From: B6
To: Jones, Jennifer L
Subject: Documents from [B6] for Patient: [B6], Client: [B6]

800.267-FDA Case Investigation for [B6] (EON-361371)
From: [Redacted]
To: Jones, Jennifer L
Sent: 9/25/2018 9:24:04 PM
Subject: Documents from [Redacted] for Patient: [Redacted], Client: [Redacted]
Attachments: [Redacted] (EON-361371)
Hi Jennifer

I spoke with the cardiologist office and they state they have sent you files last week. Please let me know if you didn’t get them. Attached is his most recent taurine results and you should have his echo as well.

I believe when we spoke you stated you wanted any testing on my other dog as well. So I am attaching his echo and taurine results. Speak with you on the 10th. Thanks

---Original Message---

From: Jones, Jennifer L
Date: 10/3/2018 3:04:43 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267-FDA Case Investigation for (EON-361371)

Thank you. We’d be happy to add those additional documents to our files. I’ll call you next Wednesday (10/10) at 2pm eastern.

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

Hi Jennifer,

---Original Message---

From: Jones, Jennifer L
Sent: Tuesday, September 25, 2018 3:20 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267-FDA Case Investigation for (EON-361371)
If you need test results, I have copies of them. Also, I re-did taurine results sent to UC Davis and have that as well. Let me know. I have some projects scheduled but don't know the times yet, but as of now I am available.

10-9 11am
10-10 2pm
10-11 11am or any time before 4pm.

Thanks

------Original Message------

From: Jones, Jennifer L
Date: 9/25/2018 2:54:26 PM
To: 
Subject: RE: 800.267-FDA Case Investigation for (EON-361371)

Good afternoon

Thank you for sending the records. After reviewing them, we'd like to request an interview. Please send me 3 dates with times you'd be available the week of October 9-11.

As an FYI, I'm still waiting on the records from your cardiologist. I rerequested them today (9/25) and hopefully will have them before our interview.

Thank you kindly,

Dr. Jones

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

It was nice speaking with you and hoping you guys can figure out with is going on with all these cases of DCM. Anyway, I contacted my primary vet and told them you would be contacting them for the info on [B6]. The vet's office info is:

[B6], VMD (PLEASE ASK FOR [B6] & SHE WILL HANDLE IT)

I have also contacted the Cardiologist office and spoke with the cardiology nurse [B6]. She said you can contact her or email the department to request the records.

[B6]

I am attaching the taurine results on both dogs for your records. Let me know if you need anything else.

Thanks again

[B6]
Good afternoon

Thank you for submitting your consumer complaint to FDA. I’m sorry to hear about [B6] illness.

As part of our investigation, we’d like to request:

- **Full Medical Records**
  - Please contact *your veterinarians* (primary veterinarian and cardiologist/specialist) and ask them to email (preferred) or fax (301-210-4685) a copy of [B6] entire medical history (not just this event).

- **After we review the records, we may request a Phone interview** about [B6] diet and environmental exposures
  - The interview will help us better understand the details in your case.

*We would like to collect the leftover food. How much is available?*

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how owners help with our case investigations.

Please respond to this email so that we can initiate our investigation.

Thank you kindly,

Dr. Jones

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
Updated MRx.

B6 4 yr MC Golden Retriever

Hx:
long term SP Cardiac Support K9-100g; cryptorchid
4/12/2016-Eats Acana kibble, Echo-DCM, VSD-restrictive à rec pimo
4/19/2016-2nd opinion on if to start pimo, on Fish oil, Cardiac support supp,
PE-Gr IV murmur coarse holosys L, Gr IV/VVI holo R, B6 bpm
Tx-start B6
4/27/2016: panting, drinking more-weather warmer now
  x-rad: cardiomeg (VHS B6), normal in dogs is mild LA enl, very D bronchointerst patt
  Labs-Chol B6, rest wnl
5/2016 possible Tau supplement-begin SP Cardiotrophin, L-carnitine;
9/19/2016-eat Acana, Orijen freeze dried; x-rad: prog enl RH, VHS 12, globoid prim RH, BUN/Ct/K wnl, Chol 326

  Echo-stable LV/LA size, no flow changes of VSD
4/13/2017-labs BUN/K/Ct wnl, proteinuria +1

4/19/2017-T B6
8/29/2017-eats Acana, on

Echo-DCM-stable, VSD

11/2017 B6
12/27/2017-on Acana/Orijen, freeze dried SP treats; Labs: wnl, x-rads: static
4/18/2018-WB Tau; Plasma B6 (not on supplementation)a started Tau 1.75g BID
5/10/2018 B6
5/14: diet change, melena
8/16/2018-possible B6
8/22/2018-diet-Real Meat Company 90% beef air dried, no legumes, IS grain free, no potatoes; Gr IV murmur
L, Gr V right, HR 150 bpm;
  x-rad: cardiomeg VHS B6/ LA enl, RH enl w/ prom main pulm a
  Echo: marked improvement LV, improved LVIDS, ESV, EPSS; LA enl, annual dil w/ MR; uncooperative,
panting, anxious-not assess VSD
9/10/2018-Davis-plasma B6 WB B6

B6 7 yr MI Golden Retriever

Tau WB B6; Plasma @ Davis
9/2018 Echo- tr MR, mild thick MV, ECG B6 bpm, nsr

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

From: Jones, Jennifer L
Cardio MRx still pending - 2nd request today

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

From: Jones, Jennifer L
Sent: Tuesday, September 25, 2018 2:52 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: 800.267-EON-361371 Acana Pork and Squash

Cardio MRx still pending - 2nd request today

4/2017: L-carnitine for dog -14 yr MC Golden Retriever
Hx: 3/2015 - cytology, begin long term 5/2016 possible Tau supplement - begin SP

4/18/2018 - WB Tau, Plasma
5/10/2018 - Gr IV/VI Left murmur
5/14 - diet change, melena
8/16/2018 - Plasma

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

From: Jones, Jennifer L
Sent: Wednesday, August 08, 2018 2:16 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov) <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: 800.267-EON-361371 Acana Pork and Squash

MRx pending + Interview, no food
FYI-Joshua Stern encouraged her to submit the report to FDA. I'm assuming that's also why we've gotten more golden retrievers.
2 dogs in this home - both low Tau
1st dog - born w/ VSD but apparently L-sided DCM
2nd dog - low Tau, no ECHO done
A PFR Report has been received and PFR Event [EON-361371] has been created in the EON System.

A "PDF" report by name "2053236-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-361371  
**ICSR #:** 2053236  
**EON Title:** PFR Event created for Acana Pork and Squash; 2053236

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<td></td>
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<tr>
<td>District Involved</td>
<td>PFR</td>
<td>B6</td>
<td>DO</td>
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</table>

**Product information**

**Individual Case Safety Report Number:** 2053236  
**Product Group:** Pet Food  
**Product Name:** Acana Pork and Squash  
**Description:** This is not an event that suddenly occurred. My dog was diagnosed with dilated cardiomyopathy at 2 years old. I enrolled him in the taurine deficient study done by Dr. Joshua Stern at UC Davis. He was eating Acana Pork & Squash since he was a puppy. His taurine was tested (4-18) and his whole blood is [B6] and plasma [B6]. Since his taurine level is low, I was told to supplement him with taurine and take him off the current dog food. I was told his food could cause taurine deficient dilated cardiomyopathy. He will be re-tested in the upcoming months. It is not know at this time if the dog food contributed to his disease or caused it. The study is still on going.

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

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<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Acana Pork and Squash</td>
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</tbody>
</table>

Sender information

B6 USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-361371

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=12&issueld=378105

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DCM case. This should be a PFR.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

From: RFR Event [mailto:rfreventcreation@fda.hhs.gov]
Sent: Friday, April 20, 2018 3:53 PM
To: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; orahqreportablefoodnotificationtriagegroup@fda.hhs.gov; Bataller, Neal <Neal.Bataller@fda.hhs.gov>; Johnston, Ying F <Ying.Johnston@fda.hhs.gov>; Edwards, Elizabeth <Elizabeth.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Yowell, Ruth <Ruth.Yowell@fda.hhs.gov>; ORA HAF EAST1 Reportable Food Notification <orahafeast1reportablefoodnotification@fda.hhs.gov>; Krieger, Darlene <Darlene.Krieger@fda.hhs.gov>; CFSAN Reportable Food Registry <CFSANReportableFoodRegistry@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; Weems, Shellie * <Shellie.Weems@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>; ORA OEIO RECALLS Branch <oraoeioirecallbranch@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; McCoig, Amber <Amber.McCoig@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>

Subject: EON-351747 RFR Event: Unclear if this is info on Blue Buffalo or something else

A RFR Report has been received and RFR Event [EON-351747] has been created in the EON System under ICSR # 2046176.

Reason this food is reportable: Other
Please describe Other: Taurine deficiency or other diet-related DCM
Product Name: Blue Buffalo Basics salmon and potato dry food - regular and grain-fr...
Type of Site: Sender Food Facility Site

<table>
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<th>FDA Districts Impacted</th>
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<tr>
<th>Organization Name:</th>
<th>Tufts Cummings School of Veterinary Medicine</th>
<th>Unclear if this is info on Blue Buffalo or something else</th>
</tr>
</thead>
</table>

| Address: | 200 Westboro Rd North Grafton, MA 01536 United States | ? MA United States |

Discovery Date: 2018-04-19

Product Group: Pet Food

Description: 7 year old castrated male Doberman pinscher with DCM. Has been eating Blue Buffalo Basics salmon and potato dry food since 2012 (rotates between regular and grain free version of this diet). Recently, diagnosed with DCM and whole blood taurine was $B_6^{mmol/ml}$. Started on cardiac medications by RDVM and just started $B_6$ and $B_6$ oil (may also start $B_6$). Unclear if taurine deficiency-related DCM or related to current concerns with "grain free" diets.

Product Recall: No

Human Symptoms Present: No

Animal Symptoms Present: Yes

Animal Symptoms Description: DCM and taurine deficiency Owner has bag of food that she's keeping until we hear from you. RDVM is $B_6$.

Product Distribution Type: Retail

Root Cause: Unknown

Discovery Code: Other

Submission Type: Initial

Reporting Type: Voluntary

Attachment Name: $B_6$ records.pdf,$B_6$ DCM 4-19-18.pdf

EON Key: EON-351747

EON Title: RFR Event created for Blue Buffalo Basics salmon and potato dry food - regular and grain-free; 2046176

To view this RFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-351747

To view the RFR Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=9&issuelId=368135

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From: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
To: Rotstein, David; Glover, Mark; Jones, Jennifer L; Ceric, Olgica; Nemser, Sarah; Queen, Jackie L; Palmer, Lee Anne
Sent: 4/23/2018 10:02:04 AM
Subject: RE: should be a PFR--DCM case-FW: EON-351747 RFR Event: Unclear if this is info on Blue Buffalo or something else

Do I need to transition this into a PFR or are we expecting a follow-up PFR report for it?

From: Rotstein, David
Sent: Friday, April 20, 2018 3:55 PM
To: Glover, Mark <Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: should be a PFR--DCM case-FW: EON-351747 RFR Event: Unclear if this is info on Blue Buffalo or something else

DCM case. This should be a PFR.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: RFR Event [mailto:rfreventcreation@fda.hhs.gov]
Sent: Friday, April 20, 2018 3:53 PM
To: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; orahqreportablefoodnotificationtriagegroup@fda.hhs.gov; Bataller, Neal <Neal.Bataller@fda.hhs.gov>; Johnston, Ying F <Ying.Johnston@fda.hhs.gov>; Edwards, Elizabeth <Elizabeth.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Yowell, Ruth <Ruth.Yowell@fda.hhs.gov>; ORA HAF EAST1 Reportable Food Notification <orahafeast1reportablefoodnotification@fda.hhs.gov>; Krieger, Darlene <Darlene.Krieger@fda.hhs.gov>; CFSAN Reportable Food Registry <CFSANReportableFoodRegistry@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; Weems, Shellie * <Shellie.Weems@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>; ORA OEIO RECALLS Branch <oraoreio recallsbranch@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; McCoig, Amber <Amber.McCoig@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L
A RFR Report has been received and RFR Event [EON-351747] has been created in the EON System under ICSR # 2046176.

**Reason this food is reportable:** Other  
**Please describe Other:** Taurine deficiency or other diet-related DCM  
**Product Name:** Blue Buffalo Basics salmon and potato dry food - regular and grain-fr...
To view the RFR Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=9&issueId=368135

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I was not expecting this report.

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

From: Rotstein, David
Sent: Monday, April 23, 2018 7:05 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: should be a PFR--DCM case-FW: EON-351747 RFR Event: Unclear if this is info on Blue Buffalo or something else

Lauren,

I am not aware of any follow-up. Jen-were you expecting this one? If not, creating PFR would be great.

dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)
Do I need to transition this into a PFR or are we expecting a follow-up PFR report for it?

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

Subject: should be a PFR--DCM case-FW: EON-351747 RFR Event: Unclear if this is info on Blue Buffalo or something else

DCM case. This should be a PFR.

David Rotstein, DVM, MPVM, Dipl. ACVP  
CVM Vet-LIRN Liaison  
CVM OSC/DC/CERT  
7519 Standish Place  
240-506-6763 (BB)

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To: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; orahqreportablefoodnotificationtriagegroup@fda.hhs.gov; Bataller, Neal <Neal.Bataller@fda.hhs.gov>; Johnston, Ying F <Ying.Johnston@fda.hhs.gov>; Edwards, Elizabeth <Elizabeth.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Yowell, Ruth <Ruth.Yowell@fda.hhs.gov>; ORAHAF EAST1 Reportable Food Notification <orahafeast1reportablefoodnotification@fda.hhs.gov>; Krieger, Darlene <Darlene.Krieger@fda.hhs.gov>; CFSAN Reportable Food Registry <CFSANReportableFoodRegistry@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>; Cleary, Michael * <Micahel.Cleary@fda.hhs.gov>; Weems, Shellei * <Shellei.Weems@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>; ORA OEIO RECALLS Branch <oraoeiorecallsbranch@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; McCoig, Amber <Amber.McCoig@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>

Subject: EON-351747 RFR Event: Unclear if this is info on Blue Buffalo or something else

A RFR Report has been received and RFR Event [EON-351747] has been created in the EON System under ICSR # 2046176.

Reason this food is reportable: Other
Please describe Other: Taurine deficiency or other diet-related DCM

Product Name: Blue Buffalo Basics salmon and potato dry food - regular and grain-free...

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<th>Type of Site:</th>
<th>Sender</th>
<th>Food Facility Site</th>
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<td>FDA Districts Impacted:</td>
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<tr>
<td>Organization Name:</td>
<td>Tufts Cummings School of Veterinary Medicine</td>
<td>Unclear if this is info on Blue Buffalo or something else</td>
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<tr>
<td>Address:</td>
<td>200 Westboro Rd North Grafton, MA 01536 United States</td>
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</tbody>
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Discovery Date: 2018-04-19
Product Group: Pet Food
Description: 7 year old castrated male Doberman pinscher with DCM. Has been eating Blue Buffalo Basics salmon and potato dry food since 2012 (rotates between regular and grain free version of this diet). Recently, diagnosed with DCM and whole blood taurine was [B6] mmol/ml. Started on cardiac medications by RDVM and just started taurine and fish oil (may also start [B6]). Unclear if taurine deficiency-related DCM or related to current concerns with "grain free" diets.

Product Recall: No
Human Symptoms Present: No
Animal Symptoms Present: Yes
Animal Symptoms Description: DCM and taurine deficiency Owner has bag of food that she's keeping until we hear from you. RDVM is [B6].

Product Distribution Type: Retail
Root Cause: Unknown

Discovery Code: Other

Submission Type: Initial
Reporting Type: Voluntary
EON Key: EON-351747
EON Title: RFR Event created for Blue Buffalo Basics salmon and potato dry food - regular and grain-free; 2046176

To view this RFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-351747

To view the RFR Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction/viewReport.jspa?decorator=none&e=0&issueType=9&issueId=368135
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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 immediately.
Report Details - EON-351879

ICSR: 2046277
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: 2018-04-23 10:33:06 EDT

Reported Problem: Problem Description: Reported as RFR (EON-351747). FDA CVM resubmitting as PFR. 7 year old castrated male Doberman pinscher with DCM. Has been eating Blue Buffalo Basics salmon and potato dry food since 2012 (rotates between regular and grain-free version of this diet). Recently, diagnosed with DCM and whole blood taurine was 88 nmol/ml. Started on cardiac medications by RDVM and just started taurine and fish oil (may also start B6). Unclear if taurine deficiency-related DCM or related to current concerns with "grain free" diets. DCM and taurine deficiency. Owner has bag of food that she's keeping until we hear from you. RDVM is B6.

Date Problem Started: 04/03/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Unknown

Product Information: Product Name: Blue Buffalo Basics salmon and potato dry food - regular and grain-free
Product Type: Pet Food
Lot Number: Unknown
Package Type: BAG
Possess Unopened Product: Unknown
Possess Opened Product: Unknown

Product Use Information: Description: rotates between regular and grain free version of this diet (since 2012)
Product Use Stopped After the Onset of the Adverse Event: Yes
Adverse Event Abate After Product Stop: Unknown
Product Use Started Again: No
Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes

Manufacturer/Distributor Information: Purchase Location Information:

Animal Information: Name: B6
Type Of Species: Dog
Type Of Breed: Doberman Pinscher
Gender: Male
Reproductive Status: Neutered
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<tbody>
<tr>
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<tr>
<td>Number of Animals Reacted</td>
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<tr>
<td>Owner Information No:</td>
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<tr>
<td>Healthcare Professional Information:</td>
<td>Practice Name: Tufts Cummings School of Veterinary Medicine</td>
</tr>
<tr>
<td>Contact: Name:</td>
<td>Lisa Freeman</td>
</tr>
<tr>
<td>Phone:</td>
<td>(508) 887-4523</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
<tr>
<td>Address:</td>
<td>200 Westboro Rd North Grafton Massachusetts 01536 United States</td>
</tr>
<tr>
<td>Date First Seen:</td>
<td>04/19/2018</td>
</tr>
<tr>
<td>Practice Name:</td>
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<tr>
<td>Type of Primary/regular Veterinarian:</td>
<td>Name: Lisa Freeman</td>
</tr>
<tr>
<td>Date First Seen:</td>
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</tr>
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<td>Phone:</td>
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<tr>
<td>Contact:</td>
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<td><a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
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<td>Reporter Wants to Remain Anonymous:</td>
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<td>Permission To Contact Sender:</td>
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<td>Preferred Method Of Contact:</td>
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<td>Reported to Other Parties:</td>
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<td>Attachment:</td>
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| Weight | |
|--------||

| Name | |
|------||

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| Name | |
|------||

| Date | |
|------||

| Name | |
|------||
**Cardiac Measurements:**

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<th>2-D</th>
<th>M-Mode</th>
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<td>MV E Vel</td>
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<td>LA Diam</td>
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<td>Ao/LA</td>
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<td>LVOT Vmax</td>
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<td>IVSd</td>
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<td>LVIDd</td>
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<tr>
<td>SV (Teich)</td>
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### Physical Exam:

HR: 170, irregularly irregular rhythm, III/VI left apical pansystolic heart murmur, moderate and synchronous pulses. -clear and euptic lungs

### ECG:

- Atrial fibrillation with an uncontrolled ventricular response rate is present throughout the exam. No significant ventricular ectopy is appreciated.

### 2D and M-Mode:

- The left ventricular internal dimensions are moderately increased at end diastole and moderately to severely increased at end systole.
- There is no hypertrophy of the interventricular septum, the left ventricular posterior wall or papillary muscles.
- The mitral valve leaflets are normal.
- The tricuspid valve leaflets are normal.
- The indices of left ventricular contractility (fractional shortening, ejection fraction and end systolic volume index - ESV indexed to body surface area) are all abnormal suggesting decreased systolic performance.
- The left atrium is moderately dilated.
- There is mild dilation of the right ventricle.

### Color and Spectral Doppler:

- The aortic spectral Doppler velocity and profile are normal.
- The pulmonic spectral Doppler velocity and profile are normal.
- There is mild mitral regurgitation with a normal spectral Doppler profile and velocity.
- The mitral regurgitation is directed throughout the center of the left atrium.
- There is mild tricuspid regurgitation with a normal spectral Doppler profile, but a MILDLY increased spectral Doppler velocity.
- The tricuspid regurgitation is directed away from the inter-atrial septum.
- Due to the presence of the atrial fibrillation, there are no trans mitral A waves. The E wave velocity is increased.

### Diagnosis:

Dilated cardiomyopathy - Moderate Atrial fibrillation

### Treatment:

- B6
Client: B6  
Patient Name: B6  
Species: Canine  
Breed:  
Gender:  
Weight:  
Age: 4 Years  
Doctor:  

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(October 24, 2015 12:17 PM)
Report Details - EON-354251

ICSR: 2048125

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: 2018-05-21 07:55:06 EDT

Reported Problem:

<table>
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<tr>
<th>Problem Description:</th>
<th>Reported as RFR EON-354199. 2 year old Great Dane with DCM and CHF. Has eaten 4Health dog food (large breed dry) since 6/2016. Taurine levels pending. Owner has switched to another food and has saved the 4Health food</th>
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<tr>
<td>Date Problem Started:</td>
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Concurrent Medical Problem: Unknown

Outcome to Date: Unknown

Product Information:

<table>
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<tr>
<th>Product Name:</th>
<th>4Health large breed dry food</th>
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<tbody>
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<td>Product Type:</td>
<td>Pet Food</td>
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<td>Lot Number:</td>
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<td>Package Type:</td>
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<td>Possess Unopened Product:</td>
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<td>Possess Opened Product:</td>
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Product Use Information:

<table>
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<tr>
<th>Description:</th>
<th>Has eaten 4Health dog food (large breed dry) since 6/2016</th>
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<tbody>
<tr>
<td>First Exposure Date:</td>
<td>06/30/2016</td>
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<tr>
<td>Product Use Stopped After the Onset of the Adverse Event:</td>
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<tr>
<td>Adverse Event Abate After Product Stop:</td>
<td>Unknown</td>
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<tr>
<td>Product Use Started Again:</td>
<td>No</td>
</tr>
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</table>

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

| Name: | |
| Type Of Species: | Dog |
| Type Of Breed: | Great Dane |
| Gender: | Unknown |
| Reproductive Status: | Unknown |
| Age: | 2 Years |
| Assessment of Prior Health: | Unknown |
| Number of Animals Given the Product: | 1 |
| Number of Animals Reacted: | 1 |
| Owner Information: | Yes |

Owner Information provided:

Contact: Name: L ____________ B6
<table>
<thead>
<tr>
<th>Healthcare Professional Information:</th>
<th></th>
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</table>

**Sender Information:**

<table>
<thead>
<tr>
<th>Name:</th>
<th>Lisa Freeman</th>
</tr>
</thead>
</table>
| Address: | 200 Westboro Rd  
North Grafton  
Massachusetts  
01536  
United States |
| Phone: | 5088874523  
Email: lisa.freeman@tufts.edu |

**Contact:**

<table>
<thead>
<tr>
<th>Reporter Wants to Remain Anonymous:</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>Permission To Contact Sender:</td>
<td>Yes</td>
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<td>Reported to Other Parties:</td>
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**Additional Documents:**

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*FOUO- For Official Use Only*
Cardiology Appointment Report

Date: 5/25/2018

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student:
B6

Presenting Complaint:
Redo DCM - CHF on

Concurrent Diseases:
None

General Medical History:
Almost back to his baseline since last discharge on . B6 . great appetite and no v/d/s. Occasional cough after he eats/drinks fast
Goes for 1.5~2 mile walk daily
Respiratory rate had been between 18-24, was at 35 once so gave a dose of . B6 . and it helped.
B6 . may be having trouble gaining weight

Diet and Supplements:
Purina proplan high performance dog food 3 cups BID
Purina proplan 1 can SID
High calory syrup covered medication
Also planning to start him on L-Carnitine, Mg., and Coq10 supplements tomorrow

Cardiovascular History:
Prior CHF diagnosis? Yes
Prior ATE? No
Prior arrhythmia? Yes occasional VPCs
Cough? Yes after drinking/eating
Shortness of breath or difficulty breathing? no
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? No
Prior heart murmur? yes grade II left apical systolic murmur

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

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

Murmur location/description: Left apical systolic murmur

Jugular vein:
Bottom 1/3 of neck
Middle 1/3 of neck

Arterial pulses:
- Weak
- Fair
- Good
- Strong

Bounding
Pulse deficits
Pulsus paradoxicus
Other:

Arrhythmia:
- None
- Sinus arrhythmia
- Premature beats

Bradycardia
Tachycardia

Gallop:
- Yes
- No
- Intermittent

Pulmonary crinkles
Wheeze
Upper airway stridor

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal LV sounds

Pulmonary crackles
Wheezes
Upper airway stridor

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension

Mild ascites
Marked ascites

Problems:
DCM and hx of HCF
Grade II/VI left systolic murmur
VPCs
Not gaining weight

Differential Diagnoses:
DCM
benign VPC, splenic mass, pain, cardiomyopathy
insufficient caloric intake, hyperthyroidism,

Diagnostic plan:
- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin T
- Other tests: T4

Echocardiogram Findings:
General/2-D findings:
Not performed

ECG findings:
**Assessment and recommendations:**
The patient is clinically doing well, although the owner had to give an extra dose of \[\text{B6}\] since discharge. If renal values are normal today, then I would recommend a small increase in his \[\text{B6}\] dose (\[\text{B6}\] extra EOD). We have also recommended a food change to help with weight gain and for low Na intake. Recheck echocardiogram, renal values, and ECG in 3-4 months.

**Final Diagnosis:**
DCM with history of LCHF

**Heart Failure Classification Score:**

**ISACHC Classification:**
- □ Ia
- □ Ib
- □ II

**ACVIM Classification:**
- □ A
- □ B1
- □ B2
- □ C
- □ D

---

NSR.
Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY
Cardiology liaison: 508-887-4696

Cardiology Inpatient

Patient ID: B6
B6 Canine
B6 Years Old Male (Neutered) Great Dane
Blue BW: Weight(lbs) 0.00

Attending Cardiologist:
- John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

Cardiology Resident:
B6

Date: B6
Weight: Weight(lbs) 0.00

Thoracic radiographs available for review?
- Yes - in ER email
- Yes - in PACS
- No

Presenting complaint and important concurrent diseases:
suspect CHF with enlarged heart, suspect DCM

Current medications and doses:
- B6 2mg/kg IV once

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.):
murmur, tachycardia, enlarged heart on rads with B-lines and pulmonary edema on rads

Questions to be answered from the Consult:
medication recommendations

Is your consult time-sensitive? (e.g., anesthesia today, owner waiting, trying to get biopsy today)
- Yes (explain)
- No

*STOP - remainder of form to be filled out by Cardiology*

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: left apical systolic

#### Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3 of neck

#### Arterial pulses:
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other (describe):

#### Arrhythmia:
- None
- Sinus arrhythmia
- Premature beats
- Bradycardia
- Tachycardia

#### Gallop:
- Yes
- No
- Intermittent
- Pronounced
- Other:

#### Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary Cradles
- Wheezes
- Upper airway stridor
- Other auscultatory findings:

#### Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

### Echocardiogram Findings:

#### General/2-D findings:

![B6]
**Doppler findings:**

B6

**Radiographic findings:**

rDVM radiographs: severe generalized cardiomegaly with left atrial enlargement. The pulmonary vessels are distented. There is a diffuse interstitial pattern in the caudal lung field.

