**

Phone: (979) 862-2861  
Fax: (979) 862-2864

Email: gilab@cvm.tamu.edu  
vetmed.tamu.edu/gilab

---

**From:** Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>  
**To:** Carey, Lauren; Cleary, Michael \*; HQ Pet Food Report Notification;  
**B6**  
**Sent:** 3/28/2019 9:01:34 PM  
**Subject:** Rachel Ray peak open range recipe (beef: Lisa Freeman - EON-383627  
**Attachments:** 2064872-report.pdf; 2064872-attachments.zip

A PFR Report has been received and Related PFR Event [EON-383627] has been created in the EON System.

A "PDF" report by name "2064872-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2064872-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-383627

**ICSR #:** 2064872

**EON Title:** Related PFR Event created for Rachel Ray peak open range recipe (beef venison lamb); 2064872

|                          |                      |                           |        |
|--------------------------|----------------------|---------------------------|--------|
| <b>AE Date</b>           | 10/06/2018           | <b>Number Fed/Exposed</b> | 1      |
| <b>Best By Date</b>      |                      | <b>Number Reacted</b>     | 1      |
| <b>Animal Species</b>    | Dog                  | <b>Outcome to Date</b>    | Stable |
| <b>Breed</b>             | Boxer (German Boxer) |                           |        |
| <b>Age</b>               | <b>B6</b> Years      |                           |        |
| <b>District Involved</b> | PFR-New England DO   |                           |        |

**Product information**

**Individual Case Safety Report Number:** 2064872

**Product Group:** Pet Food

**Product Name:** Rachel Ray peak open range recipe (beef, venison, lamb)

**Description:** DCM and arrhythmias diagnosed at time of **B6** surgery so unclear if sepsis/post-op or true DCM. Had recheck echo 10/31/18 and still has DCM. Taurine pending. Owner has changed diet to Royal Canin Boxer

**Submission Type:** Followup

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Stable

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

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

| <b>Product Name</b>                                     | <b>Lot Number or ID</b> | <b>Best By Date</b> |
|---|-------------------------|---------------------|
| Rachel Ray peak open range recipe (beef, venison, lamb) |                         |                     |

This report is linked to:

**Initial EON Event Key:** EON-370720

**Initial ICSR:** 2058685

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6**

USA

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

**B6**

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

**B6**

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**Report Details - EON-383627**

|                                  |  |
|----------------------------------|--|
| ICSR:                            | 2064872  |
| Type Of Submission:              | Followup   |
| Report Version:                  | FPSR.FDA.PETF.V.V1   |
| Type Of Report:                  | Adverse Event (a symptom, reaction or disease associated with the product) |
| Reporting Type:                  | Voluntary  |
| Report Submission Date:          | 2019-03-28 16:47:21 EDT  |
| Initial Report Date:             | 11/09/2018   |
| Parent ICSR:                     | 2058685  |
| Follow-up Report to FDA Request: | Yes  |

|                   |                             |  |
|-------------------|-----------------------------|--|
| Reported Problem: | Problem Description:        | DCM and arrhythmias diagnosed at time of <b>B6</b> surgery so unclear if sepsis/post-op or true DCM. Had recheck echo 10/31/18 and still has DCM. Taurine pending. Owner has changed diet to Royal Canin Boxer |
|                   | Date Problem Started:       | 10/06/2018   |
|                   | Concurrent Medical Problem: | Yes  |
|                   | Pre Existing Conditions:    | <b>B6</b>  |
|                   | Outcome to Date:            | Stable   |

|                      |  |   |   |
|----------------------|--|---|---|
| Product Information: | Product Name:                          | Rachel Ray peak open range recipe (beef, venison, lamb) |   |
|                      | Product Type:                          | Pet Food  |   |
|                      | Lot Number:                            |   |   |
|                      | Package Type:                          | BAG   |   |
|                      | Product Use Information:               | Description:  | Rachael Ray's since about 2017- prior to that it has been Purina One chicken and rice. The Rachael Ray that I fed him was "PEAK- open range receipt some with chicken some with lamb or beef. The dry was served with one half a can of newman's organic chicken and brown rice. I also cooked chicken breasts and rice as well as hamburger and rice every other week and used cup of this instead of the canned food. Mixed it in with the dry food. I have as of last Thursday switched him to Royal Canin dry food for Boxers with 1/2 can of science diet healthy cusine-roasted chicken, carrots and spinach stew mixed with about two cups of this dry food. |
|                      | Manufacturer /Distributor Information: |   |   |
|                      | Purchase Location Information:         |   |   |

|                     |                                      |                      |
|---------------------|--------------------------------------|----------------------|
| Animal Information: | Name:                                | <b>B6</b>            |
|                     | Type Of Species:                     | Dog                  |
|                     | Type Of Breed:                       | Boxer (German Boxer) |
|                     | Gender:                              | Male                 |
|                     | Reproductive Status:                 | Intact               |
|                     | Weight:                              | 34.8 Kilogram        |
|                     | Age:                                 | <b>B6</b> Years      |
|                     | Assessment of Prior Health:          | Good                 |
|                     | Number of Animals Given the Product: | 1                    |
|                     | Number of Animals Reacted:           | 1                    |
| Owner Information:  | Owner Information                    | Yes                  |

|   |  |                       |  |                     |  |                 |   |                    |                |                     |                        |                                      |   |                                     |               |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
|---|--|-----------------------|--|---------------------|--|-----------------|---|--------------------|----------------|---------------------|------------------------|--------------------------------------|---|-------------------------------------|---------------|---------------------|----------------|--------------|-----------------|--------------------|---------------|---------------------|----------------|--------------|-----------------|--------------------|-----------------|---------------------|-----|--------------|-----------------|
|   | <table border="1"> <tr> <td><b>provided:</b></td> <td></td> </tr> <tr> <td><b>Contact:</b></td> <td> <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table> </td> </tr> <tr> <td><b>Address:</b></td> <td> <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>  | <b>provided:</b>      |  | <b>Contact:</b>     | <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>   | <b>Name:</b>    | B6  | <b>Phone:</b>      | B6             | <b>Email:</b>       | B6                     | <b>Address:</b>                      | <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> | <b>B6</b>                           | United States |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
| <b>provided:</b>                            |  |                       |  |                     |  |                 |   |                    |                |                     |                        |                                      |   |                                     |               |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
| <b>Contact:</b>                             | <table border="1"> <tr> <td><b>Name:</b></td> <td>B6</td> </tr> <tr> <td><b>Phone:</b></td> <td>B6</td> </tr> <tr> <td><b>Email:</b></td> <td>B6</td> </tr> </table>   | <b>Name:</b>          | B6   | <b>Phone:</b>       | B6   | <b>Email:</b>   | B6  |                    |                |                     |                        |                                      |   |                                     |               |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
| <b>Name:</b>                                | B6   |                       |  |                     |  |                 |   |                    |                |                     |                        |                                      |   |                                     |               |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
| <b>Phone:</b>                               | B6   |                       |  |                     |  |                 |   |                    |                |                     |                        |                                      |   |                                     |               |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
| <b>Email:</b>                               | B6   |                       |  |                     |  |                 |   |                    |                |                     |                        |                                      |   |                                     |               |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
| <b>Address:</b>                             | <table border="1"> <tr> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>  | <b>B6</b>             | United States                                |                     |  |                 |   |                    |                |                     |                        |                                      |   |                                     |               |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
| <b>B6</b>                                   |  |                       |  |                     |  |                 |   |                    |                |                     |                        |                                      |   |                                     |               |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
| United States                               |  |                       |  |                     |  |                 |   |                    |                |                     |                        |                                      |   |                                     |               |                     |                |              |                 |                    |               |                     |                |              |                 |                    |                 |                     |     |              |                 |
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IDEXX VetConnect 1-888-433-9987

Client: **B6**  
Patient: **B6**  
Species: CANINE  
Breed:  
Gender: MALE  
Age: 8Y

Date: 03/27/2019  
Requisition #: 1A  
Accession #: **B6**  
Ordered by: **B6**

**TUFTS UNIVERSITY**  
200 WESTBORO RD  
NORTH GRAFTON, Massachusetts 01536  
508-839-5395

Account #88933

**CARDIOPET proBNP - CANINE**

| Test                      | Result    | Reference Range | Low | Normal | High      |
|---------------------------|-----------|-----------------|-----|--------|-----------|
| CARDIOPET proBNP - CANINE | <b>B6</b> | 0 - 900 pmol/L  |     |        | <b>B6</b> |

**Comments:**

1  
**B6**

Please note: Complete interpretive comments for all concentrations of Cardiotet proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased NT proBNP concentrations.

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

Diet Hx 5/3/2019

434853

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

Pet's name: **B6** Owner's name: **B6** Today's date: 5/3/19

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: **Poor** \_\_\_\_\_ **Excellent**  
 Poor \_\_\_\_\_ Excellent

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

Eats about the same amount as usual  Eats less than usual  Eats more than usual  
 Seems to prefer different foods than usual  Other \_\_\_\_\_

3. Over the last few weeks, has your pet (check one)  
 Lost weight  Gained weight  Stayed about the same weight  Don't know

1. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats and that you have fed in the last 2 years.

Please provide enough detail that we could go to the store and buy the exact same food - examples are shown in the table

| Food (include specific product and flavor)             | Form       | Amount       | How often? | Dates fed         |
|--|------------|--------------|------------|-------------------|
| Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult | dry        | 1 1/2 cup    | 2x/day     | Jan 2016-present  |
| 85% lean hamburger                                     | microwaved | 3 oz         | 1x/week    | June -Aug 2016    |
| Pupperoni original beef flavor                         | treat      | 1/2          | 1x/day     | Sept 2016-present |
| Rawhide  | treat      | 6 inch twist | 1x/week    | Dec 2018-present  |
| Purina Pro Plan  | dry        | 1 1/2        | 2x/day     | Jan 2019-present  |
| Dental Bones & Chews                                   | treat      | 1            | 3x/week    | Jan 2019-present  |
| Wholesome Dog Biscuit                                  | treat      | 5 treats     | daily      | Jan 2019-present  |
|  |            |              |            |                   |
|  |            |              |            |                   |
|  |            |              |            |                   |
|  |            |              |            |                   |
|  |            |              |            |                   |

\*Any additional diet information can be listed on the back of this sheet

2. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Yes  No If yes, please list which ones and give brands and amounts:

|   | Brand/Concentration | Amount per day             |
|---|---------------------|----------------------------|
| Taurine <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | _____               | _____                      |
| Carnitine <input type="checkbox"/> Yes <input type="checkbox"/> No          | _____               | _____                      |
| Antioxidants <input type="checkbox"/> Yes <input type="checkbox"/> No       | _____               | _____                      |
| Multivitamin <input type="checkbox"/> Yes <input type="checkbox"/> No       | _____               | _____                      |
| Fish oil <input type="checkbox"/> Yes <input type="checkbox"/> No           | _____               | _____                      |
| Coenzyme Q10 <input type="checkbox"/> Yes <input type="checkbox"/> No       | _____               | _____                      |
| Other (please list):<br>Example: Vitamin C                                  | Nature's Bounty     | 500 mg tablets - 1 per day |
|   |                     |                            |
|   |                     |                            |
|   |                     |                            |
|   |                     |                            |

3. How do you administer pills to your pet?

I do not give any medications  
 I put them directly in my pet's mouth without food  
 I put them in my pet's dog/cat food  
 I put them in a Pill Pocket or similar product  
 I put them in foods (list foods): \_\_\_\_\_



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

**Idexx NT-proBNP 5/3/2019**

IDEXX Reference Laboratories

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

Client: **B6**  
Patient: **B6**  
Species: CANINE  
Breed: GOLDEN\_RETRIEVE  
Gender: FEMALE SPAYED  
Age: 3Y

Date: **B6**  
Requisition #: 1A  
Accession #: **B6**  
Ordered by: **B6**

IDEXX VetConnect 1-888-433-9987  
TUFTS UNIVERSITY  
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Account #88933

**CARDIOPET proBNP - CANINE**

| Test                      | Result    | Reference Range | Low  | Normal | High      |
|---------------------------|-----------|-----------------|------|--------|-----------|
| CARDIOPET proBNP - CANINE | <b>B6</b> | 0 - 900 pmol/L  | HIGH |        | <b>B6</b> |

Comments:

**B6**

Client: **B6**  
Patient:

**Troponin 5/31/2019**



**Gastrointestinal Laboratory**  
Dr. J.M. Steiner  
Department of Small Animal Clinical Sciences  
Texas A&M University  
4474 TAMU  
College Station, TX 77843-4474



Website User ID: lisa.freeman@tufts.edu OR: **B6**@tufts.edu

GI Lab Assigned Clinic ID: 23523

|   |  |
|---|--|
| <b>B6</b><br>Tufts Cummings School of Vet Med - Cardiology/Nutrition<br>200 Westboro Road<br>North Grafton, MA 01536<br>USA | <b>Phone:</b> 508 887 4696<br><b>Fax:</b><br>Animal Name: <b>B6</b><br>Owner Name:<br>Species: Canine<br>Date Received: May 30, 2019 |
|---|--|

Tufts Cummings School of Vet Med -  
Cardiology/Nutrition Tracking Number:  
434853

GI Lab Accession: **B6**

| <u>Test</u>                        | <u>Result</u>   | <u>Reference Interval</u> | <u>Assay Date</u> |
|------------------------------------|-----------------|---------------------------|-------------------|
| Ultra-Sensitive Troponin I Fasting | <b>B6</b> ng/mL | ≤0.06                     | 05/31/19          |

**B6**

Comments:

**GI Lab Contact Information**

Phone: (979) 862-2861  
Fax: (979) 862-2864

Email: gilab@cvm.tamu.edu  
vetmed.tamu.edu/gilab

B6

Patient ID: B6

B6  
Canine  
years Old Female Golden Retriever  
Cream

**Cardiology Appointment Report  
DCM STUDY**

Date: B6

**Attending Cardiologist:**

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

**Cardiology Resident:**

B6

**Cardiology Technician:**

B6

Student: B6 V20

**Presenting Complaint:** DCM study recheck; o reports doing well at home, good energy, no other concerns.

**Concurrent Diseases:** None

**General Medical History:** On 1/2/19 was referred here by rDVM for elevated BNP B6, rDVM prompted to check b/c of grain-free diet. Echo in January showed mild systolic dysfunction w/mild LAE. Transitioned to new diet. CBC, chem, BNP WNL.