**Assessment and recommendations:**

Echocardiogram reveals DCM with a markedly enlarged LA and active CHF. Recommend starting B6 The patient was moderately dyspneic during the examination with diffuse crackles and recommend administering B6 mg/kg IV overnight. Once the patient is home and eating with a good appetite, then an B6 PO SID-BID should be started as well. The MR gradient was low and ideally a blood pressure should be obtained. The patient has a history of eating an atypical diet in the past and DCM related to the diet remains a possibility since the patient is relatively young. Taurine level will be submitted. Recommend continuing with a more “typical” commercial diet that is not grain free and taurine supplementation could be started as well. Recheck renal values prior to discharge. A recheck echocardiogram is recommended in 3 months or sooner if the patient develops clinical signs such as increased RR/RE, cough, exercise intolerance, or syncope.

**Final Diagnosis:**

- Advanced DCM with severe LA enlargement and active CHF r/o genetic vs. nutritional

**Heart Failure Classification Score:**

**ISACHC Classification:**

- IL
- II
- IIIa
- IIIb

**ACVIM CHF Classification:**

- A
- B1
- B2
- C
- D

**M-Mode**

- IVSd
- LVIDd
- LVPWd
- IVSs
- LVIDs
- LVPWs
- %FS
- Ao Diam
- IA Diam
- LA/Ao
- EPSS

**M-Mode Normalized**
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Discharge Instructions

Patient
Name: B6
Species: Canine
Blue Male (Neutered) Great Dane
Birthdate: B6

Owner
Name: B6
Address: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACMECC

Cardiology Resident:
B6

Student: B6 19
Cardiology Technician:
B6

Admit Date: B6
Discharge Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with congestive heart failure

Diagnostic test results and findings:
- Chest radiograph (x-ray) findings: The heart is enlarged and there is fluid in the lungs.
- Echocardiogram findings: All chambers of the heart are enlarged and there is a leak at the mitral valve.
- ECG findings: The ECG showed frequent ventricular premature contractions (VPC) with few couplets (2 VPCs occurring side by side).

Laboratory findings:
- The kidney values are slightly elevated, but should be good enough to continue the current medication.
- The results of the blood sodium level is still pending, we will call you as soon as that becomes available.

Case summary:
Thank you so much for entrusting us with B6 care. B6 presented to Tufts ER on B6 through referral from your primary veterinarian who found enlarged heart and fluid in his lungs on chest x-rays.

At Tufts, with further diagnostic tests, 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. 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 [B6] comfortable and have him breathing easier.

His ECG revealed that [B6] had some abnormal contraction of his heart called ventricular premature contractions (VPC). Many of the VPCs were isolated, but we did find couple incidences where two of the VPCs were closely associated with one another (a couplet). Since the heart failure is known to cause arrhythmias, and the medication we would use is not benign either, we would like to monitor his ECG at his next recheck in 1-2 weeks to see if the continue to have abnormal rhythms.

We have hospitalized [B6] overnight with aggressive medical management (bloodwork, ECG monitoring, medication), and [B6] recovered throughout the night. The recheck x-ray of his chest showed that there are no more fluid in his lungs, so we are comfortable sending him home with you today.

**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 35 to 40 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.
- 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 [B6] evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

**Recommended Medications:**
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/)

Because B6 had been fed a diet that is potentially deficient in taurine (amino acid that plays a role in building heart muscles) levels, we recommend supplementing B6 with taurine for at least another 6 months.

B6 may also benefit from getting L-carnitine supplement. The recommended dose of L-carnitine for B6 is 2000mg (5g/ml/kg) by mouth twice a day. You can find over-the-counter product for L-carnitine supplements, and there is no need to obtain prescription for it.

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. At this visit we will check your dog’s breathing effort and heart function, do a blood test to recheck kidney values, and recheck B6 ECG readings. If we continue to find VPCs that concerns us, we may prescribe an anti-arrhythmic medication for him.

A recheck echocardiogram is recommended in 3-4 months.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison B6 at (508) 827-4696 or email us at cardiovascular@tufts.edu for scheduling and non-emergent questions or concerns.

Sincerely,
B6

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 (508-827-4629) 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/cvm/clinical-studies

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<tr>
<th>Case</th>
<th>B6</th>
<th>Owner</th>
<th>B6</th>
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FDA-CVM-FOIA-2019-1704-011706
### Lab Results Report

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### T4 Add On/Clin Path

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Date of exam: 5/18/18

Patient Location: Ward/Cage: ICU run 2

Weight (kg) 46.10

Inpatient

Outpatient Time:

Waiting

Emergency

Sedation

BAG

OBAG

1/2 dose OBAG

Dexdomitor/Durathorphan

Anesthesia to sedate/anesthetize

Examination Desired: IA 1 view lateral

Presenting Complaint and Clinical Questions you wish to answer:

**Active heart failure** Great Dane, so please use large animal radiograph machine for 1 view lateral

Want to know if there is any signs of active congestion

Pertinent History:

2yo MN great dane with history of 2 week long cough and panting. Dx with DCM and CHF yesterday

Findings:

B6
B6

Conclusions:
- Resolution of pulmonary edema with persistence of pulmonary venous distention.
- Mildly improved moderate cardiomegaly consistent with reported DCM.

Radiologists
Primary: B6 DVM
Reviewing:

Dates
Reported: B6
Finalized:
Cardiology Appointment Report

Date: B6

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

Cardiology Resident:
B6

Cardiology Technician:
B6

Student:
B6

Presenting Complaint:
Recheck DCM - CHF on B6

Concurrent Diseases:
None

General Medical History:
Almost back to his baseline since last discharge on B6. Great appetite and no v/d/s. Occasional cough after he eats/drinks fast.
Goes for 1.5-2 mile walk daily.
Respiratory rate had been between 18-24, was at 35 once so gave a dose of furosemide and it helped. May be having trouble gaining weight.

Diet and Supplements:
Purina proplan high performance dog food 3 cups BID
Purina proplan 1 can SID
High calory syrup covered medication
Also planning to start him on L-Carnitine, Mg, and Coq10 supplements tomorrow

Cardiovascular History:
Prior CHF diagnosis? Yes
Prior ATE? No
Prior arrhythmia? Yes occasional VPCs
Cough? Yes after drinking/eating
Shortness of breath or difficulty breathing? no
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? No
Prior heart murmur? yes grade II left apical systolic murmur

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
- Normal
- Mild muscle loss

Cardiovascular Physical Exam:

Murmur Grade:
- None
- I/VI
- II/VI
- III/VI

Murmur location/description: Left apical systolic murmur

Jugular vein:
Arterial pulses:
- Weak
- Fair
- Good
- Strong

Arrhythmia:
- None
- Sinus arrhythmia
- Premature beats

Gallbladder:
- Normal
- Mild:
- Marked:
- Other:

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

Problems:
DCM and hx of HCF
Grade I/II left systolic murmur
VPCs
Not gaining weight

Differential Diagnoses:

DCM
benign VPC, splenic mass, pain, cardiomyopathy
insufficient caloric intake, hyperthyroidism,
Assessment and recommendations:
The patient is clinically doing well, although the owner had to give an extra dose of B6 since discharge. We have also recommended a food change to help with weight gain and low Na intake. Recheck echocardiogram, renal values, and ECG in 3-4 months.

Final Diagnosis:
DCM with history of LCHF

Heart Failure Classification Score:
ISACHC Classification:
- Ia
- Ib
- II

ACVIM Classification:
- A
- B1
- B2
- C
- D
Report Details - EON-355703

ICSR: 2049063
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: 2018-06-06 07:53:32 EDT

Reported Problem:

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<th>possible diet-associated DCM 4health Grain-Free Large Breed Formula Adult Dog Food. Owner was asked to save food. Plasma taurine (_B6) (ref range 60-120), WB taurine (_B6) (ref range 200-350) DCM diagnosed by ecocardiography</th>
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Product Information:

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Manufacturer/Distributor Information:

Purchase Location Information:

Animal Information:

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<td>Contact:</td>
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Healthcare Professional Information:

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<table>
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<tr>
<th>Name:</th>
<th>Lisa Freeman</th>
</tr>
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</table>
| Address:   | 200 Westboro Road  
            | North Grafton  
            | Massachusetts  
            | 01536  
            | United States |
| Contact:   | Phone: 5088874523  
            | Email: lisa.freeman@tufts.edu |
| Reporter Wants to Remain Anonymous: | No |
| Permission To Contact Sender: | Yes |
| Preferred Method Of Contact: | Email |
| Reported to Other Parties: | Unknown |

Additional Documents:

FOUO- For Official Use Only
# Report Details - EON-355703

**ICSR:** 2049063  
**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:** 2018-06-06 07:53:32 EDT

**Reported Problem:**

**Problem Description:** Possible diet-associated DCM 4health Grain-Free Large Breed Formula Adult Dog Food. Owner was asked to save food. Plasma taurine B6 (ref range 60-120), WB taurine B6 (ref range 200-350) DCM diagnosed by echocardiography.

**Date Problem Started:** 05/29/2018  
**Concurrent Medical Problem:** Unknown  
**Outcome to Date:** Unknown

**Product Information:**

**Product Name:** 4health Grain-Free Large Breed Formula Adult Dog Food  
**Product Type:** Pet Food  
**Lot Number:**  
**Package Type:** BAG  
**Possess Unopened Product:** Unknown  
**Possess Opened Product:** Yes  
**Product Use Information:**  
**Stopped After the Onset of the Adverse Event:** Unknown

**Manufacturer/Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**

**Name:**  
**Type Of Species:** Dog  
**Type Of Breed:** Unknown  
**Gender:** Unknown  
**Reproductive Status:** Unknown  
**Assessment of Prior Health:** Unknown  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1

**Owner Information:**  
**Owner Information provided:** Yes  
**Name:**  
**Phone:** B6  
**Email:**  
**Address:** B6 United States

**Healthcare Professional Information:**

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<td>Email</td>
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<td>Unknown</td>
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Additional Documents:
## Radiology Request & Report

**Patient**
- Name: B6
- Species: Canine
- Gray/Black Male (Neutered)
- Caucasian Shepherd Dog
- Birthdate: B6

**Owner**
- Name: B6

**Attending Clinician**
- B6

**Student:**

**Date of exam:** 05/29/2018

**Patient Location:** Ward/Cage: ICU R1

**Weight (kg):** 62.00

### Sedation
- □ BAG
- □ OBAG
- □ 1/2 dose OBAG
- □ Dexdomitor/Butorphanol
- □ Anesthesia to sedate/anesthetize

**Emgerncy**

**Presenting Complaint and Clinical Questions you wish to answer:**

**Emergency**

**Pertinent History:**

- Gyo MC K9 presenting for 2wk hx of ough, presented for increased RR/RE. Poss dilated LV on flash, presumptive DCM on ER US

### Findings

- B6
Conclusions:
- Moderate left-sided cardiomegaly with left atrial enlargement, venous distension and cardiogenic pulmonary edema consistent with left-sided heart failure. Echocardiogram is recommended for further evaluation. Follow up radiographs are recommended to monitor response to treatment.

Radiologists
Primary: [B6]
Reviewing:

Dates
Reported: 5/29/18
Finalized:
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), DACVIM

Cardiology Resident: B6
Cardiotherapists: B6

Student: B6 1'19

Admit Date: B6 11:24:19 AM
Discharge Date: B6

Diagnoses:
Dilated cardiomyopathy (DOM) with congestive heart failure.

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 (DOM). 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 DOM 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.

Lab work 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 of B6 if difficulty breathing is not improved by within 30-60 minutes after giving B6. 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 website (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:

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 Cardiologist liaison at (508) 887-4696 or email us at cardiac.vet@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/vms/clinical-studies

Case: _B6_  Owner: _B6_  Discharge Instructions
Cardiology Consultation

Date: B6
Weight: Weight (kg) 71.60
Requesting Clinician: Unassigned Clinician

Attending Cardiologist:
☑ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

Cardiology Resident:

Thoracic radiographs available for review?
☑ Yes - in SS
☑ Yes - in PACS
☑ No - CD in ER and ER email

Patient location: ER
Presenting complaint and important concurrent diseases:
1 mo history of resp distress, worse in past week
no coughing
decreased energy level and appetite, increased thirst
litter mate diagnosed with DCM
CBC, chem, taurine done at rDVM - haven’t gotten records yet (Taurine was: B6 done at UCD)

Current medications and doses:

At-home diet: Was on Taste of the Wild grain free diet
Switched to Purina Proplan Sensitive skin and stomach 1 month ago

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.)
Afilib on EKG
Decreased contractility on TFAST

Is your consult time-sensitive? (e.g., anesthesia today, owner waiting, trying to get biopsy today)
**Physical Examination**

**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:** Left apical murmur

**Jugular vein:**
- Bottom 1/3 of the neck
- Middle 1/3 of the neck
- Top 2/3 of the neck
- 1/2 way up the neck

**Arterial pulses:**
- Weak
- Fair, variable
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other (describe):

**Arrhythmia:**
- None
- Sinus arrhythmia
- Premature beats
- Bradycardia
- Tachycardia

**Gallop:**
- Yes
- No
- Intermittent
- Pronounced
- Other:

**Pulmonary assessments:**
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary crackles
- Wheezes
- Upper airway stridor
- Other auscultatory findings:

**Abdominal exam:**
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

*STOP - remainder of form to be filled out by Cardiology*
Echocardiogram Findings:

B6

Mitral inflow:
- E waves only - atrial fibrillation
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

ECG findings:

B6

Assessment and recommendations: Findings consistent with advanced DCM with active CHF. Severe LV dilation with systolic dysfunction is observed. B6 sustained-release and keep patient under telemetry monitoring during hospitalization to evaluate response to treatment; likely add B6 since the dog is having some ventricular ectopy. As systemic arterial pressure was estimated at 90mmHg in the echo, recommend check blood pressure. Recommend check kidney levels in daily basis during hospitalization. As patient has hx of grain free diet, Taurine supplementation may be worthwhile, despite prior normal taurine level.

Treatment plan:

B6

Final Diagnosis:
Advanced DCM with active heart failure; atrial fibrillation with rapid ventricular response, less frequent VPCs.
Moderate pleural effusion and ascites.

Heart Failure Classification Score:
ISACHC Classification:
- la
- lb
- II

ACVIM CHF Classification:
- A
- B1
- B2

- IIa
- IIb
- C
- D
Discharge Instructions

Patient
Name: B6
Species: Canine
Black Male (Neutered) Great Dane
Birthdate: B6

Owner
Name: B6
Address: B6

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

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.

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B6

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Case: Owner: Discharge Instructions: B6 B6
B6 TREATMENT SHEET

Patient: B6
Species: canine
Breed: Great Dane
Color: Black
Rabies Due: Collar on collar

IVF: Type _______ 
Rate _______ (Maintenance Rate = _______ mL/hr)

Alerts: Dog Aggressive 
Problem/DDx: CHF, Arrhythmia

Weight: 106.5 lbs

Diet: bland

TREATMENT

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NURSING NOTES ON OTHER SIDE OF TREATMENT SHEET

CHANGES FOR FOLLOWING DAY

Oxygen Time

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Room Air (20.5% - 22.5%)

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Oxygen Settings

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Written by:
Patient: B6
Species: Canine
Breed: Great Dane
Color: Black
Rabies Due: 
Sex: MM

IVF: Type: __ __ __ __ __ __ Rate: __ __ __ __ __ __ __ ml/hr

Alerts: Dog Aggressive
Problem/Dx: CHE, Atrial Fibrillation

Diet: __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ ___
Cardiology Consultation

Date: B6
Weight: Weight (kg) 20.40
Patient location: ICU 02
Requesting Clinician: B6 DVF (Emergency and Critical Care Resident)

Attending Cardiologist:
- John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

Cardiology Resident:
- B6

Thoracic radiographs available for review?
- Yes - in SS
- Yes - in PACS
- No

Presenting complaint and important concurrent diseases: Cough, cardiomegaly and pulmonary edema on rDVM rads

Current medications and doses:

*STOP - remainder of form to be filled out by Cardiology*

Physical Examination

Muscle condition:
- Normal
- Moderate cachexia
- Mild muscle loss
- Marked cachexia

Cardiovascular Physical Exam
Murmur Grade:
- None
- I/VI
- II/VI
- IV/VI
- II/VI
- VI/VI

FDA-CVM-FOIA-2019-1704-011820
Murmur location/description: systolic left apical

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3 of neck

Arterial pulses:
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other (describe): 

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

Gallop:
- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary Crackles
- Wheezes
- Upper airway stridor
- Other auscultatory findings:

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

Echocardiogram Findings:

Mitral inflow:
- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

B6
ECG findings:

**B6**

Assessment and recommendations:

Echocardiogram reveals dilated LV cavity with decreased contractile function and LAE, with DCM-like changes and secondary CHF, although the LV walls are not thinner than normal. This may be early DCM or cardiomyopathy secondary to myocarditis vs primary cardiomyopathy. Aortic velocity is slightly increased, which is not typical of DCM, but no other defects are visible that would result in increased stroke volume. Recommend submitting CBC and chemistry. Recommend continuing if patient is eating well and not azotemic. Given the somewhat unusual appearance of pulmonary edema could consider recheck thoracic radiographs after treatment. However, patient has had a positive response to and radiographs may not be essential at this time. Given the young age, atypical breed, and non-traditional diet (kangaroo and lentil) recommend submitting taurine levels (serum and whole blood) or supplementing with taurine. If there is a travel history outside of New England could consider testing for Chagas disease. Recheck exam and renal values in 10-14 days. Recheck echo in 3-4 months.

Recheck appointment scheduled with cardiology on Tuesday August 2nd at 11AM. Please call 508 897 4696 if need to reschedule.

Treatment plan:

**B6**

Final Diagnosis:

DCM vs. cardiomyopathy (primary vs. secondary to myocarditis) with secondary CHF
Mild PHF

Heart Failure Classification Score:

ISACHC Classification:
- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM CHF Classification:
- A
- B1
- B2
- C
- D
M-Mode
IVSd
LV1Dd
LVPWd
IVSs
LV1Ds
LVPWs
%FS
Ao Diam
LA Diam
LA/Ao
Max LA
EPSS

M-Mode Normalized
IVSdN
LV1DdN
LVPWdN
IVSsN
LV1DsN
LVPWsN
Ao Diam N
LA Diam N

2D
SA LA
Ao Diam
SA LA/Ao Diam
IVSd
LV1Dd
LVPWd
EDV(Teich)
IVSs
LV1Ds
LVPWs
ESV(Teich)
EF(Teich)
%FS
SV(Teich)

Doppler
MR Vmax
MR maxPG
MV E Vel
MV Dec T
MVA Vel
MV E/A Ratio
E'
A'

B6

(0.29 - 0.52)
(1.35 - 1.73)
(0.33 - 0.53)
(0.43 - 0.71)
(0.79 - 1.14)
(0.53 - 0.78)
(0.68 - 0.89)
(0.64 - 0.90)

m/s
mmHg
m/s
ms
m/s
m/s
E/E'  
PV Vmax  
PV maxPG  
AV Vmax  
AV maxPG  
TR Vmax  
TR maxPG
Cardiology Appointment Report

Date: B6

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

Cardiology Resident: B6

Cardiology Technician: B6

Student: B6 V'18

Presenting Complaint: Recheck of historical DCM (diagnosed 7/22/16)

Concurrent Diseases: None

General Medical History:
Dx with DCM-like changes, secondary CHF, mild PHT 7/22/16. Taurine levels sent out due to concern for taurine deficiency as the cause, but levels were elevated.

B6 has been doing well since his last visit, however, he started coughing at night a few weeks ago. Lasted for around 10 days. Coincided with when owner was out of town and her husband was giving B6 his meds. Concerned that he may have been giving the wrong amounts. Additional B6 were not given when he was coughing. Since owner has returned and B6 is definitely on his regular schedule, coughing has subsided and he is doing well. No exercise intolerance. Good appetite.

Diet and Supplements:
Hill's Chicken and Rice ideal balance kibble (on Heartsmart website) - 1.5 cups BID
Gets frozen carrots and other veggies as treats

Cardiovascular History:
Prior CHF diagnosis? yes
Prior ATE? no
Prior arrhythmia? no
Cough? occasional when possibly not getting all of his meds
Shortness of breath or difficulty breathing? no
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? no
Prior heart murmur? yes, intermittent I/VI holosystolic left basilar on last PE

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

Murmur location/description: L systolic basilar

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of neck
Arterial pulses:
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficit
- Pulsus paradoxus
- Other:

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

Gallop:
- Yes
- No
- Intermittent
- Pronounced
- Other:

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

Abdominal exam:
- Normal/tense
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:
(1) Hx DCM (primary vs secondary to myocarditis) with secondary CHF
(2) Hx mild PHT

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

Echocardiogram Findings:
General/2-D findings:
*Echocardiogram performed standing. Do not put on table. Does not like abdomen touched*
LV cavity is mildly dilated with mildly reduced contractile function (better side to side motion); improved from previous exam. The LA is normal to at most mildly dilated. MV is mildly thickened. The RH is mildly dilated. No pericardial or pleural effusion.

Doppler findings:
Elevated aortic velocity.

Assessment and recommendations:
Echocardiogram reveals continued improvement in contractile function and reduced LV and LA chamber dimensions. Patient is doing well at home, so recommend
radiographs and echo. Otherwise recheck echo in 6 months, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance.

**Final Diagnosis:**
DCM (primary vs. secondary to myocarditis) with history of secondary CHF - improved echocardiographic measurements today.

**Heart Failure Classification Score:**

**ISACHC Classification:**
- **Ia**
- **Ib**
- **IIa**
- **IIb**

**ACVIM Classification:**
- **C**
- **D**

**M-Mode Normalized**
- IVSdN
- LVIDdN
- LVPWdN
- IVSsN
- LVIDsN
- LVPWsN

**2D**
- SA LA
- Ao Diam
- SA LA / Ao Diam
- IVSd
- LVIDd
- LVPWd
- EDV(Teich)
- IVSs
- LVIDs
- LVPWs
- ESV(Teich)
- EF(Teich)
- %FS
- SV(Teich)

**Doppler**
Cardiology Appointment Report

Date: B6

Attending Cardiologist:
- John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

Cardiology Resident:
- B6

Cardiology Technician:
- B6

Student: B6

Presenting Complaint:
History of DCM (7/22/2016) - 6 month recheck

Concurrent Diseases:
None

General Medical History:
Diagnosed with DCM and secondary CHF July 2016. Contractility and left ventricular size were improved at the last recheck in December.

No incidents of any breathing difficulties since last visit. Owner has been walking him early in the day, but one incident where he didn't want to walk as far when it was hot in the middle of the day. He sleeps most of the day but is happy to go outside and seems comfortable. Has a great appetite. Owner is monitoring respiratory rate at least every day with no increased rate or effort. Also has allergies that are managed by the rDVM.

Diet and Supplements:
Hill's Chicken and Rice ideal balance kibble (on Heartsmart website) - 1 cups BID (decreased as activity decreased)
Frozen peas and fresh carrots occasionally as treats
Gets medications in peanut butter

Cardiovascular History:
Prior CHF diagnosis? yes
Prior ATE? no
Prior arrhythmia? no
Cough? not since last time
Shortness of breath or difficulty breathing? not since last time
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? when warm outside
Prior heart murmur? Yes, intermittent I/VI holosystolic left basilar progressed to Grade II on last PE

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:
Murmur Grade:
- None
- I/VI
- II/VI
- III/VI

Murmur location/description: Left systolic at the base

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of 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
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary crackles
- Wheezes
- Upper airway stridor

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:
History of DCM with CHF - resolving

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

Assessment and recommendations:
Today's echocardiogram shows a heart with normal structures, which is very different from when the patient first presented for CHF 2 years ago. This suggests that the initial change were a result of an acute insult (infection, toxin, diet). Given the improvement seen, we will try to decrease medication doses slowly. Recheck echocardiogram in 6 months to see if the cardiac structure remains normal.

**Final Diagnosis:**
Normal cardiac structure, history of DCM with LCHF

**Heart Failure Classification Score:**

**ISACHC Classification:**
- □ Ia
- □ Ib
- □ II

**ACVIM Classification:**
- □ A
- □ B1
- □ B2
- □ C
- □ D
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<td>AV Vmax</td>
<td>m/s</td>
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B6

Cardiology Appointment Report

Date: B6

Attending Cardiologist:

John F. Bush DVM, MS, DACVM (Cardio/Int), DACVECC

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V18

Presenting Complaint:

Recheck of historical DCM (diagnosed 7/22/16)

Concurrent Diseases:

B6

General Medical History:

Presented to Tufts ER for exercise intolerance, shallow breathing, coughing, enlarged heart, and pulmonary edema on rDVM chest rads. Echo revealed DCM-like changes, secondary CHF, mild PHT.

Patient began d/c taurine supplementation. Taurine levels were sent out and were found to be elevated.

Recheck on B6, improved respiratory effort, no coughing. However, still some exercise intolerance. Ongoing taurine supplementation. Echo findings similar to before, visible enlargement of all heart chambers. Recheck on B6, some increased respiratory effort with cough. Mild progression of LV and LA dilation on echo, slightly increased contractile function. Due to vague painfulness was anaplasma positive. Treated with B6.

Communication with Tufts, inc r in the night sometimes with more coughing. We recommended increasing B6 from B6 to B6, doing much better on new medication doses. In the last 2 months, had extra B6 times overnight for coughing/increased effort. No exercise intolerance.
Diet and Supplements:
Hill's Chicken and Rice ideal balance kibble (on Heartsmart website) - 1.5 cups BID
Gets frozen carrots and other veggies as treats

Cardiovascular History:
Prior CHF diagnosis? yes
Prior ATE? no
Prior arrhythmia? no
Cough? no
Shortness of breath or difficulty breathing? occasional, resolves with extra dose of furosemide
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? no
Prior heart murmur? yes, II/VI holosystolic left apex

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
- None
- Mild muscle loss
- Normal
- 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: systolic left basilar, intermittent

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3 of neck

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

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

Gallp:
- Yes
- No
- Intermittent
- Pronounced
- Other:

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

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems and differential diagnoses:
Hx DCM (primary vs secondary to myocarditis) with secondary CHF
Hx mild PHT

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

Echocardiogram Findings:
General/2-D findings:
LV cavity is mildly dilated with mildly reduced contractile function (better side to side motion). The LA is mildly dilated. MV is mildly thickened. The RH is mildly dilated. No pericardial or pleural effusion.

Doppler findings:
- Trace MR
- AV Vmax 1.8 m/s
Mitral inflow:
- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

ECG findings:

Assessment and recommendations:
Echocardiogram reveals improvement in contractile function and reduced LV and LA chamber dimensions. The cause for improvement is unclear; owner change diet from kangaroo to chicken, but this change was made prior to previous exams. The only changes made since previous exam were an increase in B6 and B6. Patient is doing well at home, so recommend continuing current medications unless rechecking radiographs and echo. Otherwise recheck echo in 6 months, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance.

Final Diagnosis:
DCM (primary vs. secondary to myocarditis) with history of secondary CHF (pulmonary edema, suspected ascites) - improved echocardiographic measurements today.