**Diet and Supplements:**

Purina sensitive stomach

**Cardiovascular History:**

Prior CHF diagnosis? N

Prior heart murmur? N

Prior ATE? N

Prior arrhythmia? N

Monitoring respiratory rate and effort at home? N

Cough? N

Shortness of breath or difficulty breathing? N

Syncope or collapse? N

Sudden onset lameness? N

Exercise intolerance? N

**Current Medications Pertinent to CV System:**

**B6**

**Cardiac Physical Examination:**

**B6**

**Muscle condition:**

- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

**Cardiovascular Physical Exam:**

**Murmur Grade:**

- None
- I/VI
- II/VI
- III/VI
- IV/VI
- V/VI
- VI/VI

**Murmur location/description:**

**Jugular vein:**

- Bottom 1/3 of the neck
- Middle 1/3 of the neck
- 1/2 way up the neck
- Top 2/3 of the neck

**Arterial pulses:**

- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other:

**Arrhythmia:**

- None
- Sinus arrhythmia
- Premature beats
- Bradycardia
- Tachycardia

**Gallop:**

- Yes
- No
- Intermittent
- Pronounced
- Other:

**Pulmonary assessments:**

- Eupneic
- Pulmonary crackles

- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

- Wheezes
- Upper airway stridor

**Abdominal exam:**

- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

**Problems:**

Hx of asymptomatic heart disease

**Differential Diagnoses:**

Nutritional DCM

**Diagnostic plan:**

- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests:

**Echocardiogram Findings:**

**B6**

**Mitral inflow:**

- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

**ECG findings:**

**B6**

**Assessment and recommendations:**

Stable systolic function compared to previous exams, despite mild increase in LV cavity size (r/o daily variation or interobserver variation).

B6

**B6**

**Final Diagnosis:**

Mild systolic dysfunction with mild LA enlargement- r/o early stage DCM vs. diet induced systolic dysfunction.

**Heart Failure Classification Score:**

**ISACHC Classification:**

- Ia
- Ib
- II
- IIIa
- IIIb

**ACVIM Classification:**

- A
- B1
- B2
- C
- D

M-Mode

|            |           |                      |
|------------|-----------|----------------------|
| IVSd       | <b>B6</b> | cm                   |
| LVIDd      |           | cm                   |
| LVPWd      |           | cm                   |
| IVSs       |           | cm                   |
| LVIDs      |           | cm                   |
| LVPWs      |           | cm                   |
| EDV(Teich) |           | ml                   |
| ESV(Teich) |           | ml                   |
| EF(Teich)  |           | %                    |
| %FS        |           | %                    |
| SV(Teich)  |           | ml                   |
| Max LA     |           | cm                   |
| Time       |           | ms                   |
| HR         |           | BPM                  |
| CO(Teich)  |           | l/min                |
| CI(Teich)  |           | l/min/m <sup>2</sup> |
| Ao Diam    | cm        |                      |
| LA Diam    | cm        |                      |
| LA/Ao      |           |                      |
| TAPSE      | cm        |                      |
| EPSS       | cm        |                      |

M-Mode Normalized

|        |                 |                   |
|--------|-----------------|-------------------|
| IVSdN  | <b>B6</b>       | (0.290 - 0.520)   |
| LVIDdN |                 | (1.350 - 1.730) ! |
| LVPWdN |                 | (0.330 - 0.530) ! |
| IVSsN  |                 | (0.430 - 0.710) ! |
| LVIDsN |                 | (0.790 - 1.140) ! |
| LVPWsN | (0.530 - 0.780) |                   |

2D

|            |           |    |
|------------|-----------|----|
| IVSd       | <b>B6</b> | cm |
| LVIDd      |           | cm |
| LVPWd      |           | cm |
| EDV(Teich) |           | ml |

IVSs  
LVIDs  
LVPWs  
ESV(Teich)  
EF(Teich)  
%FS  
SV(Teich)  
LV Major  
LV Minor  
Sphericity Index  
LVld A4C  
LVEDV MOD A4C  
LVLS A4C  
LVESV MOD A4C  
LVEF MOD A4C  
SV MOD A4C

B6

cm  
cm  
cm  
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MV DecT  
MV Dec Slope  
MV A Vel  
MV E/A Ratio  
E'  
E/E'  
A'  
S'  
IVRT  
AV Vmax  
AV maxPG  
PV Vmax  
PV maxPG  
E'  
A'

B6

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mmHg  
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---

**From:** PFR Event <pfpreventcreation@fda.hhs.gov>  
**To:** Cleary, Michael \*; HQ Pet Food Report Notification; B6  
**Sent:** 2/25/2019 12:52:56 PM  
**Subject:** Wellness Core grain-free ocean fish dry-Wellness core grain free turkey: Lisa Freeman - EON-380742  
**Attachments:** 2063133-report.pdf; 2063133-attachments.zip

A PFR Report has been received and PFR Event [EON-380742] has been created in the EON System.

A "PDF" report by name "2063133-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2063133-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380742

**ICSR #:** 2063133

**EON Title:** PFR Event created for Wellness Core grain-free ocean fish dry Wellness core grain free turkey chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe; 2063133

|                          |   |                           |        |
|--------------------------|---|---------------------------|--------|
| <b>AE Date</b>           | 01/15/2019  | <b>Number Fed/Exposed</b> | 6      |
| <b>Best By Date</b>      |   | <b>Number Reacted</b>     | 3      |
| <b>Animal Species</b>    | Dog   | <b>Outcome to Date</b>    | Stable |
| <b>Breed</b>             | Bulldog   |                           |        |
| <b>Age</b>               | <span style="border: 1px dashed black; padding: 2px;">B6</span> Years |                           |        |
| <b>District Involved</b> | PFR-New England DO  |                           |        |

**Product information**

**Individual Case Safety Report Number:** 2063133

**Product Group:** Pet Food

**Product Name:** Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe

**Description:** DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food



**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Stable

**Number of Animals Treated With Product:** 6

**Number of Animals Reacted With Product:** 3

| <b>Product Name</b>   | <b>Lot Number or ID</b> | <b>Best By Date</b> |
|---|-------------------------|---------------------|
| Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe |                         |                     |

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6**

USA

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

**B6**

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

**B6**

---

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through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to [FDAREportableFoods@fda.hhs.gov](mailto:FDAREportableFoods@fda.hhs.gov) immediately.

**Report Details - EON-380742**

ICSR: 2063133  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2019-02-25 07:43:42 EST

**Reported Problem:**  
**Problem Description:** DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far. 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food  
**Date Problem Started:** 01/15/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** B6  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Wellness Core grain-free ocean fish dry Wellness core grain free turkey, chicken liver & turkey liver canned Wellness Hearty Cuts grain-free in gravy chicken and turkey recipe  
**Product Type:** Pet Food  
**Lot Number:**  
**Product Use Information:** Description: Please see diet history  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Bulldog  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 19.8 Kilogram  
**Age:** B6 Years  
**Number of Animals Given the Product:** 6  
**Number of Animals Reacted:** 3  
**Owner Information:** Owner Information provided: Yes  
**Contact:** Name: B6  
 Phone: B6  
 Email: B6  
**Address:** B6  
 United States  
**Healthcare Professional Information:** Practice Name: Tufts Cummings School of Veterinary Medicine  
**Contact:** Name: Lisa Freeman  
 Phone: (508) 887-4523  
 Email: lisa.freeman@tufts.edu

|  |  |   |
|--|--|---|
|  |  | <b>Address:</b> 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |
|--|--|---|

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

|                              |                     |                                |  |
|------------------------------|---------------------|--------------------------------|--|
| <b>Additional Documents:</b> | <b>Attachment:</b>  | rpt_medical_record_preview.pdf |  |
|                              | <b>Description:</b> | Med records                    |  |
|                              | <b>Type:</b>        | Medical Records                |  |

---

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Jones, Jennifer L  
**Sent:** 10/18/2018 2:19:15 PM  
**Subject:** Updates: Taurine Result for: [B6] and [B6]  
**Attachments:** T\_23038.jpg; T\_23040.jpg

Lisa M. Freeman, DVM, PhD, DACVN  
Board Certified Veterinary Nutritionist™  
Professor  
Cummings School of Veterinary Medicine  
Friedman School of Nutrition Science and Policy  
Tufts Clinical and Translational Science Institute  
Tufts University  
[www.petfoodology.org](http://www.petfoodology.org)

**From:** Tufts Veterinary Cardiology Service  
**Sent:** Wednesday, October 17, 2018 9:28 AM  
**To:** Freeman, Lisa <lisa.freeman@tufts.edu>  
**Subject:** FW: Taurine Result

**Veterinary Cardiology Service**  
**Tufts University Cummings School of Veterinary Medicine**

**Please note:** This account is not monitored on weekends, holidays, or evenings (after 5pm). Please allow 24 - 48 business hours for a reply. For immediate service during business hours, please call the liaison office at 508-887-4696. If you need to speak with the Emergency Service, please call 508-839-5395.

Foster Hospital for Small Animals  
200 Westboro Road  
North Grafton, MA 01536  
<http://www.tufts.edu/vet/>  
508.887.4696 phone  
508.887.4363 fax

**From:** Amino Acid Lab <[ucd.aminoacid.lab@ucdavis.edu](mailto:ucd.aminoacid.lab@ucdavis.edu)>  
**Sent:** Tuesday, October 16, 2018 6:37 PM  
**To:** Clinical Pathology Lab <[clinpath@tufts.edu](mailto:clinpath@tufts.edu)>; Tufts Veterinary Cardiology Service <[cardiovet@tufts.edu](mailto:cardiovet@tufts.edu)>  
**Subject:** Taurine Result

Hello -

Thank you for using the Amino Acid Laboratory at UC Davis, School of Veterinary Medicine.

Please find attached the results for your patient. You will note that we are now using a new submission form. The new form requests some additional information that may be useful in interpreting your results. Please note, with the recent increase in the number of dogs screened for taurine deficiency, we are seeing some dogs with values within the lower reference ranges (or above the “no known risk for deficiency range”) yet are still exhibiting changes in cardiac function.

In addition to our new submission form, we have also attached 2 handouts developed by our cardiology service at UC Davis for your information. The first is a general handout on dilated cardiomyopathy in dogs. The second is a handout specifically focused on Golden Retrievers, a breed that has been over-represented in the association between grain-free diet consumption and dilated cardiomyopathy.

We hope your clinic finds this information helpful. Veterinarians are always welcome to contact our laboratory for assistance in evaluating your patient’s results.