Heart Failure Classification Score:

ISACHC Classification:
- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM Classification:
- A
- B1
- B2
- C
- D

M-Mode
- IVSd
- LV1Dd
- LVPWd
- IVSs
- LV1Ds
- LVPWs
- %FS
- Ao Diam
- LA Diam
- LA/Ao
- Max LA

M-Mode Normalized
- IVSdN
- LV1DdN
- LVPWdN

Final diagnosis: DCM (primary vs. secondary to myocarditis) with history of secondary CHF (pulmonary edema, suspected ascites) - improved echocardiographic measurements today.
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<th>Normal Range</th>
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<tr>
<td>LVIDsN</td>
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<td>LVPWsN</td>
<td>(0.53 - 0.78)</td>
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<tr>
<td>Ao Diam N</td>
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<td>LA Diam N</td>
<td>(0.54 - 0.90)</td>
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**2D**
- SV LA
- Ao Diam
- SA LA / Ao Diam
- IVSd
- LV1Dd
- LVPWd
- EDV(Teich)
- IVSs
- LV1Ds
- LVPWs
- ESV(Teich)
- ER(Teich)
- %FS
- SV(Teich)

**Doppler**
- MV E Vel
- MV DecT
- MV A Vel
- MV E/A Ratio
- E'
- A'
- E/E'
- PV Vmax
- PV maxPG
- AV Vmax
- AV maxPG

**Units**
- m/s
- ms
- ml
- %
Cardiology Appointment Report

Date: B6

Attending Cardiologist:

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

Cardiology Resident:

B6

Cardiology Technician:

B6, CVT, VTICardiology

Student: B6, V17

Presenting Complaint: Recheck generalized cardiomegaly with DCM-like changes, congestive heart failure

General Medical History:
In June 2016, B6 began coughing. rDVM thought possibly related to allergies. B6 also treated for at this time, B6 developed progressive lethargy and inappetence as well as exercise intolerance and shallow breathing pattern. Went back to rDVM where chest rads were performed. Enlarged heart and pulmonary edema were visualized. Patient was referred to Tufts ER and placed in O2. Echo was performed that demonstrated a dilated LV cavity with decreased contractility, LAE with DCM like changes, and CHF. Rule outs considered included early DCM and cardiomyopathy secondary to myocarditis. Due to patient age and atypical breed-recommended taurine levels be measured. Taurine levels both elevated. CBC/Chem showed a mildly elevated Ca but was otherwise within normal limits. Patient currently being managed on B6 supplement.

At home patient initially would not eat. Patient started all meds but B6 developed diarrhea and vomiting. Discontinued: B6. Vomiting stopped but diarrhea persisted. O returned to rDVM and got a on B6 for 7 days. O began feeding chicken thighs on B6 and patients appetite improved markedly. Now B6 is eating dry food very well. His activity level has improved dramatically increasing every day. Patient has not had any additional episodes of diarrhea while on B6. O would like to have some on hand. O reports no more coughing or increased respiratory effort rate, but there is still exercise intolerance. No syncope or collapse.
Diet and Supplements:
Owner has B6 but has not been giving it.

California Naturals (kangaroo and red lentil)- 2 cups 3x a day

Cardiovascular History:
Prior CHF diagnosis? Yes
Prior ATE? No
Prior arrhythmia? No
Cough? No coughing since prior visit, but there is a history of coughing
Shortness of breath or difficulty breathing? No residual shortness of breath following onset of meds
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? Yes
Prior heart murmur? Yes II/VI holosystolic left apex

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

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

Murmur location/description: Holosystolic, PMI left apex

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of neck

Arterial pulses:
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulse paradospus
- Other:

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

Gallop:
- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary cracks
- Wheezes
- Upper airway stridor

Abdominal exam: Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:
DCM-like changes with secondary CHF (rule out DCM or cardiomyopathy secondary to myocarditis)

**Diagnostic plan:**
- Echocardiogram (brief exam to view changes)
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests:

**Echocardiogram Findings:**

General/2-D findings:
Brief fluid check: No changes from previous exam.
Assessment and recommendations:
Patient is now doing well at home, improving every day with both appetite and energy. Renal values submitted today. Despite the young age and atypical breed, the echo findings are still consistent with DCM. Recommend continuing B6. Recommend trying to add B6 after recheck renal values to see if it is better tolerated than the B6 Taurine levels are normal.

Recommend recheck renal values at rDVM in 2-3 weeks. Redcheck echo and exam in 3-4 months, or sooner if clinical signs develop such as increase RR/RE, cough, collapse, or exercise intolerance.

Final Diagnosis:
DCM vs. cardiomyopathy (primary vs. secondary to myocarditis) with secondary CHF
Mild PHT

Heart Failure Classification Score:
ISACHC Classification:
- [ ] Ia
- [ ] Ib
- [x] IIIa
- [ ] IIIb

ACVIM Classification:
- [x] A
- [ ] B1
- [ ] B2

M-Mode
- [ ] LVd/LVd
- [ ] LVpWPD
- [ ] IVSs
- [ ] IVSd
- [ ] IVSs
- [ ] AOD
- [ ] LA Diam
- [ ] LA/Ao
- [ ] Mx LA

M-Mode Normalized
- [ ] LVd/LVd
- [ ] LVpWPD
- [ ] IVSs
- [ ] IVSd
- [ ] IVSs
- [ ] AOD
- [ ] LA Diam
- [ ] LA/Ao
- [ ] Mx LA

2D
- [ ] SA IA
- [ ] Ao Diam
- [ ] SA IA/Ao Diam

FDA-CVM-FOIA-2019-1704-011844
Cardiology Appointment Report

Date: B6

Attending Cardiologist: 

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

Cardiology Resident: B6

Cardiology Technician: B6 CVT, VTS(Cardiology)

Student: B6, V17

Presenting Complaint: Recheck for historically noted DCM and CHF

Concurrent Diseases: History of DCM and CHF

General Medical History:

Was doing "really, really well" until 2 weeks ago at which point he started having late night increases in respiratory effort with a cough; he had been given an extra ___ B6 ___ dose on two events during that week (had only had to do this once in the past 4 months previously); 1 week ago he went to his rDVM who recommended increasing ___ B6 ___ and that seems to have resolved the breathing issue and cough for the most part; he only had a very slight cough since increasing his furosemide. Owner reports rDVM said there seemed to be "fluid around kidneys and liver" last week via palpation (no US performed) and he weighed 5 more pounds last week at rDVM. Owner is concerned it was ascites; she reports before increasing ___ B6 ___ _ B6 ___ abdomen looked distended.

Activity has been decreased for the past week; less running than normal. He is sleeping more than he was prior to the last 2 weeks.

Until 2 weeks ago ___ B6 ___ has been a "crazy maniac" and was doing very well.

About a week ago ___ B6 ___ had an event that was either a ___ B6 ___ (per owner rDVM thinks it was a ___ B6 ___ ) he has not had a repeat episode and this had not happened before. ___ B6 ___ was normal both before and after this event.
**Diet and Supplements:**
Hill's Chicken and Rice ideal balance kibbles (on Heartsmart website); gets about 1.5 cups Q12
Treats are frozen peas and frozen green peas

**Cardiovascular History:**
Prior CHF diagnosis? Yes
Prior ATE? No
Prior arrhythmia? No
Cough? Yes, intermittent and then resolved with an increase in his
Shortness of breath or difficulty breathing? Yes, intermittent, resolved with increase in
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? Yes, decreased exercise when in the yard
Prior heart murmur? Yes II/VI holosystolic left apex

**Current Medications Pertinent to CV System:**

**Cardiac Physical Examination:**

**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: Left basilar systolic
Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of 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
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds- maybe somewhat increased
- Pulmonary crackles
- Wheezes
- Upper airway stridor

Abdominal exam: Very sensitive to cranial abdominal palpation once, but not repeatable; tense
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:
- DCM, CHF
- Increased respiratory effort and potential ascites over the last week with lethargy

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

ECG findings:

Assessment and recommendations:
Echocardiogram reveals mild progression in IV and IA dilation, but subjectively and numerically slightly increased contractile function. Given the episode last week that sounds like he had developed ascites +/- pulmonary edema, recommend continuing current B6 dose as long as renal values are stable. Patient has gained weight and dose is now a bit low, so recommend also increasing B6 dose. Patient seemed to have some vague discomfort that was difficult to localize, and has a history of multiple ticks this fall, 4dx was also submitted. Recheck echo and exam in 3-4 months, or sooner if clinical signs develop such as increase RR/RE, cough, collapse, or exercise intolerance.

Final Diagnosis:
DCM (primary vs. secondary to myocarditis) with secondary CHF (pulmonary edema, suspected ascites)
Mild PHT

Heart Failure Classification Score:
ISACHC Classification:
- Ia
- Ib
- II

ACVIM Classification:
- A
- B1
- B2

M-Mode:
- IVSd
- LVIDd
- LVPWd
- IVSs
- LVIDs
- LVPWs
- %FS
- Ao Diam
- LA Diam
- LA/Ao
- Max LA

M-Mode Normalized:
- IVSdN
- LVIDdN

Final diagnosis: DCM (primary vs. secondary to myocarditis) with secondary CHF (pulmonary edema, suspected ascites) Mild PHT
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<td>Ao Diam N</td>
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Cardiology Consultation

Date: B6
Weight: Weight (kg) 20.40
Patient location: ICU 02
Requesting Clinician: B6 DVF (Emergency and Critical Care Resident)

Attending Cardiologist:
☐ John F. Bush DVM MS DACVIM (Cardio) DACVECC

Cardiology Resident: B6

Thoracic radiographs available for review?
☐ Yes - in SS
☒ Yes - in PACS
☐ No

Presenting complaint and important concurrent diseases: Cough, cardiomegaly and pulmonary edema on rDVM rads

Current medications and doses: B6

*STOP - remainder of form to be filled out by Cardiology*

Physical Examination

Muscle condition:
☐ Normal
☐ Mild muscle loss
☐ Moderate cachexia
☐ Marked cachexia

Cardiovascular Physical Exam
Murmur Grade:
☐ None
☐ I/VI
☐ II/VI
☐ IV/VI
☐ V/VI
☐ VI/VI
Ill/VI

Murmur location/description: systolic left apical

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3 of neck

Arterial pulses:
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other (describe):

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

Gallop:
- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary crackles
- Wheezes
- Upper airway stridor
- Other auscultatory findings:

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

Echocardiogram findings:

B6

Doppler findings:

B6

Mitral inflow:
- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive
**ECG findings:**

B6

**Radiographic findings:**

rDVM radiographs- Moderate generalized cardiomegaly, LAE, diffuse interstitial to alveolar pattern. Pattern most likely consistent with cardiogenic pulmonary edema, but has a more milliary structure to it than typical.

**Assessment and recommendations:**

Echocardiogram reveals dilated LV cavity with decrease contractile function and LAE, with DCM-like changes and secondary CHF, although the LV walls are not thinner than normal. This may be a early DCM or cardiomyopathy secondary to myocarditis vs primary cardiomyopathy. Aortic velocity is slightly increased, which is not typical of DCM, but no other defects are visible that would result in increased stroke volume. Recommend submitting CBC and chemistry. Recommend continuing B6 if patient is eating well and not azotemic. Given the somewhat unusual appearance of pulmonary edema could consider recheck thoracic radiographs after B6 treatment. However, patient has had a positive response to B6 and radiographs may not be essential at this time. Given the young age, atypical breed, and non traditional diet (kangaroo and lentil) recommend submitting taurine levels (serum and whole blood) or supplementing with taurine. If there is a travel history outside of New England could consider testing for Chagas disease. Recheck exam and renal values in 10-14 days. Recheck echo in 3-4 months.

Reschedule appointment scheduled with cardiology on Tuesday August 2nd at 11AM. Please call 508 287 4696 if need to reschedule.

**Treatment plan:**

B6

**Final Diagnosis:**

DCM vs. cardiomyopathy (primary vs. secondary to myocarditis) with secondary CHF

Mild PHT

**Heart Failure Classification Score:**

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Discharge Instructions

Patient ID: B6

Name: B6

Species: Canine

White/Brown Male (Neutered) Beagle

Address: B6

Birthday: B6

Attending Cardiologist:

John F. Rush, DVM, MS, DACVIM (Cardiology), DACVIM (Cardiology)

Cardiology Resident:

B6

Student: B6  M19

Cardiology Technician:

B6

Admit Date: 6/13/2018 2:23:44 PM
Discharge Date: 6/13/2018

Diagnoses: Dilated cardiomyopathy (DCM) with history of congestive heart failure - improving.

Clinical Findings:

Thank you for entrusting us with B6. B6 looked great on physical exam today. We performed an echocardiogram, and as with the last visit, there continues to be improvement. B6 heart chambers have reduced to a normal size, and his contractility is that of a normal heart at this time.

As B6 is doing well, we would like to decrease the amount of B6 he is on. Instead of receiving B6 B6, please follow the instructions below. We are going to slowly reduce his other medication as well. Please refer to the schedule listed below.

Monitoring at Home:

You have been doing a wonderful job taking care of B6 at home, and we are very happy to hear that you have been able to monitor his respiratory rate and effort. Please continue to do this as you have been doing, especially as we have decreased his B6 dose. Since we are going to try to reduce B6 heart medications, please record B6 heart rate, respiratory rate and effort at least once in the morning and once at night. Around June 28th, please contact our Cardiology liaison B6 at B6 or email us at cardiology@tufts.edu to let us know how B6 is doing. It is likely most helpful if you can email us your recordings. At that point, we will discuss further reductions in his medications. We will likely continue this pattern (monitoring for 2 weeks and adjusting doses) until we have reached a level where B6 is receiving the minimum medications necessary to allow him to continue to do well.
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.

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.

**Diet Suggestions:** **B6** should continue to eat his current diet. Vegetables are a great treat for trying to lose weight. Your regular veterinarian can help manage the amount he eats to ensure he is at a healthy weight. Losing weight may make **B6** more energetic and will help him to stay healthy and happy longer.

**Exercise Recommendations:** Please continue to allow **B6** to set his limitations for exercise, as you have been doing. It seems as though the morning walks you have been taking with him are a good level for him, but if he becomes more exercise intolerant, the length may need to be reduced.

**Recommended Medications:**

![B6]

**Recheck Visits:** Since **B6** is doing so well, we would like to start reducing his heart medications. Please return in 6 months for a recheck echocardiogram.

Thank you for entrusting us with **B6** care. He is a very sweet boy, and we are very happy that he has been doing so well! Please contact our Cardiology liaison **B6** at **B6** or email us at cardiology@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 (608-885-4629) 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/cvm/cclinical-studies
Diagnoses: Dilated cardiomyopathy (DCM) with history of congestive heart failure

Clinical Findings: Thank you for bringing B6 in today for his recheck with Tufts Cardiology. B6 was looking great on examination today. No murmur was heard today. The chambers of B6 heart are smaller than in the past, and his heart's contractile function is stable to improved. We also drew blood to see how B6 is tolerating his medications. We will call you later today or tomorrow with the results of this test.

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 to 40 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.
- 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.

Diet Suggestions: B6 should continue to eat his current diet.
**Recommended Medications:**

**No changes at this time**

**B6**

**Redcheck Visits:** We recommend a recheck in about 6 months. However, if you have any concerns in the meantime, please let us know as he may need to be seen sooner.

Thank you for allowing us to participate in care. He is such a sweet boy and we are so glad he is doing so well!

Please visit our HeartSmart website for more information

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

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| Case | B6 | Owner | B6 | Discharge Instructions |
Discharge Instructions

Patient Name: B6
Owner Name: B6
Patient ID: B6
Species: Canine
White/Brown Male (Neutered) Beagle
Cross: B6
Birthday: B6

Attending Cardiologist:
[ ] John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

Cardiology Resident:

Cardiology Technician: B6 CVT, VTS(Cardiology)

Date: 3/2/2016

Diagnoses: Dilated cardiomyopathy (DCM) with history of congestive heart failure

Clinical Findings:

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. However, B6 breed, age, and clinical signs are somewhat typical for this disease. Significant arrhythmias, which can be life-threatening, can be associated with DCM, but at this stage B6 has not been having arrhythmia.

Today we rechecked B6 blood work to determine if he is tolerating his medications. We will call you with these results. Because B6 is not the typical breed or age of dog to develop DCM, we also took another quick look at B6 heart via echocardiogram today. The echocardiogram findings were very similar to his previous examination, with visible enlargement of all heart chambers. Low taurine levels have been associated with DVM, but B6 taurine levels came back yesterday, and are within normal limits.

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 to 40 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.
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/).

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.

**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/)

Your dog's usual diet may also have more sodium than recommended - we want him to continue to eat his normal diet until we are 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.). Hopefully you can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

The HeartSmart web site also has some information on supplements such as fish oil, taurine, and other supplements that you might have questions about.

**Exercise Recommendations:**
Now that B6 heart failure is better controlled, 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 with your primary care veterinarian is recommended in 1-2 weeks to recheck kidney values. If his blood work
is normal at that time we recommend increasing the [B6] twice daily.
A recheck echocardiogram is recommended in 3-4 months. We have scheduled a recheck for Thursday December 8th at 10AM. Please call or email if you need to change this appointment or if you have any concerns.

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

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FDA-CVM-FOIA-2019-1704-011863
Discharge Instructions

Patient:
Name: B6
Species: Canine
White/Brown Male (Neutered) Beagle
Cross
Birthday: B6

Owner:
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
[ ] John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

Cardiology Resident:

Student:
B6
V17

Cardiology Technician:
B6
CVT, VT(Cardiology)

Date: 12/8/2016

Diagnoses: Dilated cardiomyopathy (DCM) with history of congestive heart failure

Clinical Findings: Thank you for bringing [B6] in today for his recheck with Tufts Cardiology. You report that [B6] had been doing well until two weeks ago when he started experiencing an increase in respiratory effort and a cough. His [B6] was increased to [B6] every 8 hours by his primary veterinarian and you report this has resolved [B6] respiratory difficulty. His activity level has decreased and he is sleeping more than usual, but he has maintained a good appetite. You report that [B6] had a single episode of [B6] that may have been a [B6] he remained standing during this event and was normal both before and after this episode.

On examination today, [B6] heart sounds the same as his last exam. His heart appears stable on echocardiogram; the chambers of his heart are very mildly more dilated than they were previously, but his heart's contractile function remains stable. We did not identify any pleural effusion (fluid in the chest) or ascites (free fluid in the abdomen). We also drew blood to assess [B6] renal values since his furosemide dose has been increased; we will call you later today or tomorrow with the results of this test.

We also submitted his blood for a test called a 4DX test to see if [B6] may be experiencing a [B6] illness as he seemed potentially painful during his echocardiogram. You report that [B6] has also been sensitive to touch on his abdomen when he is sleeping for about a month and that in July he tested strongly positive for an [B6] infection.

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 to 40
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.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts Heart Smart website (http://vet.tufts.edu/heartsmart/).
- 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 a day.
- Please continue to monitor B6 for any repeated episodes of facial twitching or seizures. If this occurs again B6 should be evaluated by a veterinarian.

Diet Suggestions: Please continue to feed B6 his current diet. You can also continue to feed B6 frozen peas as a treat.

Exercise Recommendations: Try to limit B6 activity to short leashed walks until he is feeling better. 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, but we do want B6 to enjoy life and have fun.

Recommended Medications:

**B6**

Recheck Visits: A recheck appointment and echocardiogram is recommended in 3-4 months as long as B6 is doing well. You can reach the cardiology liaison B6 at B6 to schedule this appointment.

Thank you for entrusting us with the care of B6. He is a great dog and it was nice to see you both today.

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:
To ensure your pet food is in stock, please call 7-10 days in advance at 508-887-4629. Alternatively, foods can be ordered through www.chewy.com or www.jefooddirect.com.

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/cvm/clinical-studies

Case: B6  Owner: B6  Discharge Instructions
Discharge Instructions

Patient:
Name: B6
Species: Canine
White/Brown Male (Neutered) Beagle
Cross
Birthdate: B6

Owner:
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
• John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

Cardiology Resident:
B6

Student:
B6

Cardiology Technician:
B6

Date: 12/8/2017

Diagnoses: Dilated cardiomyopathy (DCM) with history of congestive heart failure.

Clinical Findings: Thank you for bringing B6 in today for his recheck with Tufts Cardiology. B6 looked great on examination today, and his echocardiogram continues to be improved. The chambers of B6's heart are smaller than in the past, and his heart's contractile function is improved. We also drew blood to see how B6 is tolerating his medications, and his bloodwork is normal today. This means that he is tolerating his current medications and no changes are required. His heart looks good enough that it seems like you could remove his mid day dose of B6, but since his blood work looks great and he is feeling great no changes are clearly necessary at this time.

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 of less than 35 to 40 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.
• 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.

Diet Suggestions: B6 should continue to eat his current diet.

Recommended Medications:

B6

Recheck Visits: We recommend a recheck in about 6 months. However, if you have any concerns in the meantime, please let us know as he may need to be seen sooner. Please call or email (508 887 4696 or cardiovet@tufts.edu) to schedule this appointment.

Thank you for allowing us to participate in B6 care. He is such a good boy and we are so glad he is doing so well!

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/veme/clinical-studies

Case: B6  Owner: B6  Discharge Instructions
Discharge Instructions

Case summary

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, although B6 did not show any signs of arrhythmia.

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.

DCM can be the consequence of taurine deficiency. Given the age and the breed of B6, we can't rule out this possibility. A dosage of taurine has been sent and we are expecting the results in 10 to 15 days. Meanwhile, B6 will be treated for this deficiency, the treatment is harmless.

Diagnosis:
1. Dilated cardiomyopathy (DCM)
2. Taurine deficiency: Results pending

Diagnostic test results and findings:

- Chest radiograph (x-ray) findings: Moderate generalized cardiomegaly, left atrial enlargement, diffuse interstitial to alveolar pattern.
- Echocardiogram findings: All chambers of the heart are enlarged and there is a leak at the mitral valve.
ECG findings: The ECG showed no arrhythmia with a heart rate between 120 and 130 bpm.
Labwork findings: The kidney values are within normal limits.

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 to 40 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 B6, 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/).
- 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/)

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.). Hopefully you can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.
The HeartSmart website also has some information on supplements such as fish oil, taurine, and other supplements that you might have questions about.

**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 the dog 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:**
Recheck appointment scheduled with cardiology on Tuesday August 2nd at 11AM. Please call 508-297-4696 if need to reschedule.
At this visit we will check your dog's breathing effort and heart function, do a blood test to recheck kidney values, and probably recheck a blood pressure. A recheck echocardiogram is recommended in 3-4 months.

Please visit our HeartSmart website for more information
http://vet.tulc.edu/heartsmart/

Thank you for bringing us [B6] he is a very cute dog. If you have any questions or concern, please e-mail me (tulc.edu) or feel free to contact our emergency service 24/7: 508-839-5395.

---

Case: [B6] Owner: [B6] Discharge Instructions:
Cardiology Appointment Report

Date: 12/8/2017

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V18

Presenting Complaint: Recheck of historical DCM (diagnosed B6)

Concurrent Diseases: None

General Medical History:

Dx with DCM-like changes, secondary CHF, mild PHT. Taurine levels sent out due to concern for taurine deficiency as the cause, but levels were elevated.

B6 has been doing well since his last visit, however, he started coughing at night a few weeks ago. Lasted for around 10 days. Coincided with when owner went out of town and her husband was giving B6 his meds- concerned that he may have been giving the wrong amounts. Additional B6 were not given when he was coughing. Since owner has returned and B6 is definitely on his regular schedule, coughing has subsided and he is doing well. No exercise intolerance. Good appetite.

Diet and Supplements:

Hill's Chicken and Rice ideal balance kibble (on Heartsmart website) - 1.5 cups BID
Gets frozen carrots and other veggies as treats

Cardiovascular History:
Prior CHF diagnosis? yes
Prior ATE? no
Prior arrhythmia? no
Cough? occasional when possibly not getting all of his meds
Shortness of breath or difficulty breathing? no
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? no
Prior heart murmur? yes, intermittent I/VI holosystolic left basilar on last PE

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:
Murmur Grade:
- None
- I/VI
- II/VI
- III/VI
- IV/VI

Murmur location/description: Holosystolic basilar

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of neck
Arterial pulses:
- Weak
- Fair
- Good
- Strong

Arrhythmia:
- None
- Sinus arrhythmia
- Premature beats

Gallop:
- Yes
- No
- Intermittent

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

Abdominal exam:
- Normal/tense
- Hepatomegaly
- Abdominal distension

Problems:
1. Hx DCM (primary vs secondary to myocarditis) with secondary CHF
2. Hx mild PHT

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

Echocardiogram Findings:

B6

Assessment and recommendations:
Echocardiogram reveals continued improvement in contractile function and reduced LV and LA chamber dimensions. Patient is doing well at home, so recommend
continuing current medications unless blood work indicates need for reduction, in which case the mid day dose of \[\text{B6}\] could be removed. The size of the LA does not suggest that \[\text{B6}\] should be required, so if owner has frequent concerns regarding need for \[\text{B6}\] then recommend rechecking radiographs and echo. Otherwise recheck echo in 6 months, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance.

**Final Diagnosis:**
DCM (primary vs. secondary to myocarditis) with history of secondary CHF - improved echocardiographic measurements today.

**Heart Failure Classification Score:**

**ISACHC Classification:**
- la
- lb
- M-Mode
- IVSd
- M-Mode NORM:

**ACVM Classification:**
- LVWd
- IVSd
- LVd
- LVpWd
- IVSs
- LVd
- LVpWs
- %FS
- Max LA

**M-Mode Normalized**
- IVSdN
- LVId DN
- LVpWdN
- IVSsN
- LVId sN
- LVpWsN

2D
- SA LA
- Ao Diam
- SA LA / Ao Diam
- IVSd
- LVId d
- LVpWd
- EDV(Teich)
- IVSs
- LVIDs
- LVpWs
- ESV(Teich)
- EF(Teich)
- %FS
- SV(Teich)

Doppler
Cardiology Appointment Report

Date: 12/8/2017

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V18

Presenting Complaint: Recheck of historical DCM (diagnosed B6)

Concurrent Diseases: None

General Medical History:
Dx with DCM-like changes, secondary CHF, mild PHT B6 Taurine levels sent out due to concern for taurine deficiency as the cause, but levels were elevated.

B6 has been doing well since his last visit, however, he started coughing at night a few weeks ago. Lasted for around 10 days. Coincided with when owner went out of town and her husband was giving B6 his meds, concerned that he may have been giving the wrong amounts. Additional B6 were not given when he was coughing. Since owner has returned and B6 is definitely on his regular schedule, coughing has subsided and he is doing well. No exercise intolerance. Good appetite.

Diet and Supplements:
Hill's Chicken and Rice ideal balance kibble (on Heartsmart website) - 1/2 cups BID
Gets frozen carrots and other veggies as treats

Cardiovascular History:
Prior CHF diagnosis? yes
Prior ATE? no
Prior arrhythmia? no
Cough? occasional when possibly not getting all of his meds
Shortness of breath or difficulty breathing? no
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? no
Prior heart murmur? yes, intermittent I/VI holosystolic left basilar on last PE

Current Medications: Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:
Murmur Grade:
- None
- I/VI
- II/VI
- III/VI

Murmur location/description: Systolic basilar

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of neck
Arterial pulses:
- Weak
- Fair
- Good
- Strong

Arrhythmia:
- None
- Sinus arrhythmia
- Premature beats

Gallop:
- Yes
- No
- Intermittent

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

Abdominal exam:
- Normal/tense
- Hepatomegaly
- Abdominal distension

Problems:
1. Hx DCM (primary vs secondary to myocarditis) with secondary CHF
2. Hx mild PHF

Diagnostic plan:
- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin
- Other tests:

Echocardiogram Findings:

- B6

Assessment and recommendations:
Echocardiogram reveals continued improvement in contractile function and reduced LV and LA chamber dimensions. Patient is doing well at home, so recommend
continuing current medications unless blood work indicates need for reduction, in which case the mid day dose B6 could be removed. The size of the LA does not suggest that B6 should be required, so if owner has frequent concerns regarding need for (B6) then recommend rechecking radiographs and echo. Otherwise recheck echo in 6 months, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance.

Final Diagnosis:
DCM (primary vs. secondary to myocarditis) with history of secondary CHF - improved echocardiographic measurements today.

Heart Failure Classification Score:

ISACHC Classification:

ACVM Classification:

M-Mode Normalized

2D

Doppler
Cardiology Appointment Report

Date: 6/13/2018

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Student:
B6

Presenting Complaint:
History of DCM (B6) - 6 month recheck

Concurrent Diseases:
None

General Medical History:
Diagnosed with DCM and secondary CHF July 2016. Contractility and left ventricular size were improved at the last recheck in December.

No incidents of any breathing difficulties since last visit. Owner has been walking him early in the day, but one incident where he didn't want to walk as far when it was hot in the middle of the day. He sleeps most of the day but is happy to go outside and seems comfortable. Has a great appetite. Owner is monitoring respiratory rate at least every day with no increased rate or effort. B6 also has allergies that are managed by the rDVM.

Diet and Supplements:
Hill's Chicken and Rice ideal balance kibble (on Heartsmart website) - 1 cups BID (decreased as activity decreased)
Frozen peas and fresh carrots occasionally as treats
Gets medications in peanut butter

Cardiovascular History:
Prior CHF diagnosis? yes
Prior ATE? no
Prior arrhythmia? no
Cough? not since last time
Shortness of breath or difficulty breathing? not since last time
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? when warm outside
Prior heart murmur? Yes, intermittent I/VI holosystolic left basilar progressed to Grade II on last PE

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
☐ Normal
☐ Mild muscle loss
☐ Moderate cachexia
☐ Marked cachexia

Cardiovascular Physical Exam:
Murmur Grade:
☐ None
☐ I/VI
☐ II/VI
☐ III/VI
☐ IV/VI

Murmur location/description: Left systolic at the base

Jugular vein:
☐ Bottom 1/3 of neck
☐ Middle 1/3 of neck
☐ Top 2/3rd of neck
Arterial pulses:
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other:
  - Bradycardia
  - Tachycardia

Arrhythmia:
- None
- Sinus arrhythmia
- Premature beats
- Pronounced
- Other:

Gallop:
- Yes
- No
- Intermittent

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary cracks
- Wheezes
- Upper airway stridor

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:
History of DCM with CHF - resolving

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:
- Summatized
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

Assessment and recommendations:
Today’s echocardiogram shows a heart with normal structures, which is very different from when the patient first presented for CHF 2 years ago. This suggests that the initial change were a result of an acute insult (infection, toxin, diet). Given the improvement seen, we will try to decrease medication doses slowly. We will first decrease his [B6] and if he continues to do well, decrease the [B6] and eventually stopping the [B6] if he continues to do well with each decrease in medication. Recheck echocardiogram in 6 months to see if the cardiac structure remains normal.

Final Diagnosis:
Normal cardiac structure, history of DCM with LCHF

Heart Failure Classification Score:
ISACHC Classification:
- Ia
- Ia
- Ib
- II

ACVIM Classification:
- A
- B
- B
- D

M-Mode
- IVSd
- LVIDd
- LVPWd
- IVSs
- LVIDs
- LVPWs
- %FS
- Ao Diam
- LA Diam
- LA/Ao
- Max LA

2D
- Ao Diam
- IVSd
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- LVPWd
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Cardiology Appointment Report

Date: 6/22/2017

Attending Cardiologist:
[ ] John F. Rush DVM, MS, DACVIM (Cardiology), DACVECC

Cardiology Resident: B6

Cardiology Technician: B6

Student: B6 V18

Presenting Complaint: Recheck of historical DCM (diagnosed) B6

Concurrent Diseases: B6

General Medical History:
Presented to Tufts EII B6 for exercise intolerance, shallow breathing, coughing, enlarged heart, and pulmonary edema on rDVM chest x-rays. Echo revealed DCM-like changes, secondary CHF, mild PHT. Patient began B6 taurine levels were sent out and were found to be elevated.
Recheck on 8/2/16, improved respiratory effort, no coughing. However, still some exercise intolerance. O/d/c taurine supplementation. Echo findings similar to before, visible enlargement of all heart chambers. Recheck on 12/8/16, some increased respiratory effort with cough. Mild progression of LV and LA dilation on echo, slightly increased contractile function. Increased B6 due to vague painfulness was anaplasma positive. Treated with doxy.
Communication 2/8/17 with Tufts, inc r in the night sometimes with more coughing. We recommended increasing B6 doing much better on new medication doses. In the last 2 months, had extra B6 3 times overnight for coughing/increased effort. No exercise intolerance.
Diet and Supplements:
Hill's Chicken and Rice ideal balance kibble (on Heartsmart website) - 1.5 cups BID
Gets frozen carrots and other veggies as treats

Cardiovascular History:
Prior CHF diagnosis? yes
Prior ATE? no
Prior arrhythmia? no
Cough? no
Shortness of breath or difficulty breathing? occasional, resolves with extra dose of furosemide
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? no
Prior heart murmur? yes, II/VI holosystolic left apex

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

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: systolic left basilar, intermittent

Jugular vein:
- □ Bottom 1/3 of neck
- □ Middle 1/3 of neck
- □ Top 2/3 of 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
- □ Mild dyspnea
- □ Marked dyspnea
- □ Normal BV sounds
- □ Pulmonary cracks
- □ Wheezes
- □ Upper airway stridor

Abdominal exam:
- □ Normal
- □ Hepatomegaly
- □ Abdominal distension
- □ Mild ascites
- □ Marked ascites

Problems and differential diagnoses:
Hx DCM (primary vs secondary to myocarditis) with secondary CHF
Hx mild PHT
Moderate ceruminous discharge AS, erythematous pinnae All r/o otitis externa

Diagnostic plan:
- □ Echocardiogram
- □ Chemistry profile
- □ ECG
- □ Renal profile
- □ Blood pressure
- □ Dialysis profile
- □ Thoracic radiographs
- □ NT-proBNP
- □ Troponin I
- □ Other tests:

Echocardiogram Findings:

B6
**Mitra! inflow:**
- Summated
- Normal
- Delayed relaxation

**ECG findings:**
HR - 128; sinus rhythm during echocardiogram

**Assessment and recommendations:**
Echocardiogram reveals improvement in contractile function and reduced LV and LA chamber dimensions. The cause for improvement is unclear; owner change diet from kangaroo to chicken, but this change was made prior to previous exams. The only changes made since previous exam were an increase in [B6] and [B6]. Patient is doing well at home, so recommend continuing current medications unless blood work indicates need for reduction. The size of the LA does not suggest that extra [B6] should be required, so if owner has frequent concerns regarding need for extra [B6], then recommend rechecking radiographs and echo. Otherwise recheck echo in 6 months, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance.

**Final Diagnosis:**
DCM (primary vs. secondary to myocarditis) with history of secondary CHF (pulmonary edema, suspected ascites) - improved echocardiographic measurements today.

**Heart Failure Classification Score:**

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**M-Mode**

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**Cardiology Appointment Report**

**Date:** 8/2/2016

**Attending Cardiologist:**
- [ ] John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC
- [ ] B6

**Cardiology Resident:**
- [ ] B6

**Cardiology Technician:**
- [ ] B6 CVT, VTS (Cardiology)

**Student:**
- [ ] B6 V17

**Presenting Complaint:** Recheck generalized cardiomegaly with DCM-like changes, congestive heart failure

**General Medical History:**
In June 2016, [B6] began coughing, rDVM thought possibly related to allergies. [B6] also treated for [B6] with [B6] at this time. [B6] developed progressive lethargy and anappetence as well as exercise intolerance and shallow breathing pattern. Went back to rDVM where chest x-rays were performed. Enlarged heart and pulmonary edema were visualized. Patient was referred to Tufts ER and placed in O2. Echocardiogram performed that demonstrated a dilated LV cavity with decreased contractility, LAE with DCM-like changes, and CHF. Rule outs considered included early DCM and cardiomyopathy secondary to myocarditis. Due to patient age and atypical breed-recommended taurine levels be measured. Taurine levels both elevated. CBC/Chem showed a mildly elevated Ca but was otherwise within normal limits. Patient currently being managed on [B6] supplement.

At home patient initially would not eat. Patient started all meds but [B6] developed diarrhea and vomiting. Discontinued [B6] Vomiting stopped but diarrhea persisted. O returned to rDVM and got a [B6] injection on 7/28/16. rDVM prescribed [B6] for 7 days. O began feeding chicken thighs on 7/28/16 and patient's appetite improved markedly. Now [B6] is eating dry food very well. His activity level has improved dramatically increasing every day. Patient has not had any additional episodes of diarrhea while on [B6]. O would like to have some on hand. O reports no more coughing or increased respiratory effort/rate, but there is still exercise intolerance. No syncope or collapse.
Diet and Supplements:
Owner has B6 but has not been giving it.

California Naturals (kangaroo and red lentil)- 2 cups 3x a day

Cardiovascular History:
Prior CHF diagnosis? Yes
Prior ATE? No
Prior arrhythmia? No
Cough? No coughing since prior visit, but there is a history of coughing
Shortness of breath or difficulty breathing? No residual shortness of breath following onset of meds
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? Yes
Prior heart murmur? Yes II/VI holosystolic left apex

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia
Cardiovascular Physical Exam:

Murmur Grade:
- None
- I/VI
- II/VI
- III/VI

Murmur location/description: Holosystolic, PMI left apex

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck

Arterial pulses:
- Weak
- Fair
- Good
- Strong

Arhythmia:
- None
- Sinus arrhythmia
- Premature beats

Gallopin:
- Yes
- No
- Intermittent

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BR sounds
- Pulmonary rales
- Wheezes
- Upper airway stridor

Abdominal exam: Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:
DCM-like changes with secondary CHF (rule out DCM or cardiomyopathy secondary to myocarditis)

Diagnostic plan:
- Echocardiogram (brief exam to view changes)
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests

Echocardiogram Findings:
General/2-D findings:
Brief fluid check: No changes from previous exam.
Assessment and recommendations:
Patient is now doing well at home, improving every day with both appetite and energy. Renal values submitted today. Despite the young age and atypical breed, the echo findings are still consistent with DCM. Recommend continuing **B6**. Recommend trying to add **B6** after recheck renal values to see if it is better tolerated than the **B6**. Taurine levels are normal, but may consider switching dog foods regardless to a more main stream low sodium formulation. Recommend recheck renal values at rDVM in 2-3 weeks. Recheck echo and exam in 3-4 months, or sooner if clinical signs develop such as increase RR/RE, cough, collapse, or exercise intolerance.

Final Diagnosis:
DCM vs. cardiomyopathy (primary vs. secondary to myocarditis) with secondary CHF
Mild PHT

Heart Failure Classification Score:

**ISACHC Classification:**
- [ ] Ia
- [ ] Ib
- [x] II

**ACVIM Classification:**
- [ ] A
- [ ] B1
- [ ] B2

**M-Mode**
- LVIDd
- LVIDs
- LVESD
- LVESV
- Ao Diam
- LA Diam
- LA/Ao
- Max LA

**M-Mode Normalized**
- LVIDdN
- LVIDsN
- LVESDN
- LVESV N
- Ao Diam N
- LA Diam N

**2D**
- SA LA
- Ao Diam
- SA LA / Ao Diam
- LVIDd
- LVESD
- EDV (Teich)

**M-MD md on LVID:**
- (0.29 - 0.52)
- (1.35 - 1.75)
- (0.33 - 0.53)
- (0.43 - 0.71)
- (0.79 - 1.14)
- (0.53 - 0.78)
- (0.68 - 0.89)
- (0.64 - 0.90)
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Cardiology Appointment Report

Date: 12/8/2016

Attending Cardiologist:

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

Cardiology Resident:

B6

Cardiology Technician:

B6 CVT, VTS(Cardiology)

Student:

B6 V17

Presenting Complaint: Recheck for historically noted DCM and CHF

Concurrent Diseases: History of DCM and CHF

General Medical History:

Was doing "really, really well" until 2 weeks ago at which point he started having late night increases in respiratory effort with a cough; he had been given an extra B6 dose on two events during that week (had only had to do this once in the past 4 months previously); 1 week ago he went to his rDVM who recommended increasing B6 from B6 and that seems to have resolved the breathing issue and cough for the most part; he only had a very slight cough since increasing his B6. Owner reports rDVM said there seemed to be "fluid around kidneys and liver" last week via palpation (no US performed) and he weighed 5 more pounds last week at rDVM. Owner is concerned it was asites; she reports before increasing B6 B6 abdomen looked distended.

Activity has been decreased for the past week; less running than normal. He is sleeping more than he was prior to the last 2 weeks.

Until 2 weeks ago B6 has been a "crazy maniac" and was doing very well.

About a week ago B6 had an event that was either a B6 (per owner rDVM thinks it was a B6). He has not had a repeat episode and this had not happened before. B6 was normal both before and after this event.
Diet and Supplements:
Hill's Chicken and Rice ideal balance kibbles (on Heartsmart website); gets about 1.5 cups Q12
Treats are frozen peas and frozen green peas

Cardiovascular History:
Prior CHF diagnosis? Yes
Prior ATE? No
Prior arrhythmia? No
Cough? Yes, intermittent and then resolved with an increase in his furosemide
Shortness of breath or difficulty breathing? Yes, intermittent, resolved with increase in furosemide
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? Yes, decreased exercise when in the yard
Prior heart murmur? Yes II/VI holosystolic left apex

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:
Murmur Grade:
- None
- I/VI
- II/VI
- III/VI

Murmur location/description: Left basilar systolic
**Jugular vein:**
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of neck

**Arterial pulses:**
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulse paradoxic
- Other:

**Arrhythmia:**
- None
- Sinus arrhythmia
- Premature beats
- Bradycardia
- Tachycardia

**Gallop:**
- Yes
- No
- Intermittent
- Pronounced
- Other:

**Pulmonary assessments:**
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds—maybe somewhat increased
- Pulmonary crackles
- Wheezes
- Upper airway stridor

**Abdominal exam:** Very sensitive to cranial abdominal palpation once, but not repeatable; tense
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

**Problems:**
- DCM, CHF
- Increased respiratory effort and potential ascites over the last week with lethargy

**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:
NSR during echo, HR 110-130 bpm

Assessment and recommendations:
Echocardiogram reveals mild progression in IV and IA dilation, but subjectively and numerically slightly increased contractile function. Given the episode last week that sounded like he had developed ascites +/- pulmonary edema, recommend continuing current B6 dose as long as renal values are stable. Patient has gained weight and B6 dose is now a bit low, so recommend also increasing B6 dose. Patient seemed to have some vague discomfort that was difficult to localize, and has a history of multiple ticks this fall, 4dx was also submitted. Recheck echo and exam in 3-4 months, or sooner if clinical signs develop such as increase RR/RE, cough, collapse, or exercise intolerance.

Final Diagnosis:
DCM (primary vs. secondary to myocarditis) with secondary CHF (pulmonary edema, suspected ascites)
Mild PHT

Heart Failure Classification Score:
ISACHC Classification:
- Ia
- Ib
- II

ACVIM Classification:
- A
- B1
- B2

M-Mode:
- IVSd
- LV1Dd
- LVIDd
- LVPWd
- IVSs
- LVIDs
- LVPWs
- %FS
- Ao Diam
- LA Diam
- LA/Ao
- Max LA

M-Mode Normalized:
- IVSdN
- LV1DdN

FDA-CVM-FOIA-2019-1704-011929
LVPWdN
IVSsN
LVlDsN
LVPWlsN
Ao Diam N
LA Diam N

2D
SA LA
Ao Diam
SA LA / Ao Diam
IVSd
LVlDd
LVPWd
EDV(Teich)
IVSs
LVlDs
LVPWss
ESV(Teich)
EF(Teich)
%FS
SV(Teich)

Doppler
MV E Vel
MV Dec T
MV A Vel
MV E/A Ratio
E'
A'
E/E'
PV Vmax
PV max PG
AV Vmax
AV max PG
TR Vmax
TR max PG

{0.33 - 0.53}
{0.43 - 0.71}
{0.79 - 1.14}
{0.53 - 0.78}
{0.68 - 0.89}
{0.64 - 0.90}
Cardiology Consultation

Date: 7/23/2016
Weight: Weight (kg) 20.40
Patient location: ICU C2
Requesting Clinician: B6 DVF (Emergency and Critical Care Resident)

Attending Cardiologist:
[ ] John F. Rush DVM MS DACVIM/Cardiology, DACVECC

Cardiology Resident:

B6

Thoracic radiographs available for review?
[ ] Yes - in SS
[ ] Yes - in PACS
[ ] No

Presenting complaint and important concurrent diseases: Cough, cardiomegaly and pulmonary edema on rDVM rads

Current medications and doses:

*STOP - remainder of form to be filled out by Cardiology*

Physical Examination

B6

Muscle condition:
[ ] Normal
[ ] Mild muscle loss
[ ] Moderate cachexia
[ ] Marked cachexia

Cardiovascular Physical Exam
Murmur Grade:
[ ] None
[ ] I/VI
[ ] IV/VI
[ ] V/VI
[ ] VI/VI
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**Echocardiogram Findings:**

- **B6**
- **B6**

**Mitrail inflow:**

- Summed
- Pseudonormal
- Normal
- Restrictive
- Delayed relaxation
ECG findings:

B6

Radiographic findings:

rDVM radiographs- Moderate generalized cardiomegaly, LAE, diffuse interstitial to alveolar pattern. Pattern most likely consistent with cardiogenic pulmonary edema, but has a more miliary structure to it than typical.

Assessment and recommendations:

Echocardiogram reveals dilated LV cavity with decrease contractile function and LAE, with DCM-like changes and secondary CHF, although the LV walls are not thinner than normal. This may be a early DCM or cardiomyopathy secondary to myocarditis vs primary cardiomyopathy. Aortic velocity is slightly increased, which is not typical of DCM, but no other defects are visible that would result in increased stroke volume. Recommend submitting CBC and chemistry. Recommend continuing B6 and adding and B6 if patient is eating well and not azotemic. Given the somewhat unusual appearance of pulmonary edema could consider recheck thoracic radiographs after B6 treatment. However, patient has had a positive response to B6 and radiographs may not be essential at this time. Given the young age, atypical breed, and non traditional diet (kangaroo and lentil) recommend submitting taurine levels (serum and whole blood) or supplementing with taurine. If there is a travel history outside of New England could consider testing for Chagas disease. Redcheck exam and renal values in 10-14 days. Redcheck echo in 3-4 months.

Redcheck appointment scheduled with cardiology on Tuesday August 2nd at 11AM. Please call 503 287 4636 if need to reschedule.

Treatment plan:

B6

Final Diagnosis:

DCM vs. cardiomyopathy (primary vs. secondary to myocarditis) with secondary CHF
Mild PHT

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II

ACVIM CHF Classification:

- A
- B1
- B2

- IIIa
- IIIb
- C
- D
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<td>on</td>
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Cardiology Consultation

Date: 7/23/2016
Weight: Weight (kg) 20.40
Patient location: ICU 02
Requesting Clinician: B6 DVF (Emergency and Critical Care Resident)

Attending Cardiologist:
John E. Bush DVM, MS, DACVIM (Cardiology), DACVECC

Cardiology Resident:

Thoracic radiographs available for review?
- Yes - in SS
- Yes - in PACS
- No

Presenting complaint and important concurrent diseases: Cough, cardiomegaly and pulmonary edema on rDVM rads

Current medications and doses:

*STOP - remainder of form to be filled out by Cardiology*

Physical Examination

Muscle condition:
- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam
Murmur Grade:
- None
- I/VI
- II/VI
- IV/VI
- V/VI
- VI/VI
Murmur location/description: systolic left apical

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3 of neck

Arterial pulses:
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other (describe):

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

Gallup:
- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary Crackles
- Wheezes
- Upper airway stridor
- Other auscultatory findings:

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

Echocardiogram findings:

Mitral inflow:
- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive
**ECG findings:**

B6

**Radiographic findings:**

rDVM radiographs: Moderate generalized cardiomegaly, LAE, diffuse interstitial to alveolar pattern. Pattern most likely consistent with cardiogenic pulmonary edema, but has a more milliary structure to it than typical.

**Assessment and recommendations:**

Echocardiogram reveals dilated LV cavity with decrease contractile function and LAE, with DCM-like changes and secondary CHF, although the LV walls are not thinner than normal. This may be a early DCM or cardiomyopathy secondary to myocarditis vs primary cardiomyopathy. Aortic velocity is slightly increased, which is not typical of DCM, but no other defects are visible that would result in increased stroke volume. Recommend submitting CBC and chemistry. Recommend continuing B6 and adding and B6 if patient is eating well and not azotemic. Given the somewhat unusual appearance of pulmonary edema could consider recheck thoracic radiographs after B6 treatment. However, patient has had a positive response to B6 and radiographs may not be essential at this time. Given the young age, atypical breed, and non traditional diet (kangaroo and lentil) recommend submitting taurine levels (serum and whole blood) or supplementing with taurine. If there is a travel history outside of New England could consider testing for Chagas disease. Recheck exam and renal values in 10-14 days. Recheck echo in 3-4 months.

Redo appointment scheduled with cardiology on Tuesday August 2nd at 11AM. Please call 508 887 4696 if need to reschedule.

**Treatment plan:**

B6

**Final Diagnosis:**

DCM vs. cardiomyopathy (primary vs. secondary to myocarditis) with secondary CHF
Mild PHT

**Heart Failure Classification Score:**

ISACHC Classification:

- [ ] IIa
- [ ] IIb
- [ ] II

ACVIM CHF Classification:

- [ ] A
- [ ] B1
- [ ] B2
- [ ] C
- [ ] D
M-Mode
IVSd
LVIDd
LVPWd
IVSs
LVIDs
LVPWs
%FS
Ao Diam
LA Diam
LA/Ao
Max LA
EPSS

M-Mode Normalized
IVSdN
LVIDdN
LVPWdN
IVSsN
LVIDsN
LVPWsN
Ao Diam N
LA Diam N

2D
SA LA
Ao Diam
SA LA / Ao Diam
IVSd
LVIDd
LVPWd
EDV(Teich)
IVSs
LVIDs
LVPWs
ESV(Teich)
EF(Teich)
%FS
SV(Teich)

Doppler
MR Vmax
MR maxPG
MVE Vel
MV DecT
MVA Vel
MVE/A Ratio
E'
A'

B6
Discharge Instructions

Patient:  B6  
Name:  B6  
Species: Canine  
White/Brown Male (Neutered) Beagle  
Cross:  
Birthday:  B6  

Attending Cardiologist:  
[ ] John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC  
B6  

Cardiology Resident:  
B6  

Student:  B6  
[ ] V19  
Cardiology Technician:  
B6  

Admit Date: 6/13/2018 2:23:44 PM  
Discharge Date: 6/13/2018

Diagnoses: Dilated cardiomyopathy (DCM) with history of congestive heart failure – improving.

Clinical Findings:  
Thank you for entrusting us with B6’s continued care. B6 looked great on physical exam today. We performed an echocardiogram, and as with the last visit, there continues to be improvement. B6 heart chambers have reduced to a normal size, and his contractility is that of a normal heart at this time.

As B6 is doing well, we would like to decrease the amount of B6 he is on. Instead of receiving B6 three times a day, we can reduce him down to twice a day. Please follow the instructions below. We are going to slowly reduce his other medication as well. Please refer to the schedule listed below.

Monitoring at Home:  
You have been doing a wonderful job taking care of B6 at home, and we are very happy to hear that you have been able to monitor his respiratory rate and effort. Please continue to do this as you have been doing, especially as we have decreased his B6 dose. Since we are going to try to reduce B6 heart medications, please record B6 heart rate, respiratory rate and effort at least once in the morning and once at night. Around June 28th, please contact our Cardiology liaison, B6 at B6 or email us at cardiology@tufts.edu to let us know how B6 is doing. It is likely most helpful if you can email us your recordings. At that point, we will discuss further reductions in his medications. We will likely continue this pattern (monitoring for 2 weeks and adjusting doses) until we have reached a level where B6 is receiving the minimum medications necessary to allow him to continue to do well.
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 dose then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.

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.

Diet Suggestions should continue to eat his current diet. Vegetables are a great treat for trying to lose weight. Your regular veterinarian can help manage the amount he eats to ensure he is at a healthy weight. Losing weight may make him more energetic and will help him to stay healthy and happy longer.

Exercise Recommendations: Please continue to allow to set his limitations for exercise, as you have been doing, it seems as though the morning walks you have been taking with him are a good level for him, but if he becomes more exercise intolerant, the length may need to be reduced.

Recommended Medications:

Recheck Visits: Since is doing so well, we would like to start reducing his heart medications. Please return in 6 months for a recheck echocardiogram.