Thank you -

The Amino Acid Laboratory  
Department of Molecular Biosciences  
School of Veterinary Medicine  
University of California, Davis

Phone: 530-752-5058

Email: [ucd.aminoacid.lab@ucdavis.edu](mailto:ucd.aminoacid.lab@ucdavis.edu)

23038 PL  
23039 WB

### Sample Submission Form

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

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

**B6**  
B6 ipat Race  
4:09 PM  
SHIP w ICE PACKS, TAURINE  
PANEL  
Lithium Heparin  
*RUSH*

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

Vet/Tech Contact: **B6**

Company Name: Tufts Cummings School of Vet Med - Clinical Pathology Laboratory

Address: 200 Westboro Road  
North Grafton, MA 01536

Email: clinpath@tufts.edu; cardiovvet@tufts.edu

Tel: 508-887-4669 Fax: 508-839-7936

Billing Contact: **B6** TAX ID: \_\_\_\_\_

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

Patient Name: **B6**

Species: canine

Owner's Name: **B6**

Sample Type:  Plasma  Whole Blood  Urine  Food  Other: \_\_\_\_\_

Test Items:  Taurine  Complete Amino Acid  Other: \_\_\_\_\_

#### Taurine Results (nmol/ml)

Plasma: **B6** (+) Whole Blood: **B6** Urine: \_\_\_\_\_ Food: \_\_\_\_\_

#### Reference Ranges (nmol/ml)

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

23040

### Sample Submission Form

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

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

**B6**  
B6 B6  
B6 2:42 PM  
SHIP W ICE PACKS, TAURINE  
(WHOLE BLOOD)  
Lithium Heparin

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

Vet/Tech Contact: **B6**

Company Name: Tufts Cummings School of Vet Med - Clinical Pathology Laboratory

Address: 200 Westboro Road  
North Grafton, MA 01536

Email: [clinpath@tufts.edu](mailto:clinpath@tufts.edu)  
Tel: 508-887-4669 Fax: 508-839-7936

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

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

Sample Type:  Plasma  Whole Blood  Urine  Food  Other: \_\_\_\_\_  
Test Items:  Taurine  Complete Amino Acid  Other: \_\_\_\_\_

Taurine Results (nmol/ml)  
Plasma: \_\_\_\_\_ Whole Blood: **B6** Urine: \_\_\_\_\_ Food: \_\_\_\_\_

#### Reference Ranges (nmol/ml)

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



**From:** PFR Event <pfpreventcreation@fda.hhs.gov>  
**To:** Cleary, Michael \*; HQ Pet Food Report Notification; B6  
**Sent:** 10/8/2018 7:12:54 PM  
**Subject:** Taste of the Wild Pacific Stream (dry): Lisa Freeman - EON-367849  
**Attachments:** 2055795-report.pdf; 2055795-attachments.zip

A PFR Report has been received and PFR Event [EON-367849] has been created in the EON System.

A "PDF" report by name "2055795-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2055795-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-367849

**ICSR #:** 2055795

**EON Title:** PFR Event created for Taste of the Wild Pacific Stream (dry); 2055795

|                          |   |                           |        |
|--------------------------|---|---------------------------|--------|
| <b>AE Date</b>           | 02/02/2018  | <b>Number Fed/Exposed</b> | 2      |
| <b>Best By Date</b>      |   | <b>Number Reacted</b>     | 1      |
| <b>Animal Species</b>    | Dog   | <b>Outcome to Date</b>    | Stable |
| <b>Breed</b>             | Doberman Pinscher   |                           |        |
| <b>Age</b>               | <span style="border: 1px dashed black; padding: 2px;">B6</span> Years |                           |        |
| <b>District Involved</b> | PFR-New England DO  |                           |        |

**Product information**

**Individual Case Safety Report Number:** 2055795

**Product Group:** Pet Food

**Product Name:** Taste of the Wild Pacific Stream (dry)

**Description:** DCM and CHF diagnosed 2/2/18. Owner did not change diet after diagnosis. Just rechecked echo and no improvement. Taurine levels pending and will echo other dog in household on same diet to screen.

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Stable

**Number of Animals Treated With Product:** 2

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

| <b>Product Name</b>                    | <b>Lot Number or ID</b> | <b>Best By Date</b> |
|--|-------------------------|---------------------|
| Taste of the Wild Pacific Stream (dry) |                         |                     |

**Sender information**

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

**Owner information**

**B6**  
USA

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

**B6**

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

**B6**

---

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**Report Details - EON-367849**

ICSR: 2055795  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2018-10-08 15:05:04 EDT

**Reported Problem:**  
**Problem Description:** DCM and CHF diagnosed 2/2/18. Owner did not change diet after diagnosis. Just rechecked echo and no improvement. Taurine levels pending and will echo other dog in household on same diet to screen.  
**Date Problem Started:** 02/02/2018  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** B6  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Taste of the Wild Pacific Stream (dry)  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Product Use Information:**  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Doberman Pinscher  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 26.8 Kilogram  
**Age:** B6 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Given the Product:** 2  
**Number of Animals Reacted:** 1  
**Owner Information:** Owner Information provided: Yes  
**Contact:** Name: B6  
 Phone: B6  
 Email: B6  
**Address:** B6  
 United States  
**Healthcare Professional Information:** Practice Name: Tufts Cummings School of Veterinary Medicine  
 Contact: Name: Lisa Freeman  
 Phone: (508) 887-4523

|                                     |                                      |   |   |  |
|-------------------------------------|--------------------------------------|---|---|--|
|                                     |                                      |   | <b>Email:</b> lisa.freeman@tufts.edu  |  |
|                                     |                                      | <b>Address:</b>   | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |  |
| <b>Sender Information:</b>          | <b>Name:</b>                         | Lisa Freeman  |   |  |
|                                     | <b>Address:</b>                      | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |   |  |
|                                     | <b>Contact:</b>                      | <b>Phone:</b>   | 5088874523  |  |
|                                     |                                      | <b>Email:</b>   | lisa.freeman@tufts.edu  |  |
|                                     | <b>Permission To Contact Sender:</b> | Yes   |   |  |
| <b>Preferred Method Of Contact:</b> | Email                                |   |   |  |
| <b>Additional Documents:</b>        | <b>Attachment:</b>                   | B6 compiled records smaller.pdf   |   |  |
|                                     | <b>Description:</b>                  | B6 compiled records   |   |  |
|                                     | <b>Type:</b>                         | Medical Records   |   |  |

---

**From:** Freeman, Lisa <Lisa.Freeman@tufts.edu>  
**To:** Jones, Jennifer L  
**Sent:** 10/11/2018 9:32:04 PM  
**Subject:** B6 Taurine result  
**Attachments:** T\_22910.jpg

Lisa M. Freeman, DVM, PhD, DACVN  
Board Certified Veterinary Nutritionist™  
Professor  
Cummings School of Veterinary Medicine  
Friedman School of Nutrition Science and Policy  
Tufts Clinical and Translational Science Institute  
Tufts University  
[www.petfoodology.org](http://www.petfoodology.org)

**From:** Tufts Veterinary Cardiology Service  
**Sent:** Thursday, October 11, 2018 4:57 PM  
**To:** Freeman, Lisa <lisa.freeman@tufts.edu>  
**Cc:** B6  
**Subject:** FW: Taurine result

**Veterinary Cardiology Service**  
**Tufts University Cummings School of Veterinary Medicine**

**Please note:** This account is not monitored on weekends, holidays, or evenings (after 5pm). Please allow 24 - 48 business hours for a reply. For immediate service during business hours, please call the liaison office at 508-887-4696. If you need to speak with the Emergency Service, please call 508-839-5395.

Foster Hospital for Small Animals  
200 Westboro Road  
North Grafton, MA 01536  
<http://www.tufts.edu/vet/>  
508.887.4696 phone  
508.887.4363 fax

**From:** Amino Acid Lab <[ucd.aminoacid.lab@ucdavis.edu](mailto:ucd.aminoacid.lab@ucdavis.edu)>  
**Sent:** Thursday, October 11, 2018 4:55 PM  
**To:** Clinical Pathology Lab <[clinpath@tufts.edu](mailto:clinpath@tufts.edu)>; Tufts Veterinary Cardiology Service <[cardiovet@tufts.edu](mailto:cardiovet@tufts.edu)>  
**Subject:** Taurine result

Hello -

Thank you for using the Amino Acid Laboratory at UC Davis, School of Veterinary Medicine.

Please find attached the results for your patient. You will note that we are now using a new submission form. The new form requests some additional information that may be useful in interpreting your results. Please note, with the recent increase in the number of dogs screened for taurine deficiency, we are seeing some dogs with values within the lower reference ranges (or above the “no known risk for deficiency range”) yet are still exhibiting changes in cardiac function.

In addition to our new submission form, we have also attached 2 handouts developed by our cardiology service at UC Davis for your information. The first is a general handout on dilated cardiomyopathy in dogs. The second is a handout specifically focused on Golden Retrievers, a breed that has been over-represented in the association between grain-free diet consumption and dilated cardiomyopathy.

We hope your clinic finds this information helpful. Veterinarians are always welcome to contact our laboratory for assistance in evaluating your patient’s results.

Thank you -

The Amino Acid Laboratory  
Department of Molecular Biosciences  
School of Veterinary Medicine  
University of California, Davis

Phone: 530-752-5058

Email: [ucd.aminoacid.lab@ucdavis.edu](mailto:ucd.aminoacid.lab@ucdavis.edu)

# 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)

# B4

# B4

**B4**



**B4**

**B4**

**B4**

# Assessment of protein and amino acid concentrations and labeling adequacy of commercial vegetarian diets formulated for dogs and cats

Kayo Kanakubo, BVSc; Andrea J. Fascetti, VMD, PhD; Jennifer A. Larsen, DVM, PhD

**Objective**—To determine measured crude protein (CP) and amino acid (AA) concentrations and assess labeling adequacy of vegetarian diets formulated for dogs and cats.

**Design**—Cross-sectional study.

**Sample**—13 dry and 11 canned vegetarian diets for dogs and cats.

**Procedures**—Concentrations of CP and AAs were determined for each diet. Values were compared with the Association of American Feed Control Officials (AAFCO) Dog and Cat Food Nutrient Profiles. Product labels were assessed for compliance with AAFCO regulations.

**Results**—CP concentration (dry-matter basis) ranged from 19.2% to 40.3% (median, 29.8%). Minimum CP concentrations for the specified species and life stage were met by 23 diets; the remaining diet passed appropriate AAFCO feeding trials. Six diets did not meet all AA minimums, compared with the AAFCO nutrient profiles. Of these 6 diets, 1 was below AAFCO minimum requirements in 4 AAs (leucine, methionine, methionine-cystine, and taurine), 2 were below in 3 AAs (methionine, methionine-cystine, and taurine), 2 were below in 2 AAs (lysine and tryptophan), and 1 was below in 1 AA (tryptophan). Only 3 and 8 diets (with and without a statement of calorie content as a requirement, respectively) were compliant with all pet food label regulations established by the AAFCO.

**Conclusion and Clinical Relevance**—Most diets assessed in this study were not compliant with AAFCO labeling regulations, and there were concerns regarding adequacy of AA content. Manufacturers should ensure regulatory compliance and nutritional adequacy of all diets, and pets fed commercially available vegetarian diets should be monitored and assessed routinely. (*J Am Vet Med Assoc* 2015;247:385–392)

# B4

**B4**

**B4**

**B4**

**B4**



**B4**

**B4**

# B4

From this month's *AJVR*

## Electrocardiogram reference intervals for clinically normal wild-born chimpanzees (*Pan troglodytes*)

Rebeca Atencia et al

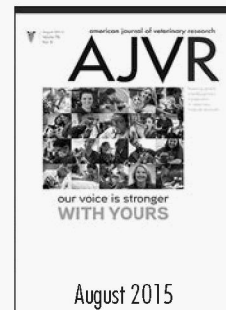
**Objective**—To generate reference intervals for ECG variables in clinically normal chimpanzees (*Pan troglodytes*).

**Animals**—100 clinically normal (51 young [ $< 10$  years old] and 49 adult [ $\geq 10$  years old]) wild-born chimpanzees.

**Procedures**—Electrocardiograms collected between 2009 and 2013 at the Tchimpounga Chimpanzee Rehabilitation Centre were assessed to determine heart rate, PR interval, QRS duration, QT interval, QRS axis, P axis, and T axis. Electrocardiographic characteristics for left ventricular hypertrophy (LVH) and morphology of the ST segment, T wave, and QRS complex were identified. Reference intervals for young and old animals were calculated as mean  $\pm$  1.96•SD for normally distributed data and as 5th to 95th percentiles for data not normally distributed. Differences between age groups were assessed by use of unpaired Student *t* tests.