Thank you for entrusting us with care. He is a very sweet boy, and we are very happy that he has been doing so well! Please contact our Cardiology liaison at or email us at cardiology@tufts.edu for scheduling and non-emergency 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 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/cvm/cclinical-studies
Report Details - EON-388244

ICSR: 2067171
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: 2019-05-20 10:49:42 EDT

Reported Problem:

Date Problem Started: 03/19/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: [B6]
Outcome to Date: Stable

Product Information:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Nudges Chicken Jerky</th>
<th>Nubs Chicken Treats</th>
<th>Sam's Club Chicken Jerky</th>
<th>Red Barn Bully sticks and slices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type</td>
<td>Pet Food</td>
<td>Pet Food</td>
<td>Pet Food</td>
<td>Pet Food</td>
</tr>
<tr>
<td>Lot Number</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Use Information</td>
<td>2-3 slices fed 2-3 times per day as a treat</td>
<td>one bone once per day as a treat</td>
<td>fed as treats 2-3 slices, 2-3 times per day</td>
<td>treats - 1 stick per day</td>
</tr>
<tr>
<td>First Exposure Date</td>
<td>02/01/2019</td>
<td>10/01/2017</td>
<td>01/01/2018</td>
<td>08/01/2018</td>
</tr>
</tbody>
</table>

Manufacturer /Distributor Information:

Purchase Location Information:

FOUO- For Official Use Only
<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Taste of the Wild Pacific Salmon Grain Free</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type:</td>
<td>Pet Food</td>
</tr>
<tr>
<td>Lot Number:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description</th>
<th>2 cups fed once per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Exposure Date:</td>
<td>01/01/2017</td>
</tr>
<tr>
<td>Last Exposure Date:</td>
<td>03/19/2019</td>
</tr>
<tr>
<td>Time Interval between Product Use and Adverse Event:</td>
<td>2 Years</td>
</tr>
<tr>
<td>Product Use Stopped After the Onset of the Adverse Event:</td>
<td>Yes</td>
</tr>
<tr>
<td>Adverse Event Abate After Product Stop:</td>
<td>Unknown</td>
</tr>
<tr>
<td>Product Use Started Again:</td>
<td>No</td>
</tr>
<tr>
<td>Perceived Relatedness to Adverse Event:</td>
<td>Possibly related</td>
</tr>
<tr>
<td>Other Foods or Products Given to the Animal During This Time Period:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Animal Information:
- Name: B6
- Type Of Species: Dog
- Type Of Breed: American Pit Bull Terrier
- Gender: Male
- Reproductive Status: Neutered
- Weight: 35.9 Kilogram
- Age: 6 Years
- Assessment of Prior Health: Good
- Number of Animals Given the Product: 1
- Number of Animals Reacted: 1
- Owner Information: No Information provided
- Healthcare Professional Information: University of Florida | Contact: Darcy Adin
<table>
<thead>
<tr>
<th><strong>Sender Information:</strong></th>
<th><strong>Name:</strong></th>
<th>Darcy Adin</th>
</tr>
</thead>
</table>
| **Address:** | 2015 SW 16th Ave  
2015 SW 16th Avenue  
Gainesville  
Florida  
32608  
United States |
| **Contact:** | Phone: 614-582-9798  
Other Phone: 352-294-8606  
Email: adind@ufl.edu |
| **Permission To Contact:** | Yes |
| **Preferred Method Of Contact:** | Email |
| **Reported to Other Parties:** | None |

**FOUO- For Official Use Only**
**Report Details - EON-388245**

**ICSR:** 2067168

**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:** 2019-05-20 10:45:10 EDT

**Reported Problem:**

**Problem Description:** A few days before, B6 was seen by UF Cardiology, he presented to a specialty clinic for a minor orthopedic complaint, at which time an ECG revealed an abnormal rhythm. On B6 became inappetant and vomited twice. Of B6 patient presented to primary care veterinarian, and of B6 patient presented to an emergency clinic where thoracic radiographs revealed mild to moderate cardiomegaly. He was referred to cardiology on B6 where he was diagnosed with Dilated Cardiomyopathy. Anorexia resolved after 2 weeks.

**Date Problem Started:** B6

**Concurrent Medical Problem:** Yes

**Pre Existing Conditions:** Patient received flax oil B6

**Outcome to Date:** Stable

**Product Information:**

**Product Name:** Taste of the Wild Prey (Angus, Beef, and Lentils)

**Product Type:** Pet Food

**Lot Number:**

**Product Use Information:**

<table>
<thead>
<tr>
<th>Description</th>
<th>3/4 cup fed twice per day</th>
</tr>
</thead>
</table>

**First Exposure Date:**

**Last Exposure Date:**

**Time Interval between Product Use and Adverse Event:** 1 Years

**Product Use Stopped After the Onset of the Adverse Event:** Yes

**Adverse Event Abate After Product Stop:** Unknown

**Product Use Started Again:** No

**Perceived Relatedness to Adverse Event:** Possibly related

**Other Foods or Products Given to the Animal During This Time Period:** Yes

---

**Manufacturer/Distributor Information:**

**Purchase Location Information:**

**Product Name:** N and D Venison and Quinoa dry

**Product Type:** Pet Food

**Lot Number:**

**Product Use Description:** 1 3/4 cup fed twice per day
<table>
<thead>
<tr>
<th>Information:</th>
<th>12/13/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Exposure Date:</td>
<td></td>
</tr>
<tr>
<td>Last Exposure Date:</td>
<td>B6</td>
</tr>
<tr>
<td>Time Interval between Product Use and Adverse Event:</td>
<td>3 Months</td>
</tr>
<tr>
<td>Product Use Stopped After the Onset of the Adverse Event:</td>
<td>Yes</td>
</tr>
<tr>
<td>Adverse Event Abate After Product Stop:</td>
<td>Unknown</td>
</tr>
<tr>
<td>Product Use Started Again:</td>
<td>No</td>
</tr>
<tr>
<td>Perceived Relatedness to Adverse Event:</td>
<td>Possibly related</td>
</tr>
<tr>
<td>Other Foods or Products Given to the Animal During This Time Period:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Manufacturer/Distributor Information:**

**Purchase Location Information:**

**Product Name:** Honest Kitchen Turkey dehydrated

**Product Type:** Pet Food

**Lot Number:**

**Product Use Information:**

<table>
<thead>
<tr>
<th>First Exposure Date:</th>
<th>01/01/2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Exposure Date:</td>
<td>B6</td>
</tr>
<tr>
<td>Time Interval between Product Use and Adverse Event:</td>
<td>4 Years</td>
</tr>
<tr>
<td>Product Use Stopped After the Onset of the Adverse Event:</td>
<td>Yes</td>
</tr>
<tr>
<td>Adverse Event Abate After Product Stop:</td>
<td>Unknown</td>
</tr>
<tr>
<td>Product Use Started Again:</td>
<td>No</td>
</tr>
<tr>
<td>Perceived Relatedness to Adverse Event:</td>
<td>Possibly related</td>
</tr>
<tr>
<td>Other Foods or Products Given to the Animal During This Time Period:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**FOUO- For Official Use Only**
Animal Information: Name: B6
Type Of Species: Dog
Type Of Breed: Great Dane
Gender: Male
Reproductive Status: Neutered
Weight: 86.1 Kilogram
Age: B6 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: Owner Information provided: No
Healthcare Professional Information: Practice Name: University of Florida
Contact: Name: Darcy Adin
Phone: (614) 582-9798
Other Phone: 3522948606
Email: adind@ufl.edu
Address: 2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville
Florida
32608
United States
Sender Information: Name: Darcy Adin
Address: 2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville
Florida
32608
United States
Contact: Phone: 6145829798
Other Phone: 3522948606
Email: adind@ufl.edu
Permission To Contact Sender: Yes
Preferred Method Of Contact: Email
Reported to Other Parties: None
**Report Details - EON-388246**

**ICSR:** 2067170

**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:** 2019-05-20 10:48:05 EDT

**Reported Problem:**

**Problem Description:** I was referred to UF Cardiology after her primary care veterinarian noted a Grade 2/6 left systolic murmur. She has been slowing down some over the past year, but still runs and plays regularly. I have a sinus arrhythmia. Patient was diagnosed with primary mitral regurgitation with systolic dysfunction.

**Date Problem Started:** 04/03/2019

**Concurrent Medical Problem:** Yes

**Pre Existing Conditions:**

**Outcome to Date:** Stable

### Product Information:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Type</th>
<th>Lot Number</th>
<th>Product Use Information</th>
<th>Manufacturer /Distributor Information</th>
<th>Purchase Location Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cosequin DS</td>
<td>Other</td>
<td></td>
<td>1/2 tablet once daily as joint supplement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smart Bones Smart Sticks (peanut butter)</td>
<td>Pet Food</td>
<td></td>
<td>5 inch treat given once per week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. Lyon's dental treat (mint)</td>
<td>Pet Food</td>
<td></td>
<td>3 inch treat fed once per week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pedigree chicken and rice</td>
<td>Pet Food</td>
<td></td>
<td>1/4 cup fed once per day</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**First Exposure Date:**

- Cosequin DS: 01/01/2016
- Smart Bones Smart Sticks: 01/01/2016
- Dr. Lyon's dental treat: 01/01/2018
- Pedigree chicken and rice: 01/01/2012
<table>
<thead>
<tr>
<th>Time Interval between Product Use and Adverse Event:</th>
<th>7 Years</th>
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</thead>
<tbody>
<tr>
<td>Product Use Stopped After the Onset of the Adverse Event:</td>
<td>No</td>
</tr>
<tr>
<td>Perceived Relatedness to Adverse Event:</td>
<td>Possibly related</td>
</tr>
<tr>
<td>Other Foods or Products Given to the Animal During This Time Period:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Manufacturer/Distributor Information:

Purchase Location Information:

Product Name: Natural Balance Venison, Sweet Potatoes
Product Type: Pet Food
Lot Number:

Product Use Information:

Description: 1/2 cup dry fed twice per day Patient also receives 2TBSP 100% pure pumpkin once daily and 1/2 hard boiled egg white once per week.
First Exposure Date: 10/01/2010

Time Interval between Product Use and Adverse Event: 9 Years
Product Use Stopped After the Onset of the Adverse Event: No
Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes

Manufacturer/Distributor Information:

Purchase Location Information:

Animal Information:

Name: B6
Type Of Species: Dog
Type Of Breed: Sheepdog - Shetland
Gender: Female
Reproductive Status: Neutered
Weight: 11.5 Kilogram
Age: 10 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
<table>
<thead>
<tr>
<th>Number of Animals Reacted:</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Owner Information:</td>
<td>No Information provided:</td>
</tr>
<tr>
<td>Healthcare Professional Information:</td>
<td>University of Florida</td>
</tr>
<tr>
<td>Practice Name:</td>
<td>University of Florida</td>
</tr>
<tr>
<td>Contact:</td>
<td>Name: Darcy Adin</td>
</tr>
<tr>
<td>Phone:</td>
<td>(614) 582-9798</td>
</tr>
<tr>
<td>Other Phone:</td>
<td>352-294-8606</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
</tr>
<tr>
<td>Address:</td>
<td>2015 SW 16th Ave</td>
</tr>
<tr>
<td></td>
<td>2015 SW 16th Avenue</td>
</tr>
<tr>
<td></td>
<td>Gainesville</td>
</tr>
<tr>
<td></td>
<td>Florida</td>
</tr>
<tr>
<td></td>
<td>32608</td>
</tr>
<tr>
<td></td>
<td>United States</td>
</tr>
<tr>
<td>Sender Information:</td>
<td>Name: Darcy Adin</td>
</tr>
<tr>
<td>Address:</td>
<td>2015 SW 16th Ave</td>
</tr>
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<td>2015 SW 16th Avenue</td>
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<td>United States</td>
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<tr>
<td>Contact:</td>
<td>Phone: 614-582-9798</td>
</tr>
<tr>
<td></td>
<td>Other Phone: 352-294-8606</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
</tr>
<tr>
<td>Permission To Contact:</td>
<td>Yes</td>
</tr>
<tr>
<td>Preferred Method Of Contact:</td>
<td>Email</td>
</tr>
<tr>
<td>Reported to Other Parties:</td>
<td>None</td>
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</tbody>
</table>

Additional Documents: FOUO- For Official Use Only 3
Report Details - EON-388253

ICSR: 2067174
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: 2019-05-20 10:54:51 EDT

<table>
<thead>
<tr>
<th>Reported Problem:</th>
<th>Problem Description:</th>
<th>Date Problem Started:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient had been stable on B6 for dilated cardiomyopathy for the past two years prior to presentation. A few weeks prior to presentation, he was started on B6 for coughing episodes. The day of presentation, an EKG performed at the primary care veterinarian showed a ventricular arrhythmia. On presentation to UF Cardiology, patient had collapsed suddenly and was in cardiopulmonary arrest. After CPR and a B6, he converted to sinus tachycardia. Patient was diagnosed with dilated cardiomyopathy. B6 was euthanized two days later due to gastric dilation volvulus (GDV).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concurrent Medical Problem:</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Pre Existing Conditions:</td>
<td>B6 was diagnosed with dilated cardiomyopathy two years prior to presentation at UF Cardiology and had been previously stable on B6 for the past two years.</td>
<td></td>
</tr>
<tr>
<td>Outcome to Date:</td>
<td>Died Euthanized</td>
<td></td>
</tr>
<tr>
<td>Date of Death:</td>
<td>B6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Information:</th>
<th>Product Name:</th>
<th>Spring Hill Fish Oil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type:</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Lot Number:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Use Information:</td>
<td>Description:</td>
<td>1 pill daily as supplement</td>
</tr>
<tr>
<td>Manufacturer /Distributor Information:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchase Location Information:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Information:</th>
<th>Product Name:</th>
<th>Paul Newman Dog Biscuits, various</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type:</td>
<td>Pet Food</td>
<td></td>
</tr>
<tr>
<td>Lot Number:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Use Information:</td>
<td>Description:</td>
<td>used as treats patient also received fat free greek yogurt once per day since 2015 and raw carrots as treats</td>
</tr>
<tr>
<td>First Exposure Date:</td>
<td>01/01/2010</td>
<td></td>
</tr>
<tr>
<td>Manufacturer /Distributor Information:</td>
<td></td>
<td></td>
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<tr>
<td>Purchase Location Information:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Information:</th>
<th>Product Name:</th>
<th>Blue Buffalo Large Breed Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type:</td>
<td>Pet Food</td>
<td></td>
</tr>
<tr>
<td>Lot Number:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Use Information:</td>
<td>Description:</td>
<td>2 cups dry fed twice per day</td>
</tr>
<tr>
<td>First Exposure Date:</td>
<td>12/31/2007</td>
<td></td>
</tr>
<tr>
<td>Last Exposure Date:</td>
<td>B6</td>
<td></td>
</tr>
<tr>
<td>Time Interval</td>
<td>9 Years</td>
<td></td>
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</table>
### Animal Information:

<table>
<thead>
<tr>
<th>Name:</th>
<th>B6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type Of Species:</strong></td>
<td>Dog</td>
</tr>
<tr>
<td><strong>Type Of Breed:</strong></td>
<td>Doberman Pinscher</td>
</tr>
<tr>
<td><strong>Gender:</strong></td>
<td>Male</td>
</tr>
<tr>
<td><strong>Reproductive Status:</strong></td>
<td>Neutered</td>
</tr>
<tr>
<td><strong>Weight:</strong></td>
<td>38 Kilogram</td>
</tr>
<tr>
<td><strong>Age:</strong></td>
<td>11 Years</td>
</tr>
<tr>
<td><strong>Assessment of Prior Health:</strong></td>
<td>Good</td>
</tr>
<tr>
<td><strong>Number of Animals Given the Product:</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Number of Animals Reacted:</strong></td>
<td>1</td>
</tr>
</tbody>
</table>

### Owner Information:

<table>
<thead>
<tr>
<th>Owner Information:</th>
<th>No</th>
</tr>
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</table>

### Healthcare Professional Information:

<table>
<thead>
<tr>
<th>Practice Name:</th>
<th>University of Florida</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong></td>
<td>Darcy Adin</td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
<td>(614) 582-9798</td>
</tr>
<tr>
<td><strong>Other Phone:</strong></td>
<td>3522948606</td>
</tr>
<tr>
<td><strong>Email:</strong></td>
<td><a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
</tr>
</tbody>
</table>
| **Address:** | 2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville
Florida
32608
United States |

### SEND Information:

<table>
<thead>
<tr>
<th>Name:</th>
<th>Darcy Adin</th>
</tr>
</thead>
</table>
| **Address:** | 2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville
Florida
32608
United States |
| **Phone:** | 6145829798 |
| **Other Phone:** | 3522948606 |
| **Email:** | adind@ufl.edu |

---

**FOUO- For Official Use Only**
<table>
<thead>
<tr>
<th>Permission To Contact</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sender:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Preferred Method Of</strong></td>
<td>Email</td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Reported to Other</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Parties:</strong></td>
<td></td>
</tr>
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</table>

Additional Documents:
Report Details - EON-388254

ICSR: 2067175
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: 2019-05-20 10:56:29 EDT

Reported Problem:

| Problem Description: | Patient presented to the UF Cardiology Service after roughly two weeks of coughing. When coughing initially started, patient was seen by primary care veterinarian and was treated with [B6]. On [B6] presented to his primary care veterinarian again. He had [B6] an enlarged heart, and pulmonary edema. Patient was referred to UF and was diagnosed with Dilated Cardiomyopathy. |

Date Problem Started: 02/20/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: [B6]
Outcome to Date: Stable

Product Information:

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Good Morning Healthy Joints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type:</td>
<td>Other</td>
</tr>
<tr>
<td>Lot Number:</td>
<td></td>
</tr>
<tr>
<td>Product Use Information:</td>
<td>supplement given twice daily</td>
</tr>
<tr>
<td>Manufacturer /Distributor Information:</td>
<td></td>
</tr>
<tr>
<td>Purchase Location Information:</td>
<td></td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Spring Valley Fish, Flax, and Borage Oil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type:</td>
<td>Other</td>
</tr>
<tr>
<td>Lot Number:</td>
<td></td>
</tr>
<tr>
<td>Product Use Information:</td>
<td>supplement given once daily</td>
</tr>
<tr>
<td>Manufacturer /Distributor Information:</td>
<td></td>
</tr>
<tr>
<td>Purchase Location Information:</td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Milkbone peanut flavor dry mini treats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type:</td>
<td>Pet Food</td>
</tr>
<tr>
<td>Lot Number:</td>
<td></td>
</tr>
<tr>
<td>Product Use Information:</td>
<td>used as treats</td>
</tr>
<tr>
<td>First Exposure Date:</td>
<td>01/01/2012</td>
</tr>
<tr>
<td>Other Foods or Products Given to the Animal During This Time Period:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

| Product Name: | 4Health Salmon and Potato canned |

FOUO- For Official Use Only
<table>
<thead>
<tr>
<th>Product Type: Pet Food</th>
<th>Pet Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot Number:</td>
<td></td>
</tr>
<tr>
<td>Product Use Information:</td>
<td></td>
</tr>
<tr>
<td>Description: 1 TPSP fed twice per day</td>
<td></td>
</tr>
<tr>
<td>First Exposure Date: 01/01/2016</td>
<td></td>
</tr>
<tr>
<td>Last Exposure Date: 02/20/2019</td>
<td></td>
</tr>
<tr>
<td>Time Interval between Product Use and Adverse Event: 3 Years</td>
<td></td>
</tr>
<tr>
<td>Product Use Stopped After the Onset of the Adverse Event: Yes</td>
<td></td>
</tr>
<tr>
<td>Adverse Event Abate After Product Stop: Unknown</td>
<td></td>
</tr>
<tr>
<td>Product Use Started Again: No</td>
<td></td>
</tr>
<tr>
<td>Perceived Relatedness to Adverse Event: Possibly related</td>
<td></td>
</tr>
<tr>
<td>Other Foods or Products Given to the Animal During This Time Period: Yes</td>
<td></td>
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**Manufacturer/Distributor Information:**

<table>
<thead>
<tr>
<th>Purchase Location Information:</th>
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</thead>
<tbody>
<tr>
<td>Product Name: Pure Balance Salmon and Potato dry</td>
</tr>
<tr>
<td>Product Type: Pet Food</td>
</tr>
<tr>
<td>Lot Number:</td>
</tr>
<tr>
<td>Product Use Information:</td>
</tr>
<tr>
<td>Description: 1 cup dry food fed twice per day</td>
</tr>
<tr>
<td>First Exposure Date: 01/01/2016</td>
</tr>
<tr>
<td>Last Exposure Date: 02/20/2019</td>
</tr>
<tr>
<td>Time Interval between Product Use and Adverse Event: 3 Years</td>
</tr>
<tr>
<td>Product Use Stopped After the Onset of the Adverse Event: Yes</td>
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<tr>
<td>Adverse Event Abate After Product Stop: Unknown</td>
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<tr>
<td>Product Use Started Again: No</td>
</tr>
<tr>
<td>Perceived Relatedness to Adverse Event: Possibly related</td>
</tr>
<tr>
<td>Other Foods or Products Given to the Animal During This Time Period: Yes</td>
</tr>
</tbody>
</table>
to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Cattle Dog - Australian (blue heeler, red heeler, Queensland cattledog)
Gender: Male
Reproductive Status: Neutered
Weight: 24 Kilogram
Age: 10 Years

Assessment of Prior
Health:
Fair

Number of Animals
Given the Product:
1
Number of Animals
Reacted:
1

Owner Information:
Owner Information provided: No

Healthcare Professional
Information:
Practice Name: University of Florida
Contact: Name: Darcy Adin
Phone: (614) 582-9798
Other Phone: 3522948606
Email: adind@ufl.edu
Address: 2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville
Florida
32608
United States

Sender Information:
Name: Darcy Adin
Address: 2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville
Florida
32608
United States
Contact: Phone: 6145829798
Other Phone: 3522948606
Email: adind@ufl.edu

Permission To Contact
Sender: Yes
Preferred Method Of
Contact: Email
Reported to Other
Parties: None

Additional Documents:
**Report Details - EON-388255**

**ICSR:** 2067176  
**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:** 2019-05-20 10:58:30 EDT

**Reported Problem:**  
**Problem Description:** B6 presented to the UF Cardiology Service for a 5 month history of progressive exercise intolerance and increased respiratory rate and effort. Patient was diagnosed with Dilated Cardiomyopathy. She has been rechecked once 5/15/19 - clinically stable but no improvement noted on echocardiogram. Her blood taurine results were discordant so she has been on supplementation

**Date Problem Started:** 02/14/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:**

**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Acana Heritage Poultry dry  
**Product Type:** Pet Food  
**Lot Number:**

**Product Use Information:**  
**Description:** 2 cups dry food fed twice per day Patient also has been receiving deer antlers once per week since Aug 2015 as treats/chews.  
**First Exposure Date:** 08/01/2015  
**Last Exposure Date:** 02/14/2019  
**Time Interval between Product Use and Adverse Event:** 3 Years  
**Product Use Stopped After the Onset of the Adverse Event:** Yes  
**Adverse Event Abate After Product Stop:**

**Product Use Started Again:** No  
**Perceived Relatedness to Adverse Event:** Possibly related

**Other Foods or Products Given to the Animal During This Time Period:** Yes

**Manufacturer /Distributor Information:**  
**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog

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<table>
<thead>
<tr>
<th><strong>Type Of Breed:</strong></th>
<th>Shepherd Dog - German</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender:</strong></td>
<td>Female</td>
</tr>
<tr>
<td><strong>Reproductive Status:</strong></td>
<td>Intact</td>
</tr>
<tr>
<td><strong>Pregnancy Status:</strong></td>
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</tr>
<tr>
<td><strong>Lactation Status:</strong></td>
<td>Not lactating</td>
</tr>
<tr>
<td><strong>Weight:</strong></td>
<td>36 Kilogram</td>
</tr>
<tr>
<td><strong>Age:</strong></td>
<td>4 Years</td>
</tr>
<tr>
<td><strong>Assessment of Prior Health:</strong></td>
<td>Good</td>
</tr>
<tr>
<td><strong>Number of Animals Given the Product:</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Number of Animals Reacted:</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Owner Information:</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Healthcare Professional Information:</strong></td>
<td>University of Florida</td>
</tr>
<tr>
<td><strong>Practice Name:</strong></td>
<td>University of Florida</td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
<td>Darcy Adin</td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
<td>(614) 582-9798</td>
</tr>
<tr>
<td><strong>Other Phone:</strong></td>
<td>3522948606</td>
</tr>
<tr>
<td><strong>Email:</strong></td>
<td><a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
</tr>
<tr>
<td><strong>Address:</strong></td>
<td>2015 SW 16th Ave</td>
</tr>
<tr>
<td></td>
<td>2015 SW 16th Avenue</td>
</tr>
<tr>
<td></td>
<td>Gainesville</td>
</tr>
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<td></td>
<td>Florida</td>
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<tr>
<td></td>
<td>32608</td>
</tr>
<tr>
<td></td>
<td>United States</td>
</tr>
</tbody>
</table>

**Sender Information:**
- **Name:** Darcy Adin
- **Address:**
  - 2015 SW 16th Ave
  - 2015 SW 16th Avenue
  - Gainesville
  - Florida
  - 32608
  - United States
- **Contact:**
  - **Phone:** (614) 582-9798
  - **Other Phone:** 3522948606
  - **Email:** adind@ufl.edu
- **Permission To Contact Sender:** Yes
- **Preferred Method Of Contact:** Email
- **Reported to Other Parties:** None

**Additional Documents:**
- FOUO- For Official Use Only
B6 presented to UF Cardiology with a history of persistent cough for the past 2-3 months which acutely became more frequent with episodes of wheezing and hacking. Patient was diagnosed with atrial fibrillation and dilated cardiomyopathy.

| Date Problem Started: | 03/19/2019 |
| Concurrent Medical Problem: | Yes |
| Pre Existing Conditions: | Yes |
| Outcome to Date: | Stable |

**Product Information:**

| Product Name: | Dasuquin (Nutramax) Glucosamine, MSM, Chonroitan, ASU |
| Product Type: | Other |
| Lot Number: | |
| Description: | joint supplement daily |

| Product Name: | Origins 6 Fish Grain Free dry |
| Product Type: | Pet Food |
| Lot Number: | |
| Description: | 2 cups fed twice per day |

| First Exposure Date: | 03/01/2013 |
| Last Exposure Date: | 03/19/2019 |
| Time Interval between Product Use and Adverse Event: | 6 Years |
| Product Use Stopped After the Onset of the Adverse Event: | Yes |
| Adverse Event Abate After Product Stop: | Unknown |
| Product Use Started Again: | No |
| Perceived Relatedness to Adverse Event: | Possibly related |
| Other Foods or Products Given to the Animal During This Time Period: | Yes |
**Animal Information:**

- **Name:** B6
- **Type Of Species:** Dog
- **Type Of Breed:** Great Dane
- **Gender:** Male
- **Reproductive Status:** Intact
- **Weight:** 65 Kilogram
- **Age:** 7 Years

**Assessment of Prior Health:** Good

**Number of Animals Given the Product:** 1
**Number of Animals Reacted:** 1

**Owner Information:**
- **Owner Information provided:** No

**Healthcare Professional Information:**
- **Practice Name:** University of Florida
- **Contact Name:** Darcy Adin
- **Phone:** (614) 582-9798
- **Other Phone:** 3522948606
- **Email:** adind@ufl.edu
- **Address:**
  - 2015 SW 16th Ave
  - 2015 SW 16th Avenue
  - Gainesville
  - Florida
  - 32608
  - United States

**Sender Information:**
- **Name:** Darcy Adin
- **Address:**
  - 2015 SW 16th Ave
  - 2015 SW 16th Avenue
  - Gainesville
  - Florida
  - 32608
  - United States
- **Phone:** 6145829798
- **Other Phone:** 3522948606
- **Email:** adind@ufl.edu

**Permission To Contact Sender:** Yes
**Preferred Method Of Contact:** Email
**Reported to Other Parties:** None

**Additional Documents:**

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FOUO- For Official Use Only
Report Details - EON-351034

ICSR: 2045680
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: 2018-04-12 13:51:10 EDT

Reported Problem:

Problem Description: **B6** was diagnosed with dilated cardiomyopathy and left sided congestive heart failure by the cardiology service at [ ] B6. Her disease has been stable. Due to reports of DCM related to taurine deficiency on grain free diets, a whole blood taurine level was submitted on 3/2/2018 by the cardiology service. Whole blood taurine was [B6] [ref range 200-350, critical <150]. owner was advised to stop current diet and start taurine supplementation.

Date Problem Started: B6
Concurrent Medical Problem: Yes
Pre Existing Conditions: Heart murmur first documented 4/3/2016 - 2/6 left basilar systolic
Outcome to Date: Stable

Product Information:
Product Name: Kirkland Signature Nature's Domain Turkey Meal and Sweet Potato Dog Food
Product Type: Pet Food
Lot Number: 
Product Use Information:
Description: Owner has been feeding daily for several years. Briefly switched diets for 3 months over 1 year prior but switched back as the Kirkland was better tolerated by the dog's GI tract.
Last Exposure Date: 03/09/2018
Product Use Stopped After the Onset of the Adverse Event: Unknown
Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes

Manufacturer/Distributor Information:
Purchase Location Information: Name: Costco Wholesale

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Female
Reproductive Status: Neutered
Weight: 31.1 Kilogram
Age: 11 Years
Assessment of Prior Good Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Report Details - EON-358518

ICSR: 2051554
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: 2018-07-09 08:35:47 EDT

Reported Problem:
Problem Description: Routine echo during treatment for Normal left ventricular wall thickness with reduced contractile function
Date Problem Started: 06/21/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:
Product Name: Merrick grain free salmon and sweet potato 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: Mixed (Dog)
Gender: Female
Reproductive Status: Neutered
Weight: 20.5 Kilogram
Age: 8-10 Years
Assessment of Prior Health: Unknown
Number of Animals Reacted: 1

Owner Information:
Owner Information provided: Yes
Contact: Name: B6
Phone:
Address:

Healthcare Professional Information:
Practice Name: Tufts Cummings School of Veterinary Medicine
Name: Lisa Freeman
Phone: (508) 887-4523
Email: lisa.freeman@tufts.edu
Address: 200 Westboro Rd, North Grafton, Massachusetts
<table>
<thead>
<tr>
<th>Sender Information:</th>
<th>Name: Lisa Freeman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>200 Westboro Rd</td>
</tr>
<tr>
<td></td>
<td>North Grafton</td>
</tr>
<tr>
<td></td>
<td>Massachusetts</td>
</tr>
<tr>
<td></td>
<td>01536</td>
</tr>
<tr>
<td></td>
<td>United States</td>
</tr>
<tr>
<td>Contact:</td>
<td>Phone: 5088874523</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
<tr>
<td>Permission To Contact Sender:</td>
<td>Yes</td>
</tr>
<tr>
<td>Preferred Method Of Contact:</td>
<td>Email</td>
</tr>
<tr>
<td>Reported to Other Parties:</td>
<td>None</td>
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</tbody>
</table>

Additional Documents:

FOUO- For Official Use Only
Report Details - EON-358518

ICSR: 2051554
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: 2018-07-09 08:35:47 EDT

Reported Problem: Problem Description: Routine echo during treatment for B6 Normal left ventricular wall thickness with reduced contractile function
Date Problem Started: 06/21/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information: Product Name: Merrick grain free salmon and sweet potato dry
Product Type: Pet Food
Lot Number:
Package Type: BAG

Animal Information: Name: B6
Type Of Species: Dog
Type Of Breed: Mixed (Dog)
Gender: Female
Reproductive Status: Neutered
Weight: 20.5 Kilogram
Age: 66 Years
Assessment of Prior Health: Unknown
Number of Animals Reacted: 1

Owner Information: Owner Information provided: Yes
Name: B6
Contact: Phone: B6
Address: B6 United States

Healthcare Professional Information: Practice Name: Tufts Cummings School of Veterinary Medicine
Name: Lisa Freeman
Phone: (508) 887-4523
Email: lisa.freeman@tufts.edu
Address: 200 Westboro Rd North Grafton Massachusetts
<table>
<thead>
<tr>
<th>Sender Information:</th>
<th>Name:</th>
<th>Lisa Freeman</th>
</tr>
</thead>
</table>
|                      | 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
DCM and CHF diagnosed 2/25/19. Eating BEG diet. 2 other dogs in household will be screened. Will change diet on B6 and reassess in 3 months. Just being discharged today. Taurine and troponin pending.

Date Problem Started: B6
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Name: CANIDAE® ALL LIFE STAGES CHICKEN MEAL & RICE FORMULA DRY DOG FOOD
Product Type: Pet Food
Lot Number:
Product Use Information: Fed this diet most of his life
Manufacturer /Distributor Information:
Purchase Location Information:

Type Of Species: Dog
Type Of Breed: Doberman Pinscher
Gender: Male
Reproductive Status: Intact
Weight: 60 Kilogram
Age: B6 Years
Assessment of Prior Health: Excellent

Number of Animals Given the Product: 3
Number of Animals Reacted: 1
Owner Information: Yes
Contact: Name: B6
Phone: B6
Email: B6
Address: B6 United States

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 |
| **Name:** | Lisa Freeman  
| **Address:** | 200 Westboro Rd  
|             | North Grafton  
|             | Massachusetts  
|             | 01536  
|             | United States |
| **Contact:** | Phone: 508-887-4523  
|             | Email: lisa.freeman@tufts.edu |
| **Permission To Contact:** | Yes |
| **Sender:** | Preferred Method Of Contact: Email |
| **Additional Documents:** | Attachment: rpt_medical_record_preview.pdf  
|             | Description: Medical records  
|             | Type: Medical Records |
Cummings Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(308) 839-5395

All Medical Records
Patient: B6
Breed: Doberman Pinscher
DOB: B6
Species: Canine
Sex: Male

Referring Information

Client: B6
Patient: B6

Initial Complaint:
Emergency

SOAP Text B6 9:28PM - B6

Subjective
NEW VISIT (ER)

Doctor: B6
Presenting complaint: B6

HISTORY:

B6
Initial Complaint:
Emergency

SOAP Text

Subjective
NEW VISIT (ER)

Doctor: [B6]
Student: [B6]
Client: B6

Patient: B6

Presenting complaint: Suspect CHF
Referral visit? Yes
Diagnostics completed prior to visit: 3 view CXR (in e-mail)

HISTORY:

Signalment: 3yo Ml Doberman Pinscher
Current history: Presenting today for suspect CHF after visiting rDVM earlier today - according to O, 3 view CXR's showed evidence of pleural effusion. They were referred to Tufts at this time. O reports that B6 began coughing last Thursday (2/21). The owners contacted their rDVM, who was suspicious of URI and prescribed antibiotics (O was unsure of name/dose of abx). The last dose of antibiotics was given yesterday B6. This morning B6 was having increased respiratory effort as well as difficulty getting comfortable while laying down.

Prior medical history: Suspect

Current medications: N/ A
Diet: Canidae All Life Stages dry food (grain free) - has been eating this for 1.5 - 2 years.
Vaccination status/flea & tick preventative use: UTD (O brought records), HWP monthly, F/T seasonally
Travel history: N/ A

EXAM:

C/V: Difficult to ascult (heart sounds muffled), NMA, tachycardic, weak femoral pulses

ASSESSMENT:

A1: Increased respiratory rate and effort r/o: congestive heart failure (DCM vs other) vs pneumonia
A2: Tachycardic r/o: CHF vs stress
A3: 

PLAN:

B6
taurine tablets
new diet

Diagnostics completed:
NOVA: B6
TFAST: B6

Diagnostics pending:
CBC/Chem associated with DCM diet trial study

Client communication: strongly suspect heart failure secondary to DCM. discussed hospitalization in O2 to get under control. discussed diet study with them. lifelong medications, asked about cardiology consultation.

Deposit & estimate status: B6

Resuscitation code (if admitting to ICU): B6

SOAP approved (DVM to sign): B6
dvm

Addendum:

History:
4 y/o IM Doberman Pinscher presented yesterday to the Tufts ER for suspect CHF after visiting rDVM-3 view CXR's showed evidence of pulmonary edema/pleural effusion. O reports that B6 began coughing last Thursday (2/21). The owners contacted their rDVM, who was suspicious of URI and prescribed antibiotics (O was unsure of name/dose of abx). The last dose of antibiotics was given B6 was having increased respiratory effort as well as difficulty getting comfortable while laying down.
Mentation: QAR, woke up from sleeping
Hydration: Overhydrated
Overall impression since arrival or since last exam: Stable to improve since presentation. The RR and RE improved overnight and [B6] appears more comfortable this morning. He had new onset atrial fibrillation and converted back to sinus rhythm which is quite unusual but is still in sinus rhythm this morning.
Appetite: No interest in food since arrival
Diet History: Canidae All Life Stages dry food (grain free) - has been eating this for 1.5 - 2 years.

Objective:

Heart: difficult to auscult, muffled heart sounds, no murmur, no obvious arrhythmia during auscultation, fair femoral pulses with no pulse deficits, jugular veins bottom 1/3 of his neck.

Diagnostics:

Echocardiogram: DCM with active CHF
EKG: Sinus rhythm during the echocardiogram and 6-lead ECG. The patient has been having intermittent atrial fibrillation.

Assessments:
A1: CHF secondary to DCM r/o diet related vs. genetic
A2: Atrial fibrillation secondary A1

Plan
History:
4 y/o IM Doberman Pinscher presented yesterday to the Tufts ER for suspect CHF after visiting rDVM-3 view CXR's showed evidence of pulmonary edema/pleural effusion. O reports that began coughing last Thursday (2/21). The owners contacted their rDVM, who was supicious of URI and prescribed antibiotics (O was unsure of name/dose of abx). The last dose of antibiotics was given was having increased respiratory effort as well as difficulty getting comfortable while laying down.

(overnight): P remained stable overnight, converted to sinus rhythm ~11PM. No interest in food overnight, eager to drink water when bowl placed in front of him.

Subjective:

Diet History: Canidae All Life Stages dry food (grain free) - has been eating this for 1.5 - 2 years.
Heart: no murmur, no obvious arrhythmia during auscultation, fair femoral pulses with no pulse deficits, jugular veins bottom 1/3 of his neck.

**Diagnostics:**

- Echocardiogram: DCM with active CHF
- EKG: Sinus rhythm during the echocardiogram and 6-lead ECG. The patient has been having intermittent atrial fibrillation.

**Assessments**

A1: CHF secondary to DCM r/o diet related vs. genetic
A2: Atrial fibrillation secondary A1

**Plan**

Resuscitation code (if admitting to ICU): red

SOAP completed by: [B6] V19
SOAP reviewed by:
### Lab Results Report

#### Anaplasma (4dx)
- **Results**: Negative
- **Reference Range**: 0 - 0

#### Ehrlichia (4dx)
- **Results**: Negative
- **Reference Range**: 0 - 0

#### Heartworm (4DX) - FHSA
- **Results**: Negative
- **Reference Range**: 0 - 0

#### Lyme (4dx)*
- **Results**: Negative
- **Reference Range**: 0 - 0

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### Test Results

<table>
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<th>Results</th>
<th>Reference Range</th>
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<td><strong>BEb</strong></td>
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<td>NOVA SAMPLE</td>
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<td>FiO2</td>
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<td><strong>PCO2</strong></td>
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<td><strong>PO2</strong></td>
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<tr>
<td><strong>PCO2</strong></td>
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<td><strong>PO2</strong></td>
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<tr>
<td><strong>PCV</strong></td>
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<td><strong>TS (FHSA)</strong></td>
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<td>g/dl</td>
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<td><strong>UREA</strong></td>
<td>8 - 30</td>
<td>mg/dL</td>
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<tr>
<td><strong>CREATININE</strong></td>
<td>0.6 - 2</td>
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<tr>
<td><strong>PHOSPHORUS</strong></td>
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<td>mg/dL</td>
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<tr>
<td><strong>CALCIUM2</strong></td>
<td>9.4 - 11.3</td>
<td>mg/dL</td>
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<tr>
<td><strong>T. PROTEIN</strong></td>
<td>5.5 - 7.8</td>
<td>g/dl</td>
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<tr>
<td><strong>ALBUMIN</strong></td>
<td>2.8 - 4</td>
<td>g/dl</td>
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<td>2.3 - 4.2</td>
<td>g/dl</td>
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<tr>
<td><strong>A/G RATIO</strong></td>
<td>0.7 - 1.6</td>
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<tr>
<td><strong>SODIUM</strong></td>
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<tr>
<td><strong>CHLORIDE</strong></td>
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<td>291 - 315</td>
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<td>AGAP</td>
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<td>OSMOLALITY (CALCULATED)</td>
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<td>mmol/L</td>
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Client: B6
Patient: B6

CBC/Chem

Tufts Cummings School Of Veterinary Medicine
200 Westboro Road
North Grafton, MA 01536

Client: B6
Patient: B6

CBC, Comprehensive, Sm Animal (Research)

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<thead>
<tr>
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<tr>
<td>WBC (ADVIA)</td>
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<td>RBC (Advia)</td>
<td>5.80-8.50 M/uL</td>
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<td>Hemoglobin (ADVIA)</td>
<td>13.3-20.5 g/dL</td>
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<td>Hematocrit (Advia)</td>
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<td>MCV (ADVIA)</td>
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<tr>
<td>MCH (ADVIA)</td>
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<tr>
<td>Mean Platelet Volume (Advia)</td>
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<td>Platelet Count (Advia)</td>
<td>173-486 K/uL</td>
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<td>Platelet Crit</td>
<td>0.129-0.403 %</td>
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<td>PDW</td>
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<td>Reticulocyte Count (Advia)</td>
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<td>Absolute Reticulocyte Count (Advia)</td>
<td>0-100 WBC</td>
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<tr>
<td>MCHr</td>
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<td>MCVr</td>
<td>7-47 %</td>
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<tr>
<td>Monocytes (%)</td>
<td>1-15 %</td>
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Microscopic Exam of Blood Smear (Advia)

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<td>Lymphocytes (%)</td>
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<tr>
<td>Monocytes (%)</td>
<td>0.10-1.50 K/uL</td>
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Research Chemistry Profile - Small Animal (Cobas)

Sample ID: 19022501401
This report continues... (Final)

Reviewed by: ________
**Tufts Cummings School Of Veterinary Medicine**

200 Westboro Road  
North Grafton, MA 01536

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

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<tr>
<td>Urea</td>
<td>8-30 mg/dL</td>
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<tr>
<td>Creatinine</td>
<td>0.6-2.0 mg/dL</td>
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<tr>
<td>Phosphorus</td>
<td>2.6-7.2 mg/dL</td>
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<tr>
<td>Calcium</td>
<td>9.4-11.3 mg/dL</td>
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<td>Magnesium 2+</td>
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<td>Albumin</td>
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<td>Globulins</td>
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<td>Chloride</td>
<td>106-116 mEq/L</td>
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<td>Potassium</td>
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<td>tcO2(Bicarb)</td>
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<td>AGAP</td>
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Sample ID: 19022501402  
REPRINT: Ongoing printing on 2/25/2019 (Final)
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Please note complete subjective comments for all concentrations of CARDIOPEIT proBNP are available in the online directory of services. Serum specimens received at room temperature may have decreased proBNP concentrations.
### Vitals Results

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<th>Time</th>
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### Vitals Results

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<tr>
<td>01:23 PM</td>
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</tr>
</tbody>
</table>
Dear B6

B6 was seen at Tufts' B6. Please see attached discharge instructions for more information.

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

Thank you,

B6 DVM (Intern - SAM)
Notice of Patient Admit

Date: B6 21:36 PM
Referring Doctor: B6
Client Name: B6
Patient Name: B6
Case No: B6

Dear B6

Your patient presented to our Emergency service. Please make note of the following information to facilitate communication with our team.

The attending doctor is: B6
The reason for admission to the FHSA is: DCM, CHF

If you have any questions regarding this particular case, please call 508-887-4988 to reach the Cardiology Service. Information is updated daily, by noon.

Thank you for your referral to our Emergency Service.
Daily Update From the Cardiology Service

Today's date: B6

Dear Dr at B6 Hospital

Thank you for referring patients to the Foster Hospital for Small Animals at the Cummings School of Tufts University.

Your patient B6 was admitted and is being cared for by the Cardiology Service.

Today, B6

- is in stable condition
- is still in the oxygen cage
- is critically ill
- might be discharged from the hospital today

Today's treatments include:
- bloodwork planned/pending
- echocardiography -
  - DCM with active CHF r/o breed-related vs. diet related
- cardiac catheter procedure planned
- ongoing treatment for CHF
- ongoing treatment for thrombosis
- ongoing treatment for arrhythmia

Additional plans:
Please allow 3-5 business days for reports to be finalized upon patient discharge.

Please call (508) 887-4696 before 5pm or email us at cardiovet@tufts.edu if you have any questions.

Thank you!

Attending Clinician: B6 DVM (Resident, Cardiology)
Faculty Clinician: B6 DVM, DACVIM
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: Housemate was diagnosed with DCM (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.

Date Problem Started: 08/20/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: B6

Outcomes 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: Yes

Contact: Name: B6

Phone:

Email:

Address: United States

Healthcare Professional Information: Practice Name: Tufts Cummings School of Veterinary Medicine

Contact: Name: Lisa Freeman
<table>
<thead>
<tr>
<th>Sender Information:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Lisa Freeman</td>
</tr>
<tr>
<td>Address:</td>
<td>200 Westboro Rd</td>
</tr>
<tr>
<td></td>
<td>North Grafton</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Contact:</td>
<td>Phone:</td>
</tr>
<tr>
<td></td>
<td>5088874523</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td><a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
<tr>
<td>Permission To Contact:</td>
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<tr>
<td>Attachment:</td>
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<tr>
<td>Description:</td>
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<td>Type:</td>
<td>Medical Records</td>
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</table>
A PFR Report has been received and PFR Event [EON-383371] has been created in the EON System.

A "PDF" report by name "2064630-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-383371  
**ICSR #:** 2064630  
**EON Title:** PFR Event created for Taste of the Wild Venison & Legume diet; 2064630

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<td>Number Reacted</td>
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<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
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<tr>
<td>Breed</td>
<td>Unknown</td>
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<tr>
<td>District Involved</td>
<td>PFR[ B6 ]</td>
<td>DO</td>
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**Product information**  
**Individual Case Safety Report Number:** 2064630  
**Product Group:** Pet Food  
**Product Name:** Taste of the Wild Venison & Legume diet  
**Description:** Originally submitted as RFR EON-383367. CVM resubmitting as PFR. The patient has been eating a grain free diet, specifically the Taste of the Wild Venison & Legume diet for years. He presented on 3/6/19 and the owner reported a mild cough but he felt it was resolving and declined a work up at that time. He presented again on 3/12/19 since the cough had not resolved and we started a work up of the patient that included thoracic radiographs. The patient was/is in congestive heart failure with an enlarged heart. The pet's breed is not a common breed for DCM and with the dietary history of a high legume grain free diet I feel that this is dietary induced.  
**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 Reacted With Product: 1

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<tbody>
<tr>
<td>Taste of the Wild Venison &amp; Legume diet</td>
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**Sender information**

B6
USA

**Owner information**

B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-383371

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=12&issueld=400469

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 immediately.
Report Details - EON-383371

ICSR: 2064630
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: 2019-03-26 09:52:47 EDT

Reported Problem: Problem Description: Originally submitted as RFR EON-383367. CVM resubmitting as PFR. The patient has been eating a grain free diet, specifically the Taste of the Wild Venison & Legume diet for years. He presented on 3/6/19 and the owner reported a mild cough but he felt it was resolving and declined a work up at that time. He presented again on 3/12/19 since the cough had not resolved and we started a work up of the patient that included thoracic radiographs. The patient was/is in congestive heart failure with an enlarged heart. The pet's breed is not a common breed for DCM and with the dietary history of a high legume grain free diet I feel that this is dietary induced.

Date Problem Started: 03/06/2019
Concurrent Medical Problem: Unknown
Outcome to Date: Unknown

Product Information: Product Name: Taste of the Wild Venison & Legume diet
Product Type: Pet Food
Lot Number: 
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information: Name: 
Type Of Species: Dog
Type Of Breed: Unknown
Gender: Male
Reproductive Status: Unknown
Assessment of Prior Health: Unknown
Number of Animals Reacted: 1

Owner Information: Owner Information provided: Yes
Contact: Name: 
Phone: B6
Email: 
Address: Unknown

Healthcare Professional Information:

Sender Information: Name: B6
Address: Unknown

FOUO- For Official Use Only
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<tr>
<td><strong>Contact:</strong> Phone: Email:</td>
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<td>Reporter Wants to Remain Anonymous: No</td>
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<td>Permission To Contact Sender: Yes</td>
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<td>Additional Documents:</td>
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FOUO- For Official Use Only
A PFR Report has been received and PFR Event [EON-362878] has been created in the EON System.

A "PDF" report by name "2053969-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 "2053969-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-362878  
**ICSR #:** 2053969  
**EON Title:** PFR Event created for Acana Free Run Poultry dry; 2053969

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<td>Animal Species</td>
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<td>Outcome to Date</td>
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<tr>
<td>Breed</td>
<td>Doberman Pinscher</td>
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<tr>
<td>Age</td>
<td>B6 Years</td>
<td></td>
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<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
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**Product information**  
**Individual Case Safety Report Number:** 2053969  
**Product Group:** Pet Food  
**Product Name:** Acana Free Run Poultry dry  
**Description:** Taken to RDVM for lameness. Dilated cardiomyopathy and CHF diagnosed 8/6/18. Started on meds pending. We saw at Tufts 8/16/18. Clinically improved but still has significant DCM and CHF plus arrhythmia. We added fish oil, and taurine. 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.  
**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

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<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Acana Free Run Poultry dry</td>
<td></td>
<td></td>
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</table>

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:
https://eon.fda.gov/eon//browse/EON-362878

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueld=379612

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### Report Details - EON-362878

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<td>Report Submission Date:</td>
<td>2018-08-20 16:33:06 EDT</td>
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**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 (instead of B6) fish oil, and taurine. 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:** B6
- **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:** 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 As 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

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<th>Type Of Species: Dog</th>
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<tbody>
<tr>
<td>Type Of Breed: Doberman Pinscher</td>
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<td>Gender: Male</td>
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<td>Reproductive Status: Neutered</td>
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<td>Weight: 45 Kilogram</td>
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<td>Age: B6 Years</td>
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<td>Assessment of Prior Health: Excellent</td>
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<td>Number of Animals: 2</td>
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<td>Given the Product:</td>
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<td>Number of Animals Reacted: 1</td>
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<td>Owner Information:</td>
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<td>Owner Information provided: Yes</td>
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<td>Contact:</td>
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<tr>
<td>Name:</td>
</tr>
<tr>
<td>Phone: B6</td>
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<tr>
<td>Email:</td>
</tr>
<tr>
<td>Address:</td>
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<tr>
<td>B6 United States</td>
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<tr>
<td>Healthcare Professional Information:</td>
</tr>
<tr>
<td>Practice Name: Tufts Cummings School of Veterinary Medicine</td>
</tr>
<tr>
<td>Contact:</td>
</tr>
<tr>
<td>Name: Lisa Freeman</td>
</tr>
<tr>
<td>Phone: (508) 887-4523</td>
</tr>
<tr>
<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
<tr>
<td>Address: 200 Westboro Rd</td>
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<tr>
<td>North Grafton</td>
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<td>Massachusetts</td>
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<td>01536 United States</td>
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<tr>
<td>Name: Lisa Freeman</td>
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<td>Address: 200 Westboro Rd</td>
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<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
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<tr>
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<td>Preferred Method Of Contact: Email</td>
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Additional Documents:  
- Attachment: cardio report B6 prx.pdf  
  Description: Cardio report  
  Type: Sonogram  
- Attachment: discharge B6 pdf  
  Description: Discharge report  
  Type: Other
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<tbody>
<tr>
<td>B6</td>
<td>Chest rads from rdvm</td>
<td>Radiographs</td>
</tr>
<tr>
<td>profile</td>
<td>Chemistry profile</td>
<td>Laboratory Report</td>
</tr>
</tbody>
</table>
Discharge Instructions

Patient
Name: B6
Species: Canine
Black/Tan Male (Neutered) Doberman
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVIM
B6

Cardiology Resident: B6

Cardiology Technician: B6

Admit Date: B6 11:40:13 AM
Discharge Date: B6

Diagnosis: Biventricular congestive heart failure secondary to dilated cardiomyopathy (DCM)

Case summary:
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 had occasional ventricular premature beats (VPCs) seen today, but not enough right now to warrant additional therapy. We do however, want to keep monitoring this.

The heart enlargement has now progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs and 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.

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 of medication. If difficulty breathing is not improved by within 30-60 minutes after giving medication, 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.

**Medications:**

<table>
<thead>
<tr>
<th>NEW MEDICATION</th>
<th>B6</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEW MEDICATION</td>
<td>B6</td>
</tr>
</tbody>
</table>

**Diet suggestions:**
We would like to change B6 diet to a low sodium diet. A few diet options would be:

- **Dry Food:**
  - Purina proplan bright mind small breed formula
  - Purina proplan adult weight management (this does not have low calories in spite of the name of the food)

- **Canned Food:**
  - Hills Science diet adult beef and barley entree

**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 for bloodwork which can be done at your primary care veterinarian.

A recheck has been scheduled for B6 on

Tuesday, November 20, 2018 at 11:00am with B6

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508) 837-4626 or email us at cardiology@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 (508-837-4629) 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/cvm/click Clinical Studies

Case: B6
Owner: B6
Discharge Instructions:
A PFR Report has been received and PFR Event [EON-369325] has been created in the EON System.

A "PDF" report by name "2057945-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 "2057945-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-369325  
**ICSR #:** 2057945  
**EON Title:** PFR Event created for Taste of the Wild High Prairie; 2057945

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<td>Number Reacted</td>
<td>1</td>
</tr>
<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Died Naturally</td>
</tr>
<tr>
<td>Breed</td>
<td>Great Dane</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>9 Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
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<td></td>
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</tbody>
</table>

**Product information**

**Individual Case Safety Report Number:** 2057945  
**Product Group:** Pet Food  
**Product Name:** Taste of the Wild High Prairie  
**Description:** DCM, CHF, atrial fibrillation WB taurine = Dog's diet previously submitted to FDA Note: this may be a duplicate submission  
**Submission Type:** Initial  
**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)  
**Outcome of reaction/event at the time of last observation:** Died Naturally  
**Number of Animals Treated With Product:** 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Taste of the Wild High Prairie</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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:  
https://eon.fda.gov/eon//browse/EON-369325

To view the PFR Event Report, please click the link below:  
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=12&issueld=386247

---

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Report Details - EON-369325

ICSR: 2057945
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: 2018-10-25 07:45:50 EDT

Reported Problem: Problem Description: DCM, CHF, atrial fibrillation WB taurine [B6] Dog’s diet previously submitted to FDA Note: this may be a duplicate submission

Date Problem Started: 02/20/2018
Concurrent Medical Problem: No
Outcome to Date: Died Naturally
Date of Death: [B6]

Product Information: Product Name: Taste of the Wild High Prairie
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: Great Dane
Gender: Male
Reproductive Status: Intact
Weight: 74 Kilogram
Age: 9 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: [B6]
Phone: [B6]
Email: 
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

FDA-CVM-FOIA-2019-1704-012475
<table>
<thead>
<tr>
<th>Sender Information:</th>
<th>Name:</th>
<th>Lisa Freeman</th>
</tr>
</thead>
</table>
|                     | Address: | 200 Westboro Rd  
|                     |         | North Grafton  
|                     |         | Massachusetts  
|                     |         | 01536  
|                     |         | United States  |
| Contact: | Phone: | 508-887-4523 |
|          | Email: | lisa.freeman@tufts.edu |
| Permission To Contact Sender: | Yes |
| Preferred Method Of Contact: | Email |
| Additional Documents: | Attachment: | compiled records.pdf |
|                        | Description: | Records |
|                        | Type: | Medical Records |
A PFR Report has been received and PFR Event [EON-388255] has been created in the EON System. A "PDF" report by name "2067176-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key**: EON-388255  
**ICSR #**: 2067176  
**EON Title**: PFR Event created for Acana Heritage Poultry dry; 2067176

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<th>Number Fed/Exposed</th>
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<tbody>
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<td>Best By Date</td>
<td>Number Reacted</td>
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<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Shepherd Dog - German</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>4 Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-Florida DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**  
**Individual Case Safety Report Number**: 2067176  
**Product Group**: Pet Food  
**Product Name**: Acana Heritage Poultry dry  
**Description**: Presented to the UF Cardiology Service for a 5 month history of progressive exercise intolerance and increased respiratory rate and effort. Patient was diagnosed with Dilated Cardiomyopathy. She has been rechecked once 5/15/19 - clinically stable but no improvement noted on echocardiogram. Her blood taurine results were discordant so she has been on 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**: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acana Heritage Poultry dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sender information**
Darcy Adin  
2015 SW 16th Ave  
2015 SW 16th Avenue  
Gainesville, FL 32608  
USA

To view this PFR Event, please click the link below:  
https://eon.fda.gov/eon/browse/EON-388255

To view the PFR Event Report, please click the link below:  
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issuelId=405432

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Report Details - EON-388255

ICSR: 2067176
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: 2019-05-20 10:58:30 EDT

Reported Problem: Problem Description:

B6 Presented to the UF Cardiology Service for a 5 month history of progressive exercise intolerance and increased respiratory rate and effort. Patient was diagnosed with Dilated Cardiomyopathy. She has been rechecked once 5/15/19 - clinically stable but no improvement noted on echocardiogram. Her blood taurine results were discordant so she has been on supplementation.