**Results**—Reference intervals were generated for young and adult wild-born chimpanzees. Most animals had sinus rhythm with small or normal P wave morphology; 24 of 51 (47%) young chimpanzees and 30 of 49 (61%) adult chimpanzees had evidence of LVH as determined on the basis of criteria for humans.

**Conclusions and Clinical Relevance**—Cardiac disease has been implicated as the major cause of death in captive chimpanzees. Species-specific ECG reference intervals for chimpanzees may aid in the diagnosis and treatment of animals with, or at risk of developing, heart disease. Chimpanzees with ECG characteristics outside of these intervals should be considered for follow-up assessment and regular cardiac monitoring. (*Am J Vet Res* 2015;76:688–693)



See the midmonth issues  
of *JAVMA*  
for the expanded  
table of contents  
for the *AJVR*  
or log on to  
[avmajournals.avma.org](http://avmajournals.avma.org)  
for access  
to all the abstracts.

See discussions, stats, and author profiles for this publication at: <https://www.researchgate.net/publication/6712303>

# Taurine and Carnitine in Canine Cardiomyopathy

Article in *Veterinary Clinics of North America Small Animal Practice* · December 2006

DOI: 10.1016/j.cvsm.2006.08.010 · Source: PubMed

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**1 author:**



Sherry L Sanderson

University of Georgia

26 PUBLICATIONS 309 CITATIONS

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All content following this page was uploaded by Sherry L Sanderson on 22 August 2017.

The user has requested enhancement of the downloaded file.

## 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

**D**ilated 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.

With advancements in echocardiology, diagnostic capabilities in canine cardiology have improved dramatically over the past 2 decades. Therapeutic advances have made surprisingly little progress. Symptomatic treatment is the standard care and outcome remains poor.

Recently, more promising therapies for dogs with DCM have resulted from a clearer understanding of the importance of biochemistry and nutrition in managing this disease. Nutrition is now widely accepted as an important adjunct to medical therapy in dogs with DCM.

*E-mail address:* sanderso@vet.uga.edu

**B4**

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**B4**

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**B4**

**B4**

**B4**

**B4**

**B4**

**B4**

**B4**

**From:** PFR Event <pfpreventcreation@fda.hhs.gov>  
**To:** Cleary, Michael \*; HQ Pet Food Report Notification; [B6]  
**Sent:** 1/22/2018 11:28:12 PM  
**Subject:** California Natural Grain-Free Kangaroo and Red Lentils Recipe; [B6]  
- EON-345833  
**Attachments:** 2040529-report.pdf; 2040529-attachments.zip

A PFR Report has been received and PFR Event [EON-345833] has been created in the EON System.

A "PDF" report by name "2040529-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2040529-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-345833

**ICSR #:** 2040529

**EON Title:** PFR Event created for California Natural Grain-Free Kangaroo and Red Lentils Recipe; 2040529

|                          |                      |                           |                 |
|--------------------------|----------------------|---------------------------|-----------------|
| <b>AE Date</b>           | 08/18/2017           | <b>Number Fed/Exposed</b> | 4               |
| <b>Best By Date</b>      |                      | <b>Number Reacted</b>     | 4               |
| <b>Animal Species</b>    | Dog                  | <b>Outcome to Date</b>    | Died Euthanized |
| <b>Breed</b>             | Retriever - Labrador |                           |                 |
| <b>Age</b>               | 5 Years              |                           |                 |
| <b>District Involved</b> | PFR [B6] DO          |                           |                 |

**Product information**

**Individual Case Safety Report Number:** 2040529

**Product Group:** Pet Food

**Product Name:** California Natural Grain-Free Kangaroo and Red Lentils Recipe

**Description:** [B6] had been diagnosed with a new heart murmur a couple of months earlier, then developed difficulty breathing and cough and was diagnosed with congestive heart failure. Echocardiogram showed evidence of dilated cardiomyopathy and chronic degenerative valve disease. [B6] is the biologic niece of

[B4] - FDA ICSR ID 2040528

**Submission Type:** Initial



**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Died Euthanized

**Number of Animals Treated With Product:** 4

**Number of Animals Reacted With Product:** 4

| Product Name  | Lot Number or ID | Best By Date |
|---|------------------|--------------|
| California Natural Grain-Free Kangaroo and Red Lentils Recipe |                  |              |

**Sender information**

**B6**

USA

**Owner information**

**B6**

USA

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

**B6**

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

**B6**

**B6**

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

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

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to [FDAREportableFoods@fda.hhs.gov](mailto:FDAREportableFoods@fda.hhs.gov) immediately.

**Report Details - EON-345833**

ICSR: 2040529  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2018-01-22 18:21:03 EST

**Reported Problem:**  
**Problem Description:** B6 had been diagnosed with a new heart murmur a couple of months earlier, then developed difficulty breathing and cough and was diagnosed with congestive heart failure. Echocardiogram showed evidence of dilated cardiomyopathy and chronic degenerative valve disease. B6 is the biologic niece of B6. FDA ICSR ID 2040528  
**Date Problem Started:** 08/18/2017  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** B6  
**Outcome to Date:** Died Euthanized  
**Date of Death:** B6

**Product Information:**  
**Product Name:** California Natural Grain-Free Kangaroo and Red Lentils Recipe  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Possess Unopened Product:** No  
**Possess Opened Product:** No  
**Product Use Information:**  
**Description:** B6 had been fed this product for years for management of food allergy.  
**Last Exposure Date:** 08/24/2017  
**Product Use Stopped After the Onset of the Adverse Event:** Yes  
**Adverse Event Abate After Product Stop:** No  
**Product Use Started Again:** No  
**Perceived Relatedness to Adverse Event:** Probably related  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Retriever - Labrador  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 25.6 Kilogram  
**Age:** 5 Years

|                                    |   |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|------------------------------------|---|---|------------------------------------|-----------|---------------------|---------------|-----------|---------------|---------------------|---------------|-----------------|-----------|---------------|
|                                    | <b>Assessment of Prior Health:</b>          | Excellent   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Number of Animals Given the Product:</b> | 4   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Number of Animals Reacted:</b>           | 4   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Owner Information:</b>                   | <table border="1"> <tr> <td><b>Owner Information provided:</b></td> <td>Yes</td> </tr> <tr> <td rowspan="4"><b>Contact:</b></td> <td><b>Name:</b></td> <td rowspan="4"><b>B6</b></td> </tr> <tr> <td><b>Phone:</b></td> </tr> <tr> <td><b>Other Phone:</b></td> </tr> <tr> <td><b>Email:</b></td> </tr> <tr> <td rowspan="2"><b>Address:</b></td> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table> | <b>Owner Information provided:</b> | Yes       | <b>Contact:</b>     | <b>Name:</b>  | <b>B6</b> | <b>Phone:</b> | <b>Other Phone:</b> | <b>Email:</b> | <b>Address:</b> | <b>B6</b> | United States |
| <b>Owner Information provided:</b> | Yes   |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
| <b>Contact:</b>                    | <b>Name:</b>                                | <b>B6</b>   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Phone:</b>                               |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Other Phone:</b>                         |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Email:</b>                               |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
| <b>Address:</b>                    | <b>B6</b>                                   |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | United States                               |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Healthcare Professional Information:</b> | <table border="1"> <tr> <td><b>Practice Name:</b></td> <td><b>B6</b></td> </tr> <tr> <td rowspan="4"><b>Contact:</b></td> <td><b>Name:</b></td> <td rowspan="4"><b>B6</b></td> </tr> <tr> <td><b>Phone:</b></td> </tr> <tr> <td><b>Other Phone:</b></td> </tr> <tr> <td><b>Email:</b></td> </tr> <tr> <td rowspan="2"><b>Address:</b></td> <td><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>        | <b>Practice Name:</b>              | <b>B6</b> | <b>Contact:</b>     | <b>Name:</b>  | <b>B6</b> | <b>Phone:</b> | <b>Other Phone:</b> | <b>Email:</b> | <b>Address:</b> | <b>B6</b> | United States |
| <b>Practice Name:</b>              | <b>B6</b>                                   |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
| <b>Contact:</b>                    | <b>Name:</b>                                | <b>B6</b>   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Phone:</b>                               |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Other Phone:</b>                         |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Email:</b>                               |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
| <b>Address:</b>                    | <b>B6</b>                                   |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | United States                               |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
| <b>Sender Information:</b>         | <b>Name:</b>                                | <b>B6</b>   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Address:</b>                             | <b>B6</b>   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    |   | United States   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Contact:</b>                             | <table border="1"> <tr> <td><b>Phone:</b></td> <td rowspan="3"><b>B6</b></td> </tr> <tr> <td><b>Other Phone:</b></td> </tr> <tr> <td><b>Email:</b></td> </tr> </table>  | <b>Phone:</b>                      | <b>B6</b> | <b>Other Phone:</b> | <b>Email:</b> |           |               |                     |               |                 |           |               |
| <b>Phone:</b>                      | <b>B6</b>                                   |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
| <b>Other Phone:</b>                |   |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
| <b>Email:</b>                      |   |   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Permission To Contact Sender:</b>        | Yes   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Preferred Method Of Contact:</b>         | Phone   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Reported to Other Parties:</b>           | Other   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
| <b>Additional Documents:</b>       | <b>Attachment:</b>                          | cardio0010.pdf  |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Description:</b>                         | Initial echo report and emergency visit report at which time euthanasia was elected   |                                    |           |                     |               |           |               |                     |               |                 |           |               |
|                                    | <b>Type:</b>                                | Medical Records   |                                    |           |                     |               |           |               |                     |               |                 |           |               |

PL 21015

WB 21016

### Amino Acid Laboratory Sample Submission Form

Amino Acid Laboratory  
1089 Veterinary Medicine Drive  
Davis, Ca 95616

Telephone: 530-752-5058, Fax: 530-752-4698

Email: [ucd.aminoacid.lab@ucdavis.edu](mailto:ucd.aminoacid.lab@ucdavis.edu)

[www.vetmed.ucdavis.edu/labs/amino-acid-laboratory](http://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory)

Veterinarian Contact: **B6**

Clinic/Company Name: **B6**

Address: **B6**

Email: **B6**

Telephone: **B6** **52**

Billing Contact: **B6**

Email: **B6**

Patient Name: **B6**

Species: Canine

Breed: Goldendoodle

Owner's Name: **B6**

Current Diet : Zignature Kangaroo

Sample type: Plasma Whole Blood Urine Food Other

Test: Taurine Complete Amino Acids Other:

Taurine Results (lab use only)

Plasma: **B6** Whole Blood: **B6** Urine: Food:

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

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

| Report Details - EON-365610                |  |
|--|--|
| ICSR:                                      | 2054966  |
| Type Of Submission:                        | Initial  |
| Report Version:                            | FPSR.FDA.PETF.V.V1   |
| Type Of Report:                            | Adverse Event (a symptom, reaction or disease associated with the product)   |
| Reporting Type:                            | Voluntary  |
| Report Submission Date:                    | 2018-09-16 11:38:42 EDT  |
| Reported Problem:                          | <b>Problem Description:</b> DCM and CHF - had been having respiratory signs for ~1 month prior to diagnosis at Tufts Littermate is <b>B6</b> (already reported by owner after being diagnosed with DCM and CHF in July 2018) Owner has another Great Dane at home (~1 year of age) eating the same diet that will be screened soon Owner approved submission of this report and talking to FDA Will send rest of medical records by email (sorry - too many to upload) |
|  | <b>Date Problem Started:</b> 09/12/2018  |
|  | <b>Concurrent Medical Problem:</b> Yes   |
|  | <b>Pre Existing Conditions:</b> Dermatitis   |
|  | <b>Outcome to Date:</b> Stable   |
| Product Information:                       | <b>Product Name:</b> 4Health beef stew canned  |
|  | <b>Product Type:</b> Pet Food  |
|  | <b>Lot Number:</b>   |
|  | <b>Package Type:</b> CAN   |
|  | <b>Product Use Information:</b> <b>Description:</b> 2 tablespoons 3x/day since Jan, 2017   |
|  | <b>Manufacturer /Distributor Information:</b>  |
|  | <b>Purchase Location Information:</b>  |
|  | <b>Product Name:</b> Taste of the Wild Prey Beef dry (will provide full diet history)  |
|  | <b>Product Type:</b> Pet Food  |
|  | <b>Lot Number:</b>   |
|  | <b>Package Type:</b> BAG   |
|  | <b>Product Use Information:</b> <b>Description:</b> 9 cups/day   |
|  | <b>First Exposure Date:</b> 06/01/2018   |
|  | <b>Manufacturer /Distributor Information:</b>  |
| <b>Purchase Location Information:</b>      |  |
| Animal Information:                        | <b>Name:</b> <b>B6</b>   |
|  | <b>Type Of Species:</b> Dog  |
|  | <b>Type Of Breed:</b> Great Dane   |
|  | <b>Gender:</b> Male  |
|  | <b>Reproductive Status:</b> Neutered   |
|  | <b>Weight:</b> 69.5 Kilogram   |
|  | <b>Age:</b> <b>B6</b> Years  |
|  | <b>Assessment of Prior Health:</b> Excellent   |
|  | <b>Number of Animals Given the Product:</b> 2  |
|  | <b>Number of Animals Reacted:</b> 1  |
| <b>Owner Information:</b> <b>Owner</b> Yes |  |