Date Problem Started: 02/14/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions:

Outcome to Date: Stable

Product Information: Product Name: Acana Heritage Poultry dry
Product Type: Pet Food
Lot Number:
Product Use Information: Description: 2 cups dry food fed twice per day Patient also has been receiving deer antlers once per week since Aug 2015 as treats/chews.
First Exposure Date: 08/01/2015
Last Exposure Date: 02/14/2019
Time Interval between Product Use and Adverse Event: 3 Years
Product Use Stopped After the Onset of the Adverse Event: Yes
Adverse Event Abate After Product Stop: Unknown
Product Use Started Again: No
Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes

Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information: Name: B6
Type Of Species: Dog
<table>
<thead>
<tr>
<th><strong>Type Of Breed:</strong></th>
<th>Shepherd Dog - German</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender:</strong></td>
<td>Female</td>
</tr>
<tr>
<td><strong>Reproductive Status:</strong></td>
<td>Intact</td>
</tr>
<tr>
<td><strong>Pregnancy Status:</strong></td>
<td>Not Pregnant</td>
</tr>
<tr>
<td><strong>Lactation Status:</strong></td>
<td>Not lactating</td>
</tr>
<tr>
<td><strong>Weight:</strong></td>
<td>36 Kilogram</td>
</tr>
<tr>
<td><strong>Age:</strong></td>
<td>4 Years</td>
</tr>
<tr>
<td><strong>Assessment of Prior Health:</strong></td>
<td>Good</td>
</tr>
</tbody>
</table>

| **Number of Animals Given the Product:** | 1 |
| **Number of Animals Reacted:** | 1 |

| **Owner Information:** | No Information provided |

| **Healthcare Professional Information:** | Practice Name: University of Florida |
| **Contact:** | Name: Darcy Adin |
| Phone: | 614-582-9798 |
| Other Phone: | 352-294-8606 |
| Email: | adind@ufl.edu |
| Address: | 2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States |

| **Sender Information:** | Name: Darcy Adin |
| **Address:** | 2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States |
| **Contact:** | Phone: 614-582-9798 |
| Other Phone: | 352-294-8606 |
| Email: | adind@ufl.edu |

| **Permission To Contact Sender:** | Yes |
| **Preferred Method Of Contact:** | Email |
| **Reported to Other Parties:** | None |

**Additional Documents:**

FOUO- For Official Use Only
A PFR Report has been received and PFR Event [EON-388253] has been created in the EON System.

A "PDF" report by name "2067174-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-388253  
**ICSR #:** 2067174  
**EON Title:** PFR Event created for Blue Buffalo Large Breed Adult, Paul Newman Dog Biscuits various, Spring Hill Fish Oil; 2067174

<table>
<thead>
<tr>
<th>AE Date</th>
<th>Number Fed Exposed</th>
<th>Best By Date</th>
<th>Number Reacted</th>
<th>Animal Species</th>
<th>Outcome to Date</th>
<th>Breed</th>
<th>Age</th>
<th>District Involved</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B6</td>
<td></td>
<td>B6</td>
<td>Dog</td>
<td>Died Euthanized</td>
<td>Doberman Pinscher</td>
<td>11 Years</td>
<td>PFR-Florida DO</td>
</tr>
</tbody>
</table>

**Product Information**

**Individual Case Safety Report Number:** 2067174  
**Product Group:** Pet Food, Other  
**Product Name:** Blue Buffalo Large Breed Adult, Paul Newman Dog Biscuits, various, Spring Hill Fish Oil  
**Description:** Patient had been stable of [B6] for dilated cardiomyopathy for the past two years prior to presentation at UF Cardiology. A few weeks prior to presentation, he was started on [B6] for coughing episodes. The day of presentation, an EKG performed at the primary care veterinarian showed a ventricular arrhythmia. On presentation to UF Cardiology, patient had collapsed suddenly and was in cardiopulmonary arrest. After CPR and [B6], he converted to sinus tachycardia. Patient was diagnosed with dilated cardiomyopathy. [B6] was euthanized two days later due to gastric dilation volvulus (GDV).  
**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: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Buffalo Large Breed Adult</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paul Newman Dog Biscuits, various</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spring Hill Fish Oil</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sender information
Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-388253

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=12&issueId=405430

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Report Details - EON-388253

ICSR: 2067174
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: 2019-05-20 10:54:51 EDT

Reported Problem:

Problem Description: Patient had been stable on tor dilated cardiomyopathy for the past two years prior to presentation at UF Cardiology. A few weeks prior to presentation, he was started on racing to coughing episodes. The day of presentation, an EKG performed at the primary care veterinarian showed a ventricular arrhythmia. On presentation to UF Cardiology, patient had collapsed suddenly and was in cardiopulmonary arrest. After CPR and he converted to sinus tachycardia. Patient was diagnosed with dilated cardiomyopathy. was euthanized two days later due to gastric dilation volvulus (GDV).

Date Problem Started: B6

Concurrent Medical Problem: Yes

Pre Existing Conditions: was diagnosed with dilated cardiomyopathy two years prior to presentation at UF Cardiology and had been previously stable on for the past two years. also underwent surgery in the past for . The implant has since been removed due to infection. was also on of unknown dose and frequency and Spring Hill Fish Oil 1 pill per day.

Outcome to Date: Died Euthanized
Date of Death: B6

Product Information:

Product Name: Spring Hill Fish Oil
Product Type: Other
Lot Number:
Product Use Information: Description: 1 pill daily as supplement

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Paul Newman Dog Biscuits, various
Product Type: Pet Food
Lot Number:
Product Use Information: Description: used as treats patient also received fat free greek yogurt once per day since 2015 and raw carrots as treats
First Exposure Date: 01/01/2010

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Blue Buffalo Large Breed Adult
Product Type: Pet Food
Lot Number:
Product Use Information: Description: 2 cups dry fed twice per day
First Exposure Date: 12/31/2007

Manufacturer /Distributor Information:

Purchase Location Information:

Time Interval: 9 Years
**Animal Information:**

- **Name:** B6
- **Type Of Species:** Dog
- **Type Of Breed:** Doberman Pinscher
- **Gender:** Male
- **Reproductive Status:** Neutered
- **Weight:** 38 Kilogram
- **Age:** 11 Years
- **Assessment of Prior Health:** Good
- **Number of Animals Given the Product:** 1
- **Number of Animals Reacted:** 1

**Owner Information:**

- **Owner Information provided:** No

**Healthcare Professional Information:**

- **Practice Name:** University of Florida
- **Contact:**
  - **Name:** Darcy Adin
  - **Phone:** (614) 582-9798
  - **Other Phone:** 3522948606
  - **Email:** adind@ufl.edu
- **Address:**
  - 2015 SW 16th Ave
  - Gainesville
  - Florida
  - 32608
  - United States

**Sender Information:**

- **Name:** Darcy Adin
- **Address:**
  - 2015 SW 16th Ave
  - Gainesville
  - Florida
  - 32608
  - United States
- **Contact:**
  - **Phone:** 6145829798
  - **Other Phone:** 3522948606
  - **Email:** adind@ufl.edu
<table>
<thead>
<tr>
<th>Permission To Contact</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sender:</td>
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<tr>
<td>Preferred Method Of</td>
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<td>Reported to Other</td>
<td>None</td>
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<td>Parties:</td>
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Additional Documents:
A PFR Report has been received and PFR Event [EON-388245] has been created in the EON System.

A "PDF" report by name "2067168-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-388245  
**ICSR #:** 2067168  
**EON Title:** PFR Event created for Honest Kitchen Turkey dehydrated, N and D Venison and Quinoa dry, Taste of the Wild Prey (Angus Beef and Lentils); 2067168

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<th>Number Fed/Exposed</th>
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<td>Best By Date</td>
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<td>Number Reacted</td>
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</tr>
<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Great Dane</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>4.5 Years</td>
<td></td>
<td></td>
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<tr>
<td>District Involved</td>
<td>PFR-Florida DO</td>
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<td></td>
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</tbody>
</table>

**Product Information**

**Individual Case Safety Report Number:** 2067168  
**Product Group:** Pet Food  
**Product Name:** Honest Kitchen Turkey dehydrated, N and D Venison and Quinoa dry, Taste of the Wild Prey (Angus Beef and Lentils)  
**Description:** A few days before [B6] was seen by UF Cardiology, he presented to a specialty clinic for a minor orthopedic complaint, at which time an ECG revealed an abnormal rhythm. On [B6] became inappetant and vomited twice. On [B6] patient presented to primary care veterinarian, and on [B6] patient presented to an emergency clinic where thoracic radiographs revealed mild to moderate cardiomegaly. He was referred to cardiology on [B6] where he was diagnosed with Dilated Cardiomyopathy. Anorexia resolved after 2 weeks.  
**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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>N and D Venison and Quinoa dry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Honest Kitchen Turkey dehydrated</td>
<td></td>
<td></td>
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<tr>
<td>Taste of the Wild Prey (Angus, Beef, and Lentils)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sender information**

Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-388245

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueln=405422

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you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.
A few days before B6 was seen by UF Cardiology, he presented to a specialty clinic for a minor orthopedic complaint, at which time an ECG revealed an abnormal rhythm. On B6 became inappetant and vomited twice. On B6 patient presented to primary care veterinarian, and on B6 patient presented to an emergency clinic where thoracic radiographs revealed mild to moderate cardiomegaly. He was referred to cardiology on B6; there he was diagnosed with Dilated Cardiomyopathy. Anorexia resolved after 2 weeks.

Date Problem Started: 03/13/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: Patient received flax oil. Patient had a recent history of right hindlimb lameness.
Outcome to Date: Stable

Product Name: Taste of the Wild Prey (Angus, Beef, and Lentils)
Product Type: Pet Food
Lot Number:
Product Use Information:
Description: 3/4 cup fed twice per day
First Exposure Date: 03/13/2018
Last Exposure Date: 03/13/2019
Time Interval between Product Use and Adverse Event: 1 Years
Product Use Stopped After the Onset of the Adverse Event: Yes
Adverse Event Abate After Product Stop: Unknown
Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes

Manufacturer/Distributor Information:
Purchase Location Information:
Product Name: N and D Venison and Quinoa dry
Product Type: Pet Food
Lot Number:
Product Use Description: 1 3/4 cup fed twice per day
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<th>Information:</th>
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<td></td>
<td>Last Exposure Date:</td>
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<tr>
<td>Time Interval between Product Use and Adverse Event:</td>
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<tr>
<td>Product Use Stopped After the Onset of the Adverse Event:</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Adverse Event Abate After Product Stop:</td>
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<td></td>
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<tr>
<td>Product Use Started Again:</td>
<td>No</td>
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</tr>
<tr>
<td>Perceived Relatedness to Adverse Event:</td>
<td>Possibly related</td>
<td></td>
</tr>
<tr>
<td>Other Foods or Products Given to the Animal During This Time Period:</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Honest Kitchen Turkey dehydrated
Product Type: Pet Food
Lot Number:
Product Use Information:
Description: 1/4 cup fed once per day Patient also receives lung pieces and beef and duck jerky as treats.
First Exposure Date: 01/01/2015
Last Exposure Date: 03/13/2019
Time Interval between Product Use and Adverse Event: 4 Years
Product Use Stopped After the Onset of the Adverse Event: Yes
Adverse Event Abate After Product Stop: Unknown
Product Use Started Again: No
Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes
**Animal Information:**

- **Name:** [Redacted]
- **Type Of Species:** Dog
- **Type Of Breed:** Great Dane
- **Gender:** Male
- **Reproductive Status:** Neutered
- **Weight:** 86.1 Kilogram
- **Age:** 86 Years

**Assessment of Prior Health:**

- **Number of Animals Given the Product:** 1
- **Number of Animals Reacted:** 1

**Owner Information:**

- **Owner Information provided:** No

**Healthcare Professional Information:**

- **Practice Name:** University of Florida
- **Name:** Darcy Adin
- **Phone:** (614) 582-9798
- **Other Phone:** 352-294-8606
- **Email:** adind@ufl.edu
- **Address:** 2015 SW 16th Ave
  Gainesville
  Florida
  32608
  United States

**Sender Information:**

- **Name:** Darcy Adin
- **Address:** 2015 SW 16th Ave
  Gainesville
  Florida
  32608
  United States
- **Phone:** 614-582-9798
- **Other Phone:** 352-294-8606
- **Email:** adind@ufl.edu

**Permission To Contact Sender:** Yes

**Preferred Method Of Contact:** Email

**Reported to Other Parties:** None

**Additional Documents:**

- FOUO- For Official Use Only
- FDA-CVM-FOIA-2019-1704-012497
From: PFR Event <pfreventcreation@fda.hhs.gov>
To: Cleary, Michael *
Subject: Natural Balance Venison: Darcy Adin - EON-388246
Attachments: 2067170-report.pdf

A PFR Report has been received and PFR Event [EON-388246] has been created in the EON System.

A "PDF" report by name "2067170-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-388246  
**ICSR #:** 2067170  
**EON Title:** PFR Event created for Natural Balance Venison Sweet Potatoes, Pedigree chicken and rice, Dr. Lyon’s dental treat (mint), Smart Bones Smart Sticks (peanut butter), Cosequin DS; 2067170

<table>
<thead>
<tr>
<th>AE Date</th>
<th>Number Fed/Exposed</th>
<th>Best By Date</th>
<th>Number Reacted</th>
<th>Animal Species</th>
<th>Outcome to Date</th>
<th>Breed</th>
<th>Age</th>
<th>District Involved</th>
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<tbody>
<tr>
<td>04/03/2019</td>
<td>1</td>
<td></td>
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<td>Dog</td>
<td>Stable</td>
<td>Sheepdog - Shetland</td>
<td>10 Years</td>
<td>PFR-Florida DO</td>
</tr>
</tbody>
</table>

**Product information**

**Individual Case Safety Report Number:** 2067170  
**Product Group:** Pet Food, Other  
**Product Name:** Natural Balance Venison, Sweet Potatoes, Pedigree chicken and rice, Dr. Lyon’s dental treat (mint), Smart Bones Smart Sticks (peanut butter), Cosequin DS  
**Description:** was referred to UF Cardiology after her primary care veterinarian noted a Grade 2/6 left systolic murmur. She has been slowing down some over the past year, but still runs and plays regularly. [B6] has a sinus arrhythmia. Patient was diagnosed with primary mitral regurgitation with systolic dysfunction.

**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  

<table>
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<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Natural Balance Venison, Sweet Potatoes</td>
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<td></td>
</tr>
<tr>
<td>Dr. Lyon’s dental treat (mint)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pedigree chicken and rice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cosequin DS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sender information**  
Darcy Adin  
2015 SW 16th Ave  
2015 SW 16th Avenue  
Gainesville, FL 32608  
USA  

To view this PFR Event, please click the link below:  
https://eon.fda.gov/eon/browse/EON-388246

To view the PFR Event Report, please click the link below:  
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=l2&issueld=405423

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

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

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

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think
you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.
**Report Details - EON: 86**

**ICSR:** 2067170

**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:** 2019-05-20 10:48:05 EDT

**Reported Problem:**

**Problem Description:** 
_OBS_ was referred to UF Cardiology after her primary care veterinarian noted a Grade 2/6 left systolic murmur. She has been slowing down some over the past year, but still runs and plays regularly. OBS has a sinus arrhythmia. Patient was diagnosed with primary mitral regurgitation with systolic dysfunction.

**Date Problem Started:** 04/03/2019

**Concurrent Medical Problem:**

**Pre Existing Conditions:**

_OBS_ has a history of _OBS_ since she was about 4 years old. She is not currently clinical for her.

**Outcome to Date:** Stable

**Product Information:**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Type</th>
<th>Lot Number</th>
<th>Product Use Information</th>
<th>Description</th>
<th>Manufacturer/Distributor Information</th>
<th>Purchase Location Information</th>
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</thead>
<tbody>
<tr>
<td>Cosequin DS</td>
<td>Other</td>
<td></td>
<td></td>
<td>1/2 tablet once daily as joint supplement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smart Bones Smart Sticks (peanut butter)</td>
<td>Pet Food</td>
<td></td>
<td></td>
<td>5 inch treat given once per week</td>
<td>Manufacturer/Distributor Information</td>
<td>Purchase Location Information</td>
</tr>
<tr>
<td>Dr. Lyon's dental treat (mint)</td>
<td>Pet Food</td>
<td></td>
<td></td>
<td>3 inch treat fed once per week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pedigree chicken and rice</td>
<td>Pet Food</td>
<td></td>
<td></td>
<td>1/4 cup fed once per day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time Interval between Product Use and Adverse Event:</td>
<td>7 Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>--------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Use Stopped After the Onset of the Adverse Event:</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived Relatedness to Adverse Event:</td>
<td>Possibly related</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Other Foods or Products Given to the Animal During This Time Period:</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Product Use Information:**
- **Description:** 1/2 cup dry fed twice per day. Patient also receives 2TBSP 100% pure pumpkin once daily and 1/2 hard boiled egg white once per week.
- **First Exposure Date:** 10/01/2010
- **Time Interval between Product Use and Adverse Event:** 9 Years
- **Product Use Stopped After the Onset of the Adverse Event:** No
- **Perceived Relatedness to Adverse Event:** Possibly related
- **Other Foods or Products Given to the Animal During This Time Period:** Yes

**Animal Information:**
- **Name:** B6
- **Type Of Species:** Dog
- **Type Of Breed:** Sheepdog - Shetland
- **Gender:** Female
- **Reproductive Status:** Neutered
- **Weight:** 11.5 Kilogram
- **Age:** 10 Years
- **Assessment of Prior Health:** Good
- **Number of Animals Given the Product:** 1
<table>
<thead>
<tr>
<th>Number of Animals Reacted:</th>
<th>1</th>
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</thead>
<tbody>
<tr>
<td>Owner Information:</td>
<td>No Information provided:</td>
</tr>
<tr>
<td>Healthcare Professional Information:</td>
<td>Practice Name: University of Florida</td>
</tr>
<tr>
<td>Contact:</td>
<td>Name: Darcy Adin</td>
</tr>
<tr>
<td></td>
<td>Phone: (614) 582-9798</td>
</tr>
<tr>
<td></td>
<td>Other Phone: 3522948606</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
</tr>
<tr>
<td>Address:</td>
<td>2015 SW 16th Ave</td>
</tr>
<tr>
<td></td>
<td>2015 SW 16th Avenue</td>
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<tr>
<td></td>
<td>Gainesville</td>
</tr>
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</tr>
<tr>
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<td>32608</td>
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<td>Name: Darcy Adin</td>
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<tr>
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<td>2015 SW 16th Ave</td>
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<td>Phone: 6145829798</td>
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<td>Other Phone: 3522948606</td>
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<tr>
<td></td>
<td>Email: <a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
</tr>
<tr>
<td>Permission To Contact Sender:</td>
<td>Yes</td>
</tr>
<tr>
<td>Preferred Method Of Contact:</td>
<td>Email</td>
</tr>
<tr>
<td>Reported to Other Parties:</td>
<td>None</td>
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Additional Documents:
A PFR Report has been received and PFR Event [EON-388256] has been created in the EON System.

A "PDF" report by name "2067173-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-388256  
**ICSR #:** 2067173  
**EON Title:** PFR Event created for Origins 6 Fish Grain Free dry, Dasuquin (Nutramax) Glucosamine MSM Chonroitan ASU; 2067173

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<th>AE Date</th>
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<tr>
<td>Best By Date</td>
<td>Number Reacted</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Great Dane</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>7 Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-Florida DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**

**Individual Case Safety Report Number:** 2067173  
**Product Group:** Pet Food, Other  
**Product Name:** Origins 6 Fish Grain Free dry, Dasuquin (Nutramax) Glucosamine, MSM, Chonroitan, ASU  
**Description:** presented to UF Cardiology with a history of persistent cough for the past 2-3 months which acutely became more frequent with episodes of wheezing and hacking. Patient was diagnosed with atrial fibrillation and dilated cardiomyopathy.

**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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dasuquin (Nutramax) Glucosamine, MSM, Chonroitan, ASU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Origins 6 Fish Grain Free dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sender information**
Darcy Adin  
2015 SW 16th Ave  
2015 SW 16th Avenue  
Gainesville, FL 32608  
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-388256

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueld=405433

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 FDAResportableFoods@fda.hhs.gov immediately.
**Report Details - EON-388256**

**ICSR:** 2067173

**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:** 2019-05-20 10:51:47 EDT

**Reported Problem:**

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<tr>
<th>Problem Description:</th>
<th>B6... presented to UF Cardiology with a history of persistent cough for the past 2-3 months which acutely became more frequent with episodes of wheezing and hacking. Patient was diagnosed with atrial fibrillation and dilated cardiomyopathy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Problem Started:</td>
<td>03/19/2019</td>
</tr>
<tr>
<td>Concurrent Medical Problem:</td>
<td>Yes</td>
</tr>
<tr>
<td>Pre Existing Conditions:</td>
<td>Previously diagnosed with [__<strong><strong><strong><strong>B6</strong></strong></strong></strong>]2012, but is not currently clinical. Patient receives Glucosamine nutramax 800mg daily, MSM nutramax 700mg daily, Chonroitan nutramax 300mg daily, and ASU nutramax 75mg daily.</td>
</tr>
<tr>
<td>Outcome to Date:</td>
<td>Stable</td>
</tr>
</tbody>
</table>

**Product Information:**

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Dasuquin (Nutramax) Glucosamine, MSM, Chonroitan, ASU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type:</td>
<td>Other</td>
</tr>
<tr>
<td>Description:</td>
<td>joint supplement daily</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Origins 6 Fish Grain Free dry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type:</td>
<td>Pet Food</td>
</tr>
<tr>
<td>Description:</td>
<td>2 cups fed twice per day</td>
</tr>
</tbody>
</table>

<p>| First Exposure Date: | 03/01/2013 |
| Last Exposure Date:  | 03/19/2019 |
| Time Interval between Product Use and Adverse Event: | 6 Years |
| Product Use Stopped After the Onset of the Adverse Event: | Yes |
| Adverse Event Abate After Product Stop: | Unknown |
| Product Use Started Again: | No |
| Perceived Relatedness to Adverse Event: | Possibly related |
| Other Foods or Products Given to the Animal During This Time Period: | Yes |</p>
<table>
<thead>
<tr>
<th>Animal Information:</th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Name:</strong></td>
<td>B6</td>
<td></td>
</tr>
<tr>
<td><strong>Type Of Species:</strong></td>
<td>Dog</td>
<td></td>
</tr>
<tr>
<td><strong>Type Of Breed:</strong></td>
<td>Great Dane</td>
<td></td>
</tr>
<tr>
<td><strong>Gender:</strong></td>
<td>Male</td>
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<tr>
<td><strong>Reproductive Status:</strong></td>
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<tr>
<td><strong>Weight:</strong></td>
<td>65 Kilogram</td>
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<td><strong>Age:</strong></td>
<td>7 Years</td>
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</tr>
<tr>
<td><strong>Assessment of Prior Good Health:</strong></td>
<td>Good</td>
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</tr>
<tr>
<td><strong>Number of Animals Given the Product:</strong></td>
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<tr>
<td><strong>Number of Animals Reacted:</strong></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Owner Information:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Owner Information provided:</strong></td>
<td>No</td>
<td></td>
</tr>
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<table>
<thead>
<tr>
<th>Healthcare Professional Information:</th>
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</tr>
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<tbody>
<tr>
<td><strong>Practice Name:</strong></td>
<td>University of Florida</td>
<td></td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
<td>Darcy Adin</td>
<td></td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
<td>(614) 582-9798</td>
<td></td>
</tr>
<tr>
<td><strong>Other Phone:</strong></td>
<td>3522948606</td>
<td></td>
</tr>
<tr>
<td><strong>Email:</strong></td>
<td><a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
<td></td>
</tr>
<tr>
<td><strong>Address:</strong></td>
<td>2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sender Information:</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong></td>
<td>Darcy Adin</td>
<td></td>
</tr>
<tr>
<td><strong>Address:</strong></td>
<td>2015 SW 16th Ave 2015 SW 16th Avenue Gainesville Florida 32608 United States</td>
<td></td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
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<td><strong>Email:</strong></td>
<td><a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
<td></td>
</tr>
<tr>
<td><strong>Permission To Contact Sender:</strong></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td><strong>Preferred Method Of Contact:</strong></td>
<td>Email</td>
<td></td>
</tr>
<tr>
<td><strong>Reported to Other Parties:</strong></td>
<td>None</td>
<td></td>
</tr>
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</table>
A PFR Report has been received and PFR Event [EON-388254] has been created in the EON System.

A "PDF" report by name "2067175-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-388254  
**ICSR #:** 2067175  
**EON Title:** PFR Event created for Pure Balance Salmon and Potato dry, 4Health Salmon and Potato canned, Milkbone peanut flavor dry mini treats, Spring Valley Fish Flax and Borage Oil, Good Morning Healthy Joints; 2067175

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<tr>
<th>AE Date</th>
<th>02/20/2019</th>
<th>Number Fed/Exposed</th>
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<tbody>
<tr>
<td>Best By Date</td>
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<td>Number Reacted</td>
<td>1</td>
</tr>
<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Cattle Dog - Australian (blue heeler, red heeler, Queensland cattledog)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>10 Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-Florida DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**

**Individual Case Safety Report Number:** 2067175  
**Product Group:** Pet Food, Other  
**Product Name:** Pure Balance Salmon and Potato dry, 4Health Salmon and Potato canned, Milkbone peanut flavor dry mini treats, Spring Valley Fish, Flax, and Borage Oil, Good Morning Healthy Joints  
**Description:** Patient presented to the UF Cardiology Service after roughly two weeks of coughing. When
coughing initially started, patient was seen by primary care veterinarian and was treated with [B6]. On 2/19/19, [B6] presented to his primary care veterinarian again. He had cyanotic mucous membranes, an enlarged heart, and pulmonary edema. Patient was referred to UF and was diagnosed with Dilated Cardiomyopathy.