|   |                                      |   |   |              |               |
|---|--------------------------------------|---|---|--------------|---------------|
|   |                                      | <b>Information provided:</b>  |   |              |               |
|   |                                      | <b>Contact:</b>   | <table border="1"> <tr> <td><b>Name:</b></td> <td rowspan="3" style="text-align: center; vertical-align: middle;"><b>B6</b></td> </tr> <tr> <td><b>Phone:</b></td> </tr> <tr> <td><b>Email:</b></td> </tr> </table> | <b>Name:</b> | <b>B6</b>     |
| <b>Name:</b>                                | <b>B6</b>                            |   |   |              |               |
| <b>Phone:</b>                               |                                      |   |   |              |               |
| <b>Email:</b>                               |                                      |   |   |              |               |
|   |                                      | <b>Address:</b>   | <table border="1"> <tr> <td style="text-align: center; vertical-align: middle;"><b>B6</b></td> </tr> <tr> <td>United States</td> </tr> </table>   | <b>B6</b>    | United States |
| <b>B6</b>                                   |                                      |   |   |              |               |
| United States                               |                                      |   |   |              |               |
| <b>Healthcare Professional Information:</b> | <b>Practice Name:</b>                | Tufts Cummings School of Veterinary Medicine                                |   |              |               |
|   | <b>Contact:</b>                      | <b>Name:</b>  | Lisa Freeman  |              |               |
|   |                                      | <b>Phone:</b>   | (508) 887-4523  |              |               |
|   |                                      | <b>Email:</b>   | lisa.freeman@tufts.edu  |              |               |
|   | <b>Address:</b>                      | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |   |              |               |
| <b>Sender Information:</b>                  | <b>Name:</b>                         | Lisa Freeman  |   |              |               |
|   | <b>Address:</b>                      | 200 Westboro Rd<br>North Grafton<br>Massachusetts<br>01536<br>United States |   |              |               |
|   | <b>Contact:</b>                      | <b>Phone:</b>   | 5088874523  |              |               |
|   |                                      | <b>Email:</b>   | lisa.freeman@tufts.edu  |              |               |
|   | <b>Permission To Contact Sender:</b> | Yes   |   |              |               |
| <b>Preferred Method Of Contact:</b>         | Email                                |   |   |              |               |
| <b>Additional Documents:</b>                | <b>Attachment:</b>                   | taurine.pdf   |   |              |               |
|   | <b>Description:</b>                  | Taurine results   |   |              |               |
|   | <b>Type:</b>                         | Laboratory Report   |   |              |               |

35 20658

**Sample Submission Form**

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

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

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

Vet/Tech Contact: **B6**  
 Company Name: \_\_\_\_\_

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

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

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

Patient Name: **B6**  
 Species: *Cat*  
 Owner's Name: **B6**

Sample Type:  Plasma  Whole Blood  Urine  Food  Other: \_\_\_\_\_  
 Test Items:  Taurine  Complete Amino Acid  Other: \_\_\_\_\_

Taurine Results (nmol/ml) **B6**  
 Plasma: \_\_\_\_\_ Whole Blood: \_\_\_\_\_ Urine: \_\_\_\_\_ Food: \_\_\_\_\_

**Reference Ranges (nmol/ml)**

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

**B6**



**B6**



# REPORT INFORMATION

## Report Profile

**Report Version** FPSR.FDA.PETF.V.V1

**Report Category** Pet Food Safety Report

**Submitted** 2018-09-16 11:38:42 EST

**FDA ICSR ID** 2054966

**Submitted by** lisa.freeman@tufts.edu

## Report Identifying Information

Enter a title to help you identify this report

**Regulatory Status** Voluntary

**Type of Submission** Initial

**What type of report are you submitting?** Adverse Event (a symptom, reaction or disease associated with the product)

# Contact Information - Reporter Sender

May the FDA contact you to follow-up, if necessary? Yes

Preferred method of contact: Email

Confirm Email lisa.freeman@tufts.edu

First Name Lisa

Last Name Freeman

Primary Phone 5088874523

Other Phone <blank>

Email lisa.freeman@tufts.edu

Country United States

Street Address Line 1 200 Westboro Rd

Street Address Line 2 <blank>

City/Town North Grafton

State Massachusetts

ZIP/Postal Code 01536

# Contact Information - Healthcare Professional

Veterinary Practice Name Tufts Cummings School of Veterinary Medicine

First Name Lisa

Last Name Freeman

Primary Phone (508) 887-4523

Email lisa.freeman@tufts.edu

Country United States

Street Address Line 1 200 Westboro Rd

City/Town North Grafton

State Massachusetts

ZIP/Postal Code 01536

# Contact Information - Animal Owner

First Name

Last Name

**B6**

Primary Phone  
Other Phone  
Email  
Country  
Street Address Line 1  
Street Address Line 2  
City/Town  
State  
ZIP/Postal Code

**B6**

Can you provide contact information for the animal owner? Yes

---

## Contact Information - Receiver

Indicate any other parties that you notified about this issue <blank>

---

## Relevant Details

Animal Name/Identifier **B6**

Number of animals given the product 2

Number of animals reacted 1

Species Dog

Breed Great Dane

Age **B6**

Select Unit of Measure Years

Weight 69.5

Select Unit of Measure Kilogram

Gender Male

Reproductive status Neutered

Was the animal pregnant at time of event? <blank>

Was the animal lactating at time of event? <blank>

Prior to the event, what was the animal's overall state of health? Excellent

---

## Problem Details

Did the animal have any health problems and/or was taking medication prior to the event? Yes

Please describe: **B6**

## Product Information

Full name of product as it appears on the package label Taste of the Wild Prey Beef dry (will provide full diet history)

Product Type Pet Food

UPC from label <blank>

Package Type BAG

Package Size <blank>

Select Unit of Measure <blank>

Last date of product purchase (estimate if necessary) <blank>

Number purchased on this date <blank>

Do you have a package/container of unopened product from this purchase? <blank>

Do you have a package/container of opened product from this purchase? <blank>

## Product Lots

## Product Use Details

Describe how the product was used or administered 9 cups/day

Date the product was first given to the animal 06/01/2018

Date last fed the animal product from this purchase: <blank>

Were there any other foods or products given to the animal during this time period? <blank>

Describe how the product was stored before and after opening <blank>

# Contact Information

---

## Relatedness Details

Amount of time from use of product to onset of the event: <blank>

Select Unit of Measure <blank>

Was product use stopped after the onset of the adverse event? <blank>

How strongly do you believe this product is related to the adverse event? <blank>

---

## Location Name and Address

Store/place of purchase <blank>

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

---

## Product Information

Full name of product as it appears on the package label 4Health beef stew canned

Product Type Pet Food

UPC from label <blank>

Package Type CAN

Package Size <blank>

Select Unit of Measure <blank>

Last date of product purchase (estimate if necessary) <blank>

Number purchased on this date <blank>

Do you have a package/container of unopened product from this purchase? <blank>

Do you have a package/container of opened product from this purchase? <blank>

---

# Product Lots

---

## Product Use Details

Describe how the product was used or administered 2 tablespoons 3x/day since Jan, 2017

Date the product was first given to the animal <blank>

Date last fed the animal product from this purchase: <blank>

Were there any other foods or products given to the animal during this time period? <blank>

Describe how the product was stored before and after opening <blank>

---

## Contact Information

---

## Relatedness Details

Amount of time from use of product to onset of the event: <blank>

Select Unit of Measure <blank>

Was product use stopped after the onset of the adverse event? <blank>

How strongly do you believe this product is related to the adverse event? <blank>

---

## Location Name and Address

Store/place of purchase <blank>

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

---

## Description and Details

Date problem started 09/12/2018

Date of recovery <blank>

**Describe what happened**

DCM and CHF - had been having respiratory signs for ~1 month prior to diagnosis at Tufts Littermate is **B6** (already reported by owner after being diagnosed with DCM and CHF in July 2018) Owner has another Great Dane at home (~1 year of age) eating the same diet that will be screened soon Owner approved submission of this report and talking to FDA Will send rest of medical records by email (sorry - too many to upload)

Was a veterinarian consulted? <blank>

Outcome to date Stable

---

## Attached Files

FILENAME taurine.pdf

Description of Attachment Taurine results

Attachment Type Laboratory Report



**B6**

**B6**

**B6**

**B6**

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

Patient: **B6**  
 Species: Canine  
 Breed: Great Dane  
 Sex: Male (Neutered)  
 Age: **B6** Years Old

**Lab Results Report**

| Chemistry 21 (Cobas)    |           | 9/13/2018 11:43:20 AM | Accession ID: <b>B6</b> |
|-------------------------|-----------|-----------------------|-------------------------|
| Test                    | Results   | Reference Range       | Units                   |
| GLUCOSE                 | <b>B6</b> | 67 - 135              | mg/dL                   |
| UREA                    |           | 8 - 30                | mg/dL                   |
| CREATININE              |           | 0.6 - 2               | mg/dL                   |
| PHOSPHORUS              |           | 2.6 - 7.2             | mg/dL                   |
| CALCIUM2                |           | 9.4 - 11.3            | mg/dL                   |
| T. PROTEIN              |           | 5.5 - 7.8             | g/dL                    |
| ALBUMIN                 |           | 2.8 - 4               | g/dL                    |
| GLOBULINS               |           | 2.3 - 4.2             | g/dL                    |
| A/G RATIO               |           | 0.7 - 1.6             |                         |
| SODIUM                  |           | 140 - 150             | mEq/L                   |
| CHLORIDE                |           | 106 - 116             | mEq/L                   |
| POTASSIUM               |           | 3.7 - 5.4             | mEq/L                   |
| NA/K                    |           | 29 - 40               |                         |
| T BILIRUBIN             |           | 0.1 - 0.3             | mg/dL                   |
| D.BILIRUBIN             |           | 0 - 0.1               | mg/dL                   |
| I BILIRUBIN             |           | 0 - 0.2               | mg/dL                   |
| ALK PHOS                |           | 12 - 127              | U/L                     |
| ALT                     |           | 14 - 86               | U/L                     |
| AST                     |           | 9 - 54                | U/L                     |
| CHOLESTEROL             |           | 82 - 355              | mg/dL                   |
| OSMOLALITY (CALCULATED) | 291 - 315 | mmol/L                |                         |

Client:  
 Veterinarian:  
 Patient ID:  
 Visit ID:

**B6**

Patient: **B6**  
 Species: Canine  
 Breed: Great Dane  
 Sex: Male (Neutered)  
 Age: **B6** Years Old

**Lab Results Report**

| Chemistry 21 (Cobas)    |           | 9/14/2018 12:28:20 PM | Accession ID: <b>B6</b> |
|-------------------------|-----------|-----------------------|-------------------------|
| Test                    | Results   | Reference Range       | Units                   |
| GLUCOSE                 | <b>B6</b> | 67 - 135              | mg/dL                   |
| UREA                    |           | 8 - 30                | mg/dL                   |
| CREATININE              |           | 0.6 - 2               | mg/dL                   |
| PHOSPHORUS              |           | 2.6 - 7.2             | mg/dL                   |
| CALCIUM2                |           | 9.4 - 11.3            | mg/dL                   |
| T. PROTEIN              |           | 5.5 - 7.8             | g/dL                    |
| ALBUMIN                 |           | 2.8 - 4               | g/dL                    |
| GLOBULINS               |           | 2.3 - 4.2             | g/dL                    |
| A/G RATIO               |           | 0.7 - 1.6             |                         |
| SODIUM                  |           | 140 - 150             | mEq/L                   |
| CHLORIDE                |           | 106 - 116             | mEq/L                   |
| POTASSIUM               |           | 3.7 - 5.4             | mEq/L                   |
| NA/K                    |           | 29 - 40               |                         |
| T BILIRUBIN             |           | 0.1 - 0.3             | mg/dL                   |
| D.BILIRUBIN             |           | 0 - 0.1               | mg/dL                   |
| I BILIRUBIN             |           | 0 - 0.2               | mg/dL                   |
| ALK PHOS                |           | 12 - 127              | U/L                     |
| ALT                     |           | 14 - 86               | U/L                     |
| AST                     |           | 9 - 54                | U/L                     |
| CHOLESTEROL             |           | 82 - 355              | mg/dL                   |
| OSMOLALITY (CALCULATED) | 291 - 315 | mmol/L                |                         |

Date Performed: 09/11/2018 09:48 PM

Patient Info:  
 ID: B6  
 Name: B6  
 Owner: B6  
 Provider: 26

Species: Canine  
 Breed: Great Dane  
 Birthdate: B6  
 Sex: MN

Clinic:  
**B6**

IVLS-20180911\_213512\_74864.pdf

|          |                      |
|----------|----------------------|
| GLU      | 74-143 mg/dL         |
| CREA     | 0.5-1.8 mg/dL        |
| BUN      | 7-27 mg/dL           |
| BUN/CREA |                      |
| PHOS     | 2.5-6.8 mg/dL        |
| CA       | 7.9-12.0 mg/dL       |
| TP       | 5.2-8.2 g/dL         |
| ALB      | 2.3-4.0 g/dL         |
| GLOB     | 2.5-4.5 g/dL         |
| ALB/GLOB |                      |
| ALT      | 10-125 U/L           |
| ALKP     | 23-212 U/L           |
| GGT      | 0-11 U/L             |
| TBIL     | 0.0-0.9 mg/dL        |
| CHOL     | 110-320 mg/dL        |
| AMYL     | 500-1500 U/L         |
| LIPA     | 200-1800 U/L         |
| Na       | 144-160 mmol/L       |
| K        | 3.5-5.8 mmol/L       |
| Na/K     |                      |
| Cl       | 109-122 mmol/L       |
| Osm Calc | m                    |
| RBC      | 5.65-8.87 M/ $\mu$ L |
| HCT      | 37.3-61.7%           |
| HGB      | 13.1-20.5 g/dL       |

B6

**B6**

|           |                      |
|-----------|----------------------|
| MCV       | 61.6-73.5fL          |
| MCH       | 21.2-25.9pg          |
| MCHC      | 32.0-37.9g/dL        |
| RDW       | 13.6-21.7%           |
| %RETIC    | %                    |
| RETIC     | 10.0-110.0K/ $\mu$ L |
| RETIC-HGB | 22.3-29.6pg          |
| WBC       | 5.05-16.76K/ $\mu$ L |
| %NEU      | %                    |
| %LYM      | %                    |
| %MONO     | %                    |
| %EOS      | %                    |
| %BASO     | %                    |
| NEU       | 2.95-11.64K/ $\mu$ L |
| LYM       | 1.05-5.10K/ $\mu$ L  |
| MONO      | 0.16-1.12K/ $\mu$ L  |
| EOS       | 0.06-1.23K/ $\mu$ L  |
| BASO      | 0.00-0.10K/ $\mu$ L  |
| nRBC      |                      |
| PLT       | 148-484K/ $\mu$ L    |
| MPV       | 8.7-13.2fL           |
| PDW       | 9.1-19.4fL           |
| PCT       | 0.14-0.46%           |

**B6**

**B6**



**B6**

**B6**

**B6**

**B6**

Acc: **B6**

**B6**

Tx's checked by \_\_\_\_\_

IVF Rate checked by \_\_\_\_\_

TREATMENT SHEET

Patient: **B6**  
 Species: Canine  
 Breed: Great Dane  
 Color: Black  
 Rabies Due:

Sex: MN  
 DoB: **B6**

*2 leashes & collar on cage*

IVF: Type \_\_\_\_\_ Rate \_\_\_\_\_  
 (Maintenance Rate = \_\_\_\_\_ mL/hr)

Dr: **B6** Date: **B6**

Alerts: *Dog Aggressive per O*

Tech: **B6** Ward: *SOR 1*

Problem/DDx: *CHF, Arrhythmia*

Admit Date: **B6**

*(IVC)*

IV CATHETER

Diet: *bland*

Date \_\_\_\_\_ Gage \_\_\_\_\_ Site \_\_\_\_\_ Set by \_\_\_\_\_

Weight: *166.5* lbs \_\_\_\_\_ kg

Date \_\_\_\_\_ Gage \_\_\_\_\_ Site \_\_\_\_\_ Set by \_\_\_\_\_

| Treatment | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|-----------|---|---|---|---|---|---|---|---|---|----|----|----|---|---|---|---|---|---|---|---|---|----|----|----|
|           | A | A | A | A | A | A | A | A | A | A  | A  | P  | P | P | P | P | P | P | P | P | P | P  | P  | P  |

**B6**

NURSING NOTES ON OTHER SIDE OF TREATMENT SHEET!

CHANGES FOR FOLLOWING DAY

Oxygen Time  
 Date IN \_\_\_\_\_ Time IN \_\_\_\_\_  
 Date Out \_\_\_\_\_ Time Out \_\_\_\_\_  
Room Air (20.5% - 22.5%)  
 Date IN \_\_\_\_\_ Time Out \_\_\_\_\_  
Oxygen Settings  
 Hi \_\_\_\_\_ Low \_\_\_\_\_  
 Air temp \_\_\_\_\_ Floor heat: ON / OFF  
 Written By: \_\_\_\_\_

**B6**

Acc: **B6**

**B6**

TREATMENT SHEET

Tx's checked by \_\_\_\_\_

IVF Rate checked by \_\_\_\_\_

Patient: **B6**  
 Species: Canine  
 Breed: Great Dane  
 Color: Black  
 Rabies Due:

Sex: MN  
 DoB: **B6**

IVF: Type \_\_\_\_\_ Rate \_\_\_\_\_  
 (Maintenance Rate = \_\_\_\_\_ mL/hr)

Dr: **B6** Date: **B6**

Alerts: Dog Aggressive  
 Problem/DDx: CHF, Arrhythmia

Tech: \_\_\_\_\_ Ward: \_\_\_\_\_

Admit Date \_\_\_\_\_

Weight: 166.5 lbs \_\_\_\_\_ kg

Diet: \_\_\_\_\_

IV CATHETER

Date: **B6** Gage: 18 Site: cep Set by: **B6**

Date \_\_\_\_\_ Gage \_\_\_\_\_ Site \_\_\_\_\_ Set by \_\_\_\_\_

| Treatment | 1 | 2 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|-----------|---|---|---|---|---|---|---|---|---|---|---|----|----|----|---|---|---|---|---|---|---|---|---|----|----|----|
|           | A | A | A | A | A | A | A | A | A | A | A | A  | A  | P  | P | P | P | P | P | P | P | P | P | P  | P  | P  |
| Food      |   |   |   |   |   |   |   |   |   |   |   |    |    |    |   |   |   |   |   |   |   |   |   |    |    |    |
| Water     |   |   |   |   |   |   |   |   |   |   |   |    |    |    |   |   |   |   |   |   |   |   |   |    |    |    |
| Stool     |   |   |   |   |   |   |   |   |   |   |   |    |    |    |   |   |   |   |   |   |   |   |   |    |    |    |
| Urine     |   |   |   |   |   |   |   |   |   |   |   |    |    |    |   |   |   |   |   |   |   |   |   |    |    |    |

**B6**

NURSING NOTES ON OTHER SIDE OF TREATMENT SHEET!

CHANGES FOR FOLLOWING DAY

Oxygen Time

Date IN \_\_\_\_\_ Time IN \_\_\_\_\_

Date Out \_\_\_\_\_ Time Out \_\_\_\_\_

Room Air (20.5% - 22.5%)

Date IN \_\_\_\_\_ Time Out \_\_\_\_\_

Oxygen Settings

Hi \_\_\_\_\_ Low \_\_\_\_\_  
 Air temp \_\_\_\_\_ Floor heat: ON / OFF

Written By: \_\_\_\_\_

**B6**

**B6**

**B6**



**B6**

35 **B6**

**Sample Submission Form**

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

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

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

Vet/Tech Contact: **B6**  
 Company Name: \_\_\_\_\_  
 Address: **B6**  
 \_\_\_\_\_  
**B6**  
 Email: **B6**  
 Tel: **B6** Fax: **B6**  
 Billing Contact: **B6** TAX ID: \_\_\_\_\_  
 Email: **B6** Tel: **B6**  
 Patient Name: **B6**  
 Species: *Cat, Jane*  
 Owner's Name: **B6**

Sample Type:  Plasma  Whole Blood  Urine  Food  Other: \_\_\_\_\_  
 Test Items:  Taurine  Complete Amino Acid  Other: \_\_\_\_\_

Taurine Results (nmol/ml) **B6**  
 Plasma: \_\_\_\_\_ Whole Blood: \_\_\_\_\_ Urine: \_\_\_\_\_ Food: \_\_\_\_\_

**Reference Ranges (nmol/ml)**

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

**CARDIOLOGY DIET HISTORY FORM**

Please answer the following questions about your pet

Pet's name:

**B6**

Owner's name:

**B6**

Today's date:

9/12/18

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)

Example: Poor \_\_\_\_\_ | \_\_\_\_\_ Excellent  
 Poor \_\_\_\_\_ | \_\_\_\_\_ Excellent

2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)  
 Eats about the same amount as usual     Eats less than usual     Eats more than usual  
 Seems to prefer different foods than usual     Other \_\_\_\_\_

3. Over the last few weeks, has your pet (check one)  
 Lost weight     Gained weight     Stayed about the same weight     Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

**Food (include specific product and flavor)      Form      Amount      How often?      Fed since**  
 Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

| Food (include specific product and flavor)             | Form       | Amount        | How often?      | Fed since  |
|--|------------|---------------|-----------------|------------|
| Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult | dry        | 1 1/2 cup     | 2x/day          | Jan 2018   |
| 85% lean hamburger                                     | microwaved | 3 oz          | 1x/week         | Jan 2015   |
| Pupperoni original beef flavor                         | treat      | 1/2           | 1x/day          | Aug 2015   |
| Rawhide  | treat      | 6 inch twist  | 1x/week         | Dec 2015   |
| Taste of the Wild Pacific Stream puppy                 | dry        | 12 cups       | 3 times         | April 2016 |
| 4 Health Beef + Stew                                   | wet        | 2 tablespoons | 3 times         | Jan 2017   |
| Taste of Wild Prey Beef                                | dry        | 9 cups        | 3 times         | June 2017  |
| Purina Pro Plan Senior Sensitive Skin                  | dry        | 8-10 cups     | 3 times         | Aug 2018   |
| Freeze dried liver treats                              | treat      | 4-5 pieces    | 1 once<br>9 day | June 2018  |

\*Any additional diet information can be listed on the back of this sheet

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Yes  No If yes, please list which ones and give brands and amounts:

|  | Brand/Concentration | Amount per day             |
|--|---------------------|----------------------------|
| Taurine <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No      | _____               | _____                      |
| Carnitine <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No    | _____               | _____                      |
| Antioxidants <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | _____               | _____                      |
| Multivitamin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | _____               | _____                      |
| Fish oil <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No     | _____               | _____                      |
| Coenzyme Q10 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | _____               | _____                      |
| Other (please list):<br>Example: Vitamin C                                       | Nature's Bounty     | 500 mg tablets – 1 per day |
| _____  | _____               | _____                      |
| _____  | _____               | _____                      |
| _____  | _____               | _____                      |
| _____  | _____               | _____                      |

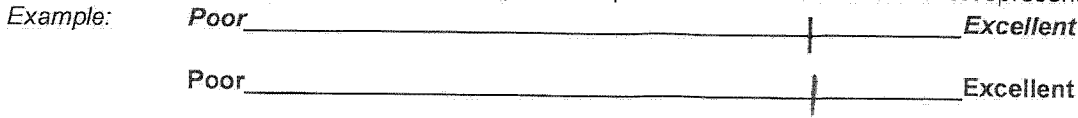
6. How do you administer pills to your pet?  
 I do not give any medications  
 I put them directly in my pet's mouth without food  
 I put them in my pet's dog/cat food  
 I put them in a Pill Pocket or similar product  
 I put them in foods (list foods): \_\_\_\_\_

**CARDIOLOGY DIET HISTORY FORM**

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Today's date: 9/12/18

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)



2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

Eats about the same amount as usual     Eats less than usual     Eats more than usual

Seems to prefer different foods than usual     Other \_\_\_\_\_

3. Over the last few weeks, has your pet (check one)

Lost weight     Gained weight     Stayed about the same weight     Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you pet is eating.