**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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Spring Valley Fish, Flax, and Borage Oil</td>
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</tr>
<tr>
<td>Milkbone peanut flavor dry mini treats</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pure Balance Salmon and Potato dry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good Morning Healthy Joints</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sender information**  
Darcy Adin  
2015 SW 16th Ave  
2015 SW 16th Avenue  
Gainesville, FL 32608  
USA

To view this PFR Event, please click the link below:  
https://eon.fda.gov/eon/browse/EON-388254

To view the PFR Event Report, please click the link below:  
https://eon.fda.gov/eon//EventCustomDetailsAction/viewReport.jsa?decorator=none&e=0&issueType=12&issueId=405431

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

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.
Patient presented to the UF Cardiology Service after roughly two weeks of coughing. When coughing initially started, patient was seen by primary care veterinarian and was treated with B6. On B6, presented to his primary care veterinarian again. He had cyanotic mucous membranes, an enlarged heart, and pulmonary edema. Patient was referred to UF and was diagnosed with Dilated Cardiomyopathy.

Date Problem Started: 02/20/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:

**Product Name:** Good Morning Healthy Joints
**Product Type:** Other
**Lot Number:**
**Product Use Information:** Description: supplement given twice daily

**Product Name:** Spring Valley Fish, Flax, and Borage Oil
**Product Type:** Other
**Lot Number:**
**Product Use Information:** Description: supplement given once daily

**Product Name:** Milkbone peanut flavor dry mini treats
**Product Type:** Pet Food
**Lot Number:**
**Product Use Information:** Description: used as treats

First Exposure Date: 01/01/2012
Other Foods or Products Given to the Animal During This Time Period: Yes
<table>
<thead>
<tr>
<th>Product Type:</th>
<th>Pet Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot Number:</td>
<td></td>
</tr>
<tr>
<td><strong>Product Use Information:</strong></td>
<td></td>
</tr>
<tr>
<td>Description:</td>
<td>1 Tbsp fed twice per day</td>
</tr>
<tr>
<td>First Exposure Date:</td>
<td>01/01/2016</td>
</tr>
<tr>
<td>Last Exposure Date:</td>
<td>02/20/2019</td>
</tr>
<tr>
<td>Time Interval between Product Use and Adverse Event:</td>
<td>3 Years</td>
</tr>
<tr>
<td><strong>Product Use Stopped After the Onset of the Adverse Event:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Adverse Event Abate After Product Stop:</strong></td>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Product Use Started Again:</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Perceived Relatedness to Adverse Event:</strong></td>
<td>Possibly related</td>
</tr>
<tr>
<td><strong>Other Foods or Products Given to the Animal During This Time Period:</strong></td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Manufacturer /Distributor Information:**

**Purchase Location Information:**

**Product Name:** Pure Balance Salmon and Potato Dry

<p>| Product Type: | Pet Food |</p>
<table>
<thead>
<tr>
<th>Manufacturer/Distributor Information:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase Location Information:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Animal Information:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>B6</td>
</tr>
<tr>
<td>Type Of Species:</td>
<td>Dog</td>
</tr>
<tr>
<td>Type Of Breed:</td>
<td>Cattle Dog - Australian (blue heeler, red heeler, Queensland cattledog)</td>
</tr>
<tr>
<td>Gender:</td>
<td>Male</td>
</tr>
<tr>
<td>Reproductive Status:</td>
<td>Neutered</td>
</tr>
<tr>
<td>Weight:</td>
<td>24 Kilogram</td>
</tr>
<tr>
<td>Age:</td>
<td>10 Years</td>
</tr>
</tbody>
</table>

| Assessment of Prior Health: | Fair |

| Number of Animals Given the Product: | 1 |
| Number of Animals Reacted:          | 1 |

| Owner Information: | Owner Information provided: No |

<table>
<thead>
<tr>
<th>Healthcare Professional Information:</th>
<th>Practice Name: University of Florida</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact:</td>
<td>Name: Darcy Adin</td>
</tr>
<tr>
<td></td>
<td>Phone: (614) 582-9798</td>
</tr>
<tr>
<td></td>
<td>Other Phone: 3522948606</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
</tr>
<tr>
<td></td>
<td>Address: 2015 SW 16th Ave</td>
</tr>
<tr>
<td></td>
<td>2015 SW 16th Avenue</td>
</tr>
<tr>
<td></td>
<td>Gainesville</td>
</tr>
<tr>
<td></td>
<td>Florida</td>
</tr>
<tr>
<td></td>
<td>32608</td>
</tr>
<tr>
<td></td>
<td>United States</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sender Information:</th>
<th>Name: Darcy Adin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>2015 SW 16th Ave</td>
</tr>
<tr>
<td></td>
<td>2015 SW 16th Avenue</td>
</tr>
<tr>
<td></td>
<td>Gainesville</td>
</tr>
<tr>
<td></td>
<td>Florida</td>
</tr>
<tr>
<td></td>
<td>32608</td>
</tr>
<tr>
<td></td>
<td>United States</td>
</tr>
<tr>
<td>Contact:</td>
<td>Phone: 6145829798</td>
</tr>
<tr>
<td></td>
<td>Other Phone: 3522948606</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:adind@ufl.edu">adind@ufl.edu</a></td>
</tr>
</tbody>
</table>

| Permission To Contact Sender: | Yes |
| Preferred Method Of Contact:  | Email |
| Reported to Other Parties:    | None |
From: PFR Event <pfreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification;
Sent: 5/20/2019 2:56:40 PM
Subject: Taste of the Wild Pacific Salmon Grain Free: Darcy Adin - EON-388244
Attachments: 2067171-report.pdf

A PFR Report has been received and PFR Event [EON-388244] has been created in the EON System.

A "PDF" report by name "2067171-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

**EON Key:** EON-388244  
**ICSR #:** 2067171  
**EON Title:** PFR Event created for Taste of the Wild Pacific Salmon Grain Free, Red Barn Bully sticks and slices, Sam's Club Chicken Jerky, Nubs Chicken Treats, Nudges Chicken Jerkey; 2067171

<table>
<thead>
<tr>
<th>AE Date</th>
<th>03/19/2019</th>
<th>Number Fed/Exposed</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Best By Date</td>
<td></td>
<td>Number Reacted</td>
<td>1</td>
</tr>
<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>American Pit Bull Terrier</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>[B6] Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-Florida DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**

**Individual Case Safety Report Number:** 2067171  
**Product Group:** Pet Food  
**Product Name:** Taste of the Wild Pacific Salmon Grain Free, Red Barn Bully sticks and slices, Sam's Club Chicken Jerky, Nubs Chicken Treats, Nudges Chicken Jerkey  
**Description:** [B6] presented to UF Cardiology for evaluation of a heart murmur and arrhythmia discovered by his primary care veterinarian [B6] had a recent history of a progressively worsening cough. On ECG, [B6] had intermittent ventricular premature complexes (right bundle branch block) [B6] was diagnosed with mitral regurgitation with systolic dysfunction.  
**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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sam's Club Chicken Jerky</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nudges Chicken Jerkey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red Barn Bully sticks and slices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nubs Chicken Treats</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sender information
Darcy Adin
2015 SW 16th Ave
2015 SW 16th Avenue
Gainesville, FL 32608
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-388244

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=405421

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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 immediately.
**Report Details - EON-388244**

**ICSR:** 2067171

**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:** 2019-05-20 10:49:42 EDT

**Reported Problem:**

**Problem Description:** B6 presented to UF Cardiology for evaluation of a heart murmur and arrhythmia discovered by his primary care veterinarian. B6 had a recent history of a progressively worsening cough. On ECG, B6 had intermittent ventricular premature complexes (right bundle branch block). B6 was diagnosed with mitral regurgitation with systolic dysfunction.

**Date Problem Started:** 03/19/2019

**Concurrent Medical Problem:** Yes

**Pre Existing Conditions:** History of dermatologic skin issues, but no other relevant medical history. Patient is on Heartgard and Seresto collar as preventatives.

**Outcome to Date:** Stable

**Product Information:**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Nudges Chicken Jerkey</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Type:</strong></td>
<td>Pet Food</td>
</tr>
<tr>
<td><strong>Lot Number:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Product Use Information:</strong></td>
<td>2-3 slices fed 2-3 times per day as a treat</td>
</tr>
<tr>
<td><strong>First Exposure Date:</strong></td>
<td>02/01/2019</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Nubs Chicken Treats</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Type:</strong></td>
<td>Pet Food</td>
</tr>
<tr>
<td><strong>Lot Number:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Product Use Information:</strong></td>
<td>one bone once per day as a treat</td>
</tr>
<tr>
<td><strong>First Exposure Date:</strong></td>
<td>10/01/2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Sam's Club Chicken Jerky</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Type:</strong></td>
<td>Pet Food</td>
</tr>
<tr>
<td><strong>Lot Number:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Product Use Information:</strong></td>
<td>fed as treats 2-3 slices, 2-3 times per day</td>
</tr>
<tr>
<td><strong>First Exposure Date:</strong></td>
<td>01/01/2018</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Red Barn Bully sticks and slices</th>
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</thead>
<tbody>
<tr>
<td><strong>Product Type:</strong></td>
<td>Pet Food</td>
</tr>
<tr>
<td><strong>Lot Number:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Product Use Information:</strong></td>
<td>treats - 1 stick per day</td>
</tr>
<tr>
<td><strong>First Exposure Date:</strong></td>
<td>08/01/2018</td>
</tr>
<tr>
<td><strong>Manufacturers/Distributor Information:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Purchase Location Information:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Product Name:</strong> Taste of the Wild Pacific Salmon Grain Free</td>
<td></td>
</tr>
<tr>
<td><strong>Product Type:</strong> Pet Food</td>
<td></td>
</tr>
<tr>
<td><strong>Lot Number:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Product Use Information:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Description:</strong> 2 cups fed once per day</td>
<td></td>
</tr>
<tr>
<td><strong>First Exposure Date:</strong> 01/01/2017</td>
<td></td>
</tr>
<tr>
<td><strong>Last Exposure Date:</strong> 03/19/2019</td>
<td></td>
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<tr>
<td><strong>Time Interval between Product Use and Adverse Event:</strong> 2 Years</td>
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</tr>
<tr>
<td><strong>Product Use Stopped After the Onset of the Adverse Event:</strong> Yes</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse Event Abate After Product Stop:</strong> Unknown</td>
<td></td>
</tr>
<tr>
<td><strong>Perceived Relatedness to Adverse Event:</strong> Possibly related</td>
<td></td>
</tr>
<tr>
<td><strong>Other Foods or Products Given to the Animal During This Time Period:</strong> Yes</td>
<td></td>
</tr>
<tr>
<td><strong>Animal Information:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Name:</strong> B6</td>
<td></td>
</tr>
<tr>
<td><strong>Type Of Species:</strong> Dog</td>
<td></td>
</tr>
<tr>
<td><strong>Type Of Breed:</strong> American Pit Bull Terrier</td>
<td></td>
</tr>
<tr>
<td><strong>Gender:</strong> Male</td>
<td></td>
</tr>
<tr>
<td><strong>Reproductive Status:</strong> Neutered</td>
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<tr>
<td><strong>Weight:</strong> 35.9 Kilogram</td>
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<tr>
<td><strong>Age:</strong> 6 Years</td>
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<tr>
<td><strong>Assessment of Prior Health:</strong> Good</td>
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<tr>
<td><strong>Number of Animals Given the Product:</strong> 1</td>
<td></td>
</tr>
<tr>
<td><strong>Number of Animals Reacted:</strong> 1</td>
<td></td>
</tr>
<tr>
<td><strong>Owner Information:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Owner Information provided:</strong> No</td>
<td></td>
</tr>
<tr>
<td><strong>Healthcare Professional Information:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Practice Name:</strong> University of Florida</td>
<td></td>
</tr>
<tr>
<td><strong>Contact:</strong> Name: Darcy Adin</td>
<td></td>
</tr>
<tr>
<td><strong>Sender Information:</strong></td>
<td><strong>Name:</strong></td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------</td>
</tr>
</tbody>
</table>
| **Address:**            | 2015 SW 16th Ave  
                        | 2015 SW 16th Avenue  
                        | Gainesville  
                        | Florida  
                        | 32608  
                        | United States |
| **Contact:**            | **Phone:** | (614) 582-9798  
                        | **Other Phone:** | 3522948606  
                        | **Email:** | adind@ufl.edu |
| **Permission To Contact** | **Sender:** | Yes |
| **Preferred Method Of Contact:** | Email |
| **Reported to Other Parties:** | None |

**Additional Documents:**

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DOCUMENT PRODUCED IN NATIVE
From: Rotstein, David <l=EXCHANGELABS/O=EXCHANGE ADMINISTRATIVE GROUP
(O=FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EB69F322906BADD DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 9/21/2018 6:02:40 PM
Subject: Boxer with cardiac disease FW: Blue Wilderness Senior Dog Food
EON-366404
Attachments: 2055205-report.pdf; 2055205-attachments.zip

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: PFR Event <pfreventcreation@fda.hhs.gov>
Sent: Friday, September 21, 2018 2:01 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>
Subject: Blue Wilderness Senior Dog Food: Steven Rosenthal - EON-366404

A PFR Report has been received and PFR Event [EON-366404] has been created in the EON System.

A "PDF" report by name "2055205-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 "2055205-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-366404
ICSR #: 2055205
EON Title: PFR Event created for Blue Wilderness Senior Dog Food; 2055205

<table>
<thead>
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<th>AE Date</th>
<th>Number Fed/Exposed</th>
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<tbody>
<tr>
<td>08/28/2018</td>
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</table>

<table>
<thead>
<tr>
<th>Best By Date</th>
<th>Number Reacted</th>
<th>Outcome to Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Animal Species</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td></td>
</tr>
</tbody>
</table>

B6
Breed: Boxer (German Boxer)
Age: 9 Years
District Involved: PFR B6 DO

Product information
Individual Case Safety Report Number: 2055205
Product Group: Pet Food
Product Name: Blue Wilderness Senior Dog Food
Description: Presented as an after hours consultation due to tachypnea and cough, previous diagnosis of prostate enlargement, cough and tachypnea over the past few weeks, eating a grain free diet, had some GI issues as a puppy, seems active and no collapse episodes, no episodes of collapse or weakness, no known family history of heart disease. T fast scan at PCDVM mild pericardial effusion
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 Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Wilderness Senior Dog Food</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sender information
B6
USA

Owner information
B6

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-366404

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=383318

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Tufts case

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Monday, August 20, 2018 4:44 PM
To: Cleary, Michael* <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>
Subject: Acana Free Run Poultry dry: Lisa Freeman - EON-362878

A PFR Report has been received and PFR Event [EON-362878] has been created in the EON System.

A "PDF" report by name "2053969-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 "2053969-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-362878
ICSR #: 2053969
EON Title: PFR Event created for Acana Free Run Poultry dry; 2053969

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<tr>
<th>AE Date</th>
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<th>Number Fed/Exposed</th>
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<tr>
<td>Animal Species</td>
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<td>Outcome to Date</td>
<td>Stable</td>
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<tr>
<td>----------------</td>
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<td>-----------------</td>
<td>--------</td>
</tr>
<tr>
<td>Breed</td>
<td>Doberman Pinscher</td>
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<tr>
<td>Age</td>
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<tr>
<td>District Involved</td>
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**Product information**

**Individual Case Safety Report Number:** 2053969  
**Product Group:** Pet Food  
**Product Name:** Acana Free Run Poultry dry  
**Description:** Taken to RDVM for lameness. Dilated cardiomyopathy and CHF diagnosed 8/6/18. Started on med[5] We saw at Tufts 8/16/18. Clinically improved but still has significant DCM and CHF plus arrhythmia. We added[5]fish oil, and taurine. 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.  
**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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
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</thead>
<tbody>
<tr>
<td>Acana Free Run Poultry dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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:  
https://eon.fda.gov/eon/browse/EON-362878

To view the PFR Event Report, please click the link below:  
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&
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 immediately.
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 fish oil and taurine. 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: B6
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

Animal Information:

Name: B6
<table>
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<tr>
<th>Type Of Species:</th>
<th>Dog</th>
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<tr>
<td>Type Of Breed:</td>
<td>Doberman Pinscher</td>
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<td>Gender:</td>
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<td>Weight:</td>
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<tr>
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<td>[B6] Years</td>
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<td>Assessment of Prior Health:</td>
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<td>Number of Animals Given the Product:</td>
<td>2</td>
</tr>
<tr>
<td>Number of Animals Reacted:</td>
<td>1</td>
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</tbody>
</table>

Owner Information:
- Yes
- Name:
- Phone: 
- Email: 
- Address: 

Healthcare Professional Information:
- Practice Name: Tufts Cummings School of Veterinary Medicine
- 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
- 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: ![cardio report.pdf](attachment:B6_cardio_report_B6.pdf)
  - Description: Cardio report
  - Type: Sonogram
- Attachment: ![discharge report.pdf](attachment:B6_discharge_B6.pdf)
  - Description: Discharge report
  - Type: Other
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<th>Attachment:</th>
<th>Description: Chest rads from rdvm</th>
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<tr>
<td>Attachment:</td>
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<td>Type: Laboratory Report</td>
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Cardiology Appointment Report

Date: 8/16/2018

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

Cardiology Resident: B6

Cardiology Technician: B6

Presenting Complaint: Work up of DCM/CHF

Concurrent Diseases: B6

General Medical History:
Owner has had him for 5 years. Was obese and behavioral issues. Owner has worked well with the behavior issues. Owner has noticed that he used to be energetic and play a lot, and now he is not, however, after starting medications, is slightly better.

Diet and Supplements: Acana

Cardiovascular History:
Prior CHF diagnosis? YES
Prior heart murmur? YES
Prior ATE? NO
Prior arrhythmia? NO
Monitoring respiratory rate and effort at home? YES
Cough? YES (hacking, throat clearing)
Shortness of breath or difficulty breathing? YES
Syncope or collapse? NO
Sudden onset lameness? YES (LFL)
Exercise intolerance? YES

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
- Normal
- Mild muscle loss

Cardiovascular Physical Exam:

Murmur Grade:
- None
- I/VI
- II/VI
- III/VI

Murmur location/description: systolic; left apical systolic

Jugular vein:
- Bottom 1/3 of the neck
- Middle 1/3 of the neck

Arterial pulses:
- Weak
- Fair
- Good
- Strong

Arrhythmia:
- None
- Sinus arrhythmia
Premature beats

Gallup:
- Yes
- No
- Intermittent

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

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:
murmur, shortness of breath, lameness, historical ascites and pleural effusion

Differential Diagnoses:
DCM, DMVD, CHF secondary to DCM

Diagnostic plan:
- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests: Taurine level

Echocardiogram Findings:
General/2-D findings:
Decreased LV thicknesses with dilated LV cavity size. Decreased contractile function. Moderately enlarged LA. Mild amount of pleural effusion. Mild thickening of the MV and TV. No ascites.

Assessment and recommendations:
DCM with signs of active CHF, although he is better than prior to starting medication (no more ascites). However, given that there is still some pleural effusion, the diuretic dose that the patient is on right now is not sufficient. 
B6 

in 2 weeks. Recheck echocardiogram in 3-4 months.

Final Diagnosis:
DCM with CHF

Heart Failure Classification Score:

ISACHC Classification:
- Ia
- Ib
- Iib

ACVIM Classification:
- A
- B1
- B2

2D
SA LA
Ao Diam
SA LA / Ao Diam
IVSd
LVIDd
LVPWd
EDV(TeiCh)
IVSs
LVIDs
LVPWs
ESV(TeiCh)
EF(TeiCh)
%FS
SV(TeiCh)
LVID A4C
LVEDV MOD A4C
LVls A4C
LVESV MOD A4C
LVEF MOD A4C
SV MOD A4C

M-Mode
IVSd
LVIDd
LVPWd
IVSs
LVIDs
LVPWs
%FS
Ao Diam
LA Diam
LA/Ao
Max LA
EPSS

Doppler
MV E Vel
MV DecT
MV A Vel
MV E/A Ratio
PV Vmax
PV maxPG
AV Vmax
AV maxPG
m/s
ms
m/s
mmHg
m/s
mmHg
Discharge Instructions

Patient
Name: B6
Species: Canine
Black/Tan Male (Neutered) Doberman
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVCM

Cardiology Resident: B6

Cardiology Technician: B6

Admit Date: B6 11:40:18 AM
Discharge Date: B6

Diagnosis: Biventricular congestive heart failure secondary to dilated cardiomyopathy (DCM)

Case summary:
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 had occasional ventricular premature beats (VPCs) seen today, but not enough right now to warrant additional therapy. We do however, want to keep monitoring this.

The heart enlargement has now progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs and 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.

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 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.
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.

**Medications:**

**Diet suggestions:**

We would like to change the diet to a low sodium diet. A few diet options would be:

**Dry Food:**

Royal Canin Early Cardiac diet
Purina proplan bright mind small breed formula
Purina proplan adult weight management (this does not have low calories in spite of the name of the food)

**Canned Food:**

Hills Science diet adult beef and barley entree

**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 your dog 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 for bloodwork which can be done at your primary care veterinarian.

A recheck has been scheduled for B6 on Tuesday, November 20, 2018 at 11:00am with B6.

Thank you for entrusting us with care. Please contact our Cardiology liaison at (508) 887-4626 or email us at cardiology@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 (508-887-4626) 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/cvm/clinical-studies

Case: B6
Owner: B6
Discharge Instructions
### Lab Results Report

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**Cummings Veterinary Medical Center**

**AT TUFTS UNIVERSITY**

Cardiology Liaison: 508-887-4696

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**Cardiology Appointment Report**

**Date:** 6/12/2018

**Attending Cardiologist:**

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

**Patient ID:** B6

**Canine**

**B6**

**Years Old Male (Neutered) Caucasian**

**Shepherd Dog**

**Gray/Black**

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**Presenting Complaint:**

Recheck DCM and CHF from 5/29/18

**Concurrent Diseases:**

None

**General Medical History:**

Dx with murmur at approximately 2 years of age

**Diet and Supplements:**

Royal Canin large breed

Taurine (250 mg tablets) - 4 tablets (1000 mg) PO SID

**Cardiovascular History:**

Prior CHF diagnosis? Yes

Prior ATE? None

Prior arrhythmia? None

Cough? None
Shortness of breath or difficulty breathing? None
Syncope or collapse? None
Sudden onset lameness? None
Exercise intolerance? Normal per owner
Prior heart murmur? Yes

Current Medications Pertinent to CV System:

Muscle condition:
- Normal
- Mild muscle loss

Cardiovascular Physical Exam:
Murmur Grade:
- None
- I/VI
- II/VI
- III/VI
- IV/VI

Murmur location/description: No murmur auscultated despite Hx, difficult auscultation due to panting

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of neck

Arterial pulses:
Weal
F. -

□ Good

Bcuulg

P'tie ~
P'tie paaloxm

Other:

S. - sm

Amythnia

Prem. u.ebeats

Bradp. anlia

Tadiyl. anlia

Gallop:

□ Yes

□ No

□ Intermittent

Pulmonary assessments:

□ Eupneic - panting

□ Mild dyspnea

□ Marked dyspnea

□ Normal BV sounds

□ Bradycardia

□ Tachycardia

Pulmonary cracks

□ Wheezes

□ Upper airway stridor

Abdominal exam:

□ Normal

□ Hepatomegaly

□ Abdominal distension

□ Mild ascites

□ Marked ascites

Problems:

DCM

CHF - controlled with medications

Diagnostic plan:

□ Echocardiogram

□ Chemistry profile

□ ECG

□ Renal profile

□ Blood pressure

□ Dialysis profile

□ Thoracic radiographs

□ NT-proBNP

□ Troponin I

□ Other tests:

Blood Pressure (mmHg):


B6

Assessment and recommendations:
Previous echocardiogram on 5/29/18 revealed DCM with L-CHF. Serum taurine level was borderline or mildly decreased; whole blood levels of taurine within normal limits. Sample of B6 grain free dog food and label collected from owner today for submission to FDA. Patient currently receiving taurine supplementation; this should be continued if tolerated by B6. Clinically appears stable on current medications. Patient has been switched to Royal Canin Large Breed diet. Patient panting during examination but no apparent increased respiratory effort. Recommend B6.

Final Diagnosis:
DCM with CHF (currently controlled on medications)

Heart Failure Classification Score:
ISACHC Classification:
- [ ] Ia
- [ ] Ib
- [ ] II

ACVIM Classification:
- [ ] C
- [ ] D
Date: 5/29/2018
Weight: Weight (kg) 60.30

Presenting complaint and important concurrent diseases: Increased respiratory rate and effort for 1 day + recent history of cough (~2 wks). No exercise intolerance noted.

Key indication for consultation: Increased respiratory rate/effort + dilated LV noted on TFAST.

Questions to be answered from the Consult:
- Differentiate cardiac vs respiratory cause of cough
- Assess cardiac structure and function

*STOP- remainder of form to be filled out by Cardiology*
Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3 of neck

Arterial pulses:
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other (describe):

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

Gallop:
- Yes
- No
- Intermittent S3
- Pronounced
- Other:

Pulmonary assessments:
- Eupnea
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary Cradles
- Wheezes
- Upper airway stridor
- Other auscultatory findings:

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

Echocardiogram Findings:

Assessment and recommendations:
Echocardiogram reveals DCM with L-CHF. Patient is on a grain-free diet. Submitted taurine levels. Will
submit diet and label to FDA. There also may or may not have a high VSD—may have covered over and no longer be patent; does not appear to be problematic at this time.

**Treatment plan:**

**Final Diagnosis:** DCM with CHF

**Heart Failure Classification Score:**

- ISACHC Classification:
  - □ Ia
  - □ Ib
  - □ IIb

- ACVIM CHF Classification:
  - □ A
  - □ B1
  - □ B2

**M-Mode:**

- IVSd
- LVId
- LVPWd
- IVSs
- LVIds
- LVPWs
- %FS
- Ao Diam
- LA Diam
- LA/Ao
- Max LA
- EPSS

**M-Mode Normalized:**

- IVSdN: (0.29 - 0.52)
- LVIdN: (1.35 - 1.73)
- LVPWdN: (0.33 - 0.53)
- IVSsN: (0.43 - 0.71)
- LVIdsN: (0.79 - 1.14)
- LVPWsN: (0.53 - 0.78)
- Ao Diam N: (0.68 - 0.89)
- LA Diam N: (0.64 - 0.90)

**2D:**

- SA LA
- Ao Diam

B6
SA IA / Ao Diam
IVSd
LVIDd
LVPWd
EDV(Teich)
IVSs
LVIDs
LVPWs
ESV(Teich)
EF(Teich)
%FS
SV(Teich)
Discharge Instructions

Patient
Names: B6
Species: Canine
Gray/black Male (Neutered) Caucasian Shepherd Dog
Birthdate: B6

Owner
Names: B6
Address: B6

Patient ID: B6

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

Cardiology Resident: B6
Resident: B6
Student: B6
Cardiology Technician: B6

Admit Date: B6 555:16 PM
Discharge Date: B6

Diagnoses:
1. Dilated cardiomyopathy (DCM)
2. Congestive Heart Failure (CHF)

Diagnostic test results and findings:
Chest radiograph (x-ray) findings: The heart is enlarged and there is fluid in the lungs.
Echocardiogram findings: The left ventricle of the heart is enlarged and there is a leak at the mitral valve.
ECG findings: Occasional abnormal (ventricular) beats.
Bloodwork: unremarkable bloodwork with no pre-existing elevations in kidney values.

Case summary:
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 require medical management. The heart enlargement has now progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs. 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 B6 comfortable and have him breathing easier. As we discussed, this