**Food (include specific product and flavor)      Form      Amount      How often?      Fed since**  
 Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

| Food (include specific product and flavor)             | Form       | Amount        | How often?      | Fed since  |
|--|------------|---------------|-----------------|------------|
| Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult | dry        | 1 1/2 cup     | 2x/day          | Jan 2018   |
| 85% lean hamburger                                     | microwaved | 3 oz          | 1x/week         | Jan 2015   |
| Pupperoni original beef flavor                         | treat      | 1/2           | 1x/day          | Aug 2015   |
| Rawhide  | treat      | 6 inch twist  | 1x/week         | Dec 2015   |
| Taste of the Wild Pacific Stream puppy                 | dry        | 12 cups       | 3 times         | April 2016 |
| 4 Health Beef + Stew                                   | wet        | 2 tablespoons | 3 times         | Jan 2017   |
| Taste of Wild Prey Beef                                | dry        | 9 cups        | 3 times         | June 2017  |
| Purina Pro Plan Senior Sensitive Skin                  | dry        | 8-10 cups     | 3 times         | Aug 2018   |
| Freeze dried liver treats                              | treat      | 4-5 pieces    | 1 once<br>a day | June 2018  |

\*Any additional diet information can be listed on the back of this sheet

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Yes  No If yes, please list which ones and give brands and amounts:

|  | Brand/Concentration | Amount per day             |
|--|---------------------|----------------------------|
| Taurine <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No      | _____               | _____                      |
| Carnitine <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No    | _____               | _____                      |
| Antioxidants <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | _____               | _____                      |
| Multivitamin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | _____               | _____                      |
| Fish oil <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No     | _____               | _____                      |
| Coenzyme Q10 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | _____               | _____                      |
| Other (please list):<br>Example: Vitamin C                                       | Nature's Bounty     | 500 mg tablets – 1 per day |
| _____  | _____               | _____                      |
| _____  | _____               | _____                      |
| _____  | _____               | _____                      |
| _____  | _____               | _____                      |

6. How do you administer pills to your pet?

I do not give any medications

I put them directly in my pet's mouth without food

I put them in my pet's dog/cat food

I put them in a Pill Pocket or similar product

I put them in foods (list foods): \_\_\_\_\_

### Discharge Instructions

**Patient**

Name: B6

Species: Canine

Black Male (Neutered) Great Dane

Birthdate: B6

**Owner**

Name: B6

Address: B6

Patient ID: B6

**Attending Cardiologist:**

John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

**Cardiology Resident:**

B6

**Cardiology Technician:**

B6

Student: B6, V19

Admit Date: 9/12/2018 11:24:19 AM

Discharge Date: 9/14/2018

**Diagnoses:**

Dilated cardiomyopathy (DCM) with congestive heart failure.

Atrial fibrillation with ventricular arrhythmia

**Case summary:**

Thank you for bringing B6 to Tufts for treatment of his heart disease. B6 has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. B6 has two abnormal heart rhythms right now that he is receiving medication for- atrial fibrillation and ventricular arrhythmias. The heart enlargement has now progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs or belly. Unfortunately this is a progressive disease and we cannot reverse the changes to the heart muscle, however we can use cardiac medications and some changes to the diet to make your dog comfortable and have him breathing easier.

**Diagnostic test results and findings:**

**Echocardiogram findings:** All chambers of the heart are enlarged. There is severe dysfunction of the heart's ability to contract. The mitral valve leaflets are not closing together well due to the dilation of the heart (they are being pulled apart as the heart increases in size). Moderate amount of pleural effusion (fluid around the lungs) and ascites (fluid in the abdomen).

**ECG findings:** The ECG showed atrial fibrillation with occasional ventricular arrhythmia. Atrial fibrillation is an abnormal heart rhythm. Once dogs develop atrial fibrillation it is extremely rare for them to regain their normal

heart rhythm. Our main goal now is to decrease the heart rate as much as possible since right now his heart rate is too high. The ventricular arrhythmia that he is having is malignant, meaning it can potentially lead to collapsing episodes and unfortunately even death. The amiodarone medication he is on will hopefully further control this ventricular rhythm as it further saturates the heart tissue as we keep dosing it. Labwork findings: His kidneys are tolerating the medications well right now. We will want to recheck these values soon.

#### Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- **An increase in breathing rate or effort will usually mean that you should give an extra dose** . If difficulty breathing is not improved by within 30-60 minutes after giving extra  then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

#### Recommended Medications:

**B6**

#### Diet suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (<http://vet.tufts.edu/heartsmart/diet/>)

Your dog's usual diet may also have more sodium than recommended - we want him/her to continue to eat his/her normal diet for the first 7 to 14 days so we can make sure he is tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50:50, etc.). We also want [ B6 ] to eat a main stream, non grain-free diet from now on.

**Exercise Recommendations:**

For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that [ B6 ] is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

**Recheck Visits:**

A recheck visit is recommended in 1-2 weeks after any medication adjustments are made. At this visit we will check your dog's breathing effort and heart function, check his ECG, and check for fluid around the lungs and in the belly. Please call or email to schedule this appointment with us. A recheck echocardiogram is recommended in 3-4 months.

Thank you for entrusting us with [ B6 ] care. He is such a sweet boy! Please contact our Cardiology liaison at (508)-887-4696 or email us at [cardiovet@tufts.edu](mailto:cardiovet@tufts.edu) for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information  
<http://vet.tufts.edu/heartsmart/>

---

**Prescription Refill Disclaimer:**

*For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.*

**Ordering Food:**

*Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.*

**Clinical Trials:**

*Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: [vet.tufts.edu/cvmc/clinical-studies](http://vet.tufts.edu/cvmc/clinical-studies)*

---

Case: [ B6 ]

Owner: [ B6 ]

Discharge Instructions:

**B6**



**B6**



# REPORT INFORMATION

## Report Profile

**Report Version** FPSR.FDA.PETF.V.V1  
**Report Category** Pet Food Safety Report  
**Submitted** 2018-09-16 11:38:42 EST  
**FDA ICSR ID** 2054966  
**Submitted by** lisa.freeman@tufts.edu

## Report Identifying Information

Enter a title to help you identify this report

**Regulatory Status** Voluntary

**Type of Submission** Initial

**What type of report are you submitting?** Adverse Event (a symptom, reaction or disease associated with the product)

# Contact Information - Reporter Sender

May the FDA contact you to follow-up, if necessary? Yes

Preferred method of contact: Email

Confirm Email lisa.freeman@tufts.edu

First Name Lisa

Last Name Freeman

Primary Phone 5088874523

Other Phone <blank>

Email lisa.freeman@tufts.edu

Country United States

Street Address Line 1 200 Westboro Rd

Street Address Line 2 <blank>

City/Town North Grafton

State Massachusetts

ZIP/Postal Code 01536

# Contact Information - Healthcare Professional

Veterinary Practice Name Tufts Cummings School of Veterinary Medicine

First Name Lisa

Last Name Freeman

Primary Phone (508) 887-4523

Email lisa.freeman@tufts.edu

Country United States

Street Address Line 1 200 Westboro Rd

City/Town North Grafton

State Massachusetts

ZIP/Postal Code 01536

# Contact Information - Animal Owner

First Name

B6

Last Name

Primary Phone **B6**

Other Phone <blank>

Email **B6**

Country United States

Street Address Line 1 **B6**

Street Address Line 2 <blank>

City/Town

State **B6**

ZIP/Postal Code

Can you provide contact information for the animal owner? Yes

---

## Contact Information - Receiver

Indicate any other parties that you notified about this issue <blank>

---

## Relevant Details

Animal Name/Identifier **B6**

Number of animals given the product 2

Number of animals reacted 1

Species Dog

Breed Great Dane

Age **B6**

Select Unit of Measure Years

Weight 69.5

Select Unit of Measure Kilogram

Gender Male

Reproductive status Neutered

Was the animal pregnant at time of event? <blank>

Was the animal lactating at time of event? <blank>

Prior to the event, what was the animal's overall state of health? Excellent

---

## Problem Details

Did the animal have any health problems and/or was taking medication prior to the event? Yes

Please describe: **B6**

## Product Information

Full name of product as it appears on the package label Taste of the Wild Prey Beef dry (will provide full diet history)

Product Type Pet Food

UPC from label <blank>

Package Type BAG

Package Size <blank>

Select Unit of Measure <blank>

Last date of product purchase (estimate if necessary) <blank>

Number purchased on this date <blank>

Do you have a package/container of unopened product from this purchase? <blank>

Do you have a package/container of opened product from this purchase? <blank>

## Product Lots

## Product Use Details

Describe how the product was used or administered 9 cups/day

Date the product was first given to the animal 06/01/2018

Date last fed the animal product from this purchase: <blank>

Were there any other foods or products given to the animal during this time period? <blank>

Describe how the product was stored before and after opening <blank>

# Contact Information

---

## Relatedness Details

Amount of time from use of product to onset of the event: <blank>

Select Unit of Measure <blank>

Was product use stopped after the onset of the adverse event? <blank>

How strongly do you believe this product is related to the adverse event? <blank>

---

## Location Name and Address

Store/place of purchase <blank>

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

---

## Product Information

Full name of product as it appears on the package label 4Health beef stew canned

Product Type Pet Food

UPC from label <blank>

Package Type CAN

Package Size <blank>

Select Unit of Measure <blank>

Last date of product purchase (estimate if necessary) <blank>

Number purchased on this date <blank>

Do you have a package/container of unopened product from this purchase? <blank>

Do you have a package/container of opened product from this purchase? <blank>

---

# Product Lots

---

## Product Use Details

Describe how the product was used or administered 2 tablespoons 3x/day since Jan, 2017

Date the product was first given to the animal <blank>

Date last fed the animal product from this purchase: <blank>

Were there any other foods or products given to the animal during this time period? <blank>

Describe how the product was stored before and after opening <blank>

---

## Contact Information

---

## Relatedness Details

Amount of time from use of product to onset of the event: <blank>

Select Unit of Measure <blank>

Was product use stopped after the onset of the adverse event? <blank>

How strongly do you believe this product is related to the adverse event? <blank>

---

## Location Name and Address

Store/place of purchase <blank>

Country <blank>

Street Address Line 1 <blank>

Street Address Line 2 <blank>

City/Town <blank>

State <blank>

ZIP/Postal Code <blank>

---

## Description and Details

Date problem started 09/12/2018

Date of recovery <blank>

**Describe what happened**

DCM and CHF - had been having respiratory signs for ~1 month prior to diagnosis at Tufts Littermate is **B6** (already reported by owner after being diagnosed with DCM and CHF in July 2018) Owner has another Great Dane at home (~1 year of age) eating the same diet that will be screened soon Owner approved submission of this report and talking to FDA Will send rest of medical records by email (sorry - too many to upload)

Was a veterinarian consulted? <blank>

Outcome to date Stable

---

## Attached Files

FILENAME taurine.pdf

Description of Attachment Taurine results

Attachment Type Laboratory Report



**B6**

**B6**

**B6**

**B6**

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

Patient: **B6**  
 Species: Canine  
 Breed: Great Dane  
 Sex: Male (Neutered)  
 Age: **B6** Years Old

**Lab Results Report**

| Chemistry 21 (Cobas)    |           | 9/13/2018 11:43:20 AM | Accession ID: <b>B6</b> |
|-------------------------|-----------|-----------------------|-------------------------|
| Test                    | Results   | Reference Range       | Units                   |
| GLUCOSE                 | <b>B6</b> | 67 - 135              | mg/dL                   |
| UREA                    |           | 8 - 30                | mg/dL                   |
| CREATININE              |           | 0.6 - 2               | mg/dL                   |
| PHOSPHORUS              |           | 2.6 - 7.2             | mg/dL                   |
| CALCIUM2                |           | 9.4 - 11.3            | mg/dL                   |
| T. PROTEIN              |           | 5.5 - 7.8             | g/dL                    |
| ALBUMIN                 |           | 2.8 - 4               | g/dL                    |
| GLOBULINS               |           | 2.3 - 4.2             | g/dL                    |
| A/G RATIO               |           | 0.7 - 1.6             |                         |
| SODIUM                  |           | 140 - 150             | mEq/L                   |
| CHLORIDE                |           | 106 - 116             | mEq/L                   |
| POTASSIUM               |           | 3.7 - 5.4             | mEq/L                   |
| NA/K                    |           | 29 - 40               |                         |
| T BILIRUBIN             |           | 0.1 - 0.3             | mg/dL                   |
| D.BILIRUBIN             |           | 0 - 0.1               | mg/dL                   |
| I BILIRUBIN             |           | 0 - 0.2               | mg/dL                   |
| ALK PHOS                |           | 12 - 127              | U/L                     |
| ALT                     |           | 14 - 86               | U/L                     |
| AST                     |           | 9 - 54                | U/L                     |
| CHOLESTEROL             |           | 82 - 355              | mg/dL                   |
| OSMOLALITY (CALCULATED) | 291 - 315 | mmol/L                |                         |

Client:  
 Veterinarian:  
 Patient ID:  
 Visit ID:

**B6**

Patient: **B6**  
 Species: Canine  
 Breed: Great Dane  
 Sex: Male (Neutered)  
 Age: **B6** Years Old

**Lab Results Report**

| Chemistry 21 (Cobas)    |           | 9/14/2018 12:28:20 PM | Accession ID: <b>B6</b> |
|-------------------------|-----------|-----------------------|-------------------------|
| Test                    | Results   | Reference Range       | Units                   |
| GLUCOSE                 | <b>B6</b> | 67 - 135              | mg/dL                   |
| UREA                    |           | 8 - 30                | mg/dL                   |
| CREATININE              |           | 0.6 - 2               | mg/dL                   |
| PHOSPHORUS              |           | 2.6 - 7.2             | mg/dL                   |
| CALCIUM2                |           | 9.4 - 11.3            | mg/dL                   |
| T. PROTEIN              |           | 5.5 - 7.8             | g/dL                    |
| ALBUMIN                 |           | 2.8 - 4               | g/dL                    |
| GLOBULINS               |           | 2.3 - 4.2             | g/dL                    |
| A/G RATIO               |           | 0.7 - 1.6             |                         |
| SODIUM                  |           | 140 - 150             | mEq/L                   |
| CHLORIDE                |           | 106 - 116             | mEq/L                   |
| POTASSIUM               |           | 3.7 - 5.4             | mEq/L                   |
| NA/K                    |           | 29 - 40               |                         |
| T BILIRUBIN             |           | 0.1 - 0.3             | mg/dL                   |
| D.BILIRUBIN             |           | 0 - 0.1               | mg/dL                   |
| I BILIRUBIN             |           | 0 - 0.2               | mg/dL                   |
| ALK PHOS                |           | 12 - 127              | U/L                     |
| ALT                     |           | 14 - 86               | U/L                     |
| AST                     |           | 9 - 54                | U/L                     |
| CHOLESTEROL             |           | 82 - 355              | mg/dL                   |
| OSMOLALITY (CALCULATED) | 291 - 315 | mmol/L                |                         |

**B6**

**B6**



**B6**

35 20658

**Sample Submission Form**

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

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

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

Vet/Tech Contact: **B6**  
 Company Name: \_\_\_\_\_

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

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

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

Patient Name: **B6**  
 Species: *Great Dane*  
 Owner's Name: **B6**

Sample Type:  Plasma  Whole Blood  Urine  Food  Other: \_\_\_\_\_  
 Test Items:  Taurine  Complete Amino Acid  Other: \_\_\_\_\_

Taurine Results (nmol/ml) **B6**  
 Plasma: \_\_\_\_\_ Whole Blood: \_\_\_\_\_ Urine: \_\_\_\_\_ Food: \_\_\_\_\_

**Reference Ranges (nmol/ml)**

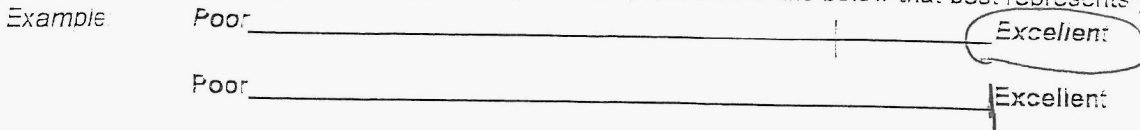
|     | Plasma       |                                      | Whole Blood  |                                      |
|-----|--------------|--------------------------------------|--------------|--------------------------------------|
|     | Normal Range | No Known Risk for Taurine Deficiency | Normal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

# CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet:

Pet's name: **B6**      Owner's name: **B6**      Today's date: 9/3/18

1. How would you assess your pet's appetite? (mark the point on the line below that best represents your pet's appetite)



2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)

- Eats about the same amount as usual     Eats less than usual     Eats more than usual  
 Seems to prefer different foods than usual     Other: \_\_\_\_\_

3. Over the last few weeks, has your pet (check one)

- Lost weight     Gained weight     Stayed about the same weight     Don't know

4. Please list below ALL pet foods, people food, treats, snack, dental chews, rawhides, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what your pet is eating.

**Food (include specific product and flavor)      Form      Amount      How often?      Fed since**  
 Examples are shown in the table – please provide enough detail that we could go to the store and buy the exact same food.

| Food (include specific product and flavor)            | Form       | Amount         | How often? | Fed since |
|---|------------|----------------|------------|-----------|
| Nutro Grain Free Chicken, Lentil & Sweet Potato Adult | dry        | 1 1/2 cups     | 2x/day     | Jan 2018  |
| 85% lean hamburger                                    | microwaved | 3 oz           | 1x/week    | Jan 2018  |
| Pupperoni original beef flavor                        | treat      | 1/2            | 1x/day     | Aug 2018  |
| Rawhides  | treat      | 6 inch twist   | 1x/week    | Dec 2018  |
| Honest Kitchen Turkey, Beef, or Chicken moist         | moist      | 1 1/2 cups     | 1x/day     | Nov 2017  |
| Bravo canned - rotate - rabbit                        | moist      | 1 can          | 1x/day     | ~2 yrs    |
| Hounds & Cats canned - rotate                         | moist      | 1 can          | 1x/day     | ~5 yrs    |
| Dingle sticks - Bravo rabbit                          | dried      | 1 1/2 inch     | weekly     | 11 yrs    |
| Eden Naturals - Bravo                                 | dried      | 1 1/2 inch     | weekly     | 11 yrs    |
| Zucchini - rotate (Just started again)                |            | 3 cups         | 1x/day     |           |
| Honest Kitchen Veggie & Fruit mix - add meat          |            | 1 1/2 - 2 cups | 1x/day     | 4 yrs     |
| Mostly feed Honest Kitchen                            |            |                |            |           |
| Homemade - turkey, beef, salmon -                     |            | varies         | 1x/day     | 11 yrs    |

*treats*

\*Any additional diet information can be listed on the back of this sheet:

*Vital Essentials food & Primal food & treats*

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?  Yes  No    If yes, please list which ones and give brands and amounts

|  | Brand/Concentration  | Amount per day                    |
|--|--|-----------------------------------|
| Taurine                                    | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No                        | _____                             |
| Carnitine                                  | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No                        | _____                             |
| Antioxidants                               | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No                        | _____                             |
| Multivitamin                               | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No                        | _____                             |
| Fish oil                                   | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <i>Nordic Naturals</i> | <i>1 Tablespoon</i>               |
| Coenzyme Q10                               | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No                        | _____                             |
| Other (please list):<br>Example: Vitamin C | <i>Nature's Bounty</i>   | <i>500 mg tablets - 1 per day</i> |
| _____                                      | _____  | _____                             |
| _____                                      | _____  | _____                             |
| _____                                      | _____  | _____                             |
| _____                                      | _____  | _____                             |

6. How do you administer pills to your pet?

- I do not give any medications  
 I put them directly in my pet's mouth without food  
 I put them in my pet's dog/cat food  
 I put them in a Pili Pocket or similar product  
 I put them in foods (list foods): cheese, liver wurst,

20543

**Amino Acid Laboratory Sample Submission Form**

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

Veterinarian Contact: **B6**

Clinic/Company Name: **B6**

Address: **B6**

Email: \_\_\_\_\_

Telephone: **B6**

Fax: # **B6**  
 Email

Billing Contact: **B6**

Patient Name: **B6**

Species: 1<9

Breed: Golden Retriever

Owner's Name: **B6**

Current Diet: \_\_\_\_\_

Sample type: Plasma Whole Blood Urine Food Other \_\_\_\_\_

Test: Taurine Complete Amino Acids Other: \_\_\_\_\_

Taurine Results (lab use only) **B6**  
 Plasma: \_\_\_\_\_ Whole Blood: **B6** Urine: \_\_\_\_\_ Food: \_\_\_\_\_

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

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

**From:** Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>  
**To:** Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David  
**Sent:** 9/7/2018 8:54:26 PM  
**Subject:** Another Tufts! FW: Zignature Kangaroo limited ingredient grain free dry: Lisa Freeman - EON-364572  
**Attachments:** 2054747-report.pdf; 2054747-attachments.zip

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



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**From:** PFR Event <pfreventcreation@fda.hhs.gov>  
**Sent:** Friday, September 07, 2018 4:44 PM  
**To:** Cleary, Michael \* <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; B6  
**Subject:** Zignature Kangaroo limited ingredient grain free dry: Lisa Freeman - EON-364572

A PFR Report has been received and PFR Event [EON-364572] has been created in the EON System.

A "PDF" report by name "2054747-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2054747-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-364572  
**ICSR #:** 2054747  
**EON Title:** PFR Event created for Zignature Kangaroo limited ingredient grain free dry; 2054747

|                       |            |                           |                      |
|-----------------------|------------|---------------------------|----------------------|
| <b>AE Date</b>        | 07/23/2016 | <b>Number Fed/Exposed</b> |                      |
| <b>Best By Date</b>   |            | <b>Number Reacted</b>     | 1                    |
| <b>Animal Species</b> | Dog        | <b>Outcome to Date</b>    | Recovered Completely |

|                          |                    |  |  |
|--------------------------|--------------------|--|--|
| <b>Breed</b>             | Mixed (Dog)        |  |  |
| <b>Age</b>               | 5 Years            |  |  |
| <b>District Involved</b> | PFR-New England DO |  |  |

**Product information**

**Individual Case Safety Report Number:** 2054747

**Product Group:** Pet Food

**Product Name:** Zignature Kangaroo limited ingredient grain free dry

**Description:** Developed DCM and CHF on Zignature Kangaroo limited ingredient grain free dry. Changed to Hill's ideal balance chicken and rice dry at time of diagnosis and has improved significantly on last echo (6/13/18) - fractional shortening and heart size now normal and starting to wean off meds

**Submission Type:** Initial

**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)

**Outcome of reaction/event at the time of last observation:** Recovered Completely

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

| Product Name   | Lot Number or ID | Best By Date |
|--|------------------|--------------|
| Zignature Kangaroo limited ingredient grain free dry |                  |              |

**Sender information**

Lisa Freeman  
 200 Westboro Rd  
 North Grafton, MA 01536  
 USA

**Owner information**

**B6** USA

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

**B6**

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

**B6**

=====

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

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

**Report Details - EON-364572**

ICSR: 2054747  
 Type Of Submission: Initial  
 Report Version: FPSR.FDA.PETF.V.V1  
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)  
 Reporting Type: Voluntary  
 Report Submission Date: 2018-09-07 16:41:17 EDT

**Reported Problem:**  
**Problem Description:** Developed DCM and CHF on Zignature Kangaroo limited ingredient grain free dry. Changed to Hill's ideal balance chicken and rice dry at time of diagnosis and has improved significantly on last echo (6/13/18) - fractional shortening and heart size now normal and starting to wean off meds  
**Date Problem Started:** 07/23/2016  
**Concurrent Medical Problem:** No  
**Outcome to Date:** Recovered Completely

**Product Information:**  
**Product Name:** Zignature Kangaroo limited ingredient grain free dry  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Storage Conditions:** Owner may be able to figure out exact date of starting Zignature based on online purchases  
**Product Use Information:**  
**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Mixed (Dog)  
**Gender:** Male  
**Reproductive Status:** Neutered  
**Weight:** 26.2 Kilogram  
**Age:** 5 Years  
**Assessment of Prior Health:** Excellent  
**Number of Animals Reacted:** 1  
**Owner Information:**  
 Owner Information provided: Yes  
**Contact:**  
 Name: B6  
 Phone: B6  
 Email: B6  
**Address:**  
 B6  
 United States  
**Healthcare Professional Information:**  
**Practice Name:** Tufts Cummings School of Veterinary Medicine  
**Contact:**  
 Name: Lisa Freeman  
 Phone: (508) 887-4523  
 Email: lisa.freeman@tufts.edu



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|                                     | <b>Permission To Contact Sender:</b> | Yes   |   |
| <b>Preferred Method Of Contact:</b> | Email                                |   |   |
| <b>Additional Documents:</b>        | <b>Attachment:</b>                   | cardio consult 7-23-16.pdf  |   |
|                                     | <b>Description:</b>                  | Will send the rest by email - too many files to upload individually         |   |
|                                     | <b>Type:</b>                         | Medical Records   |   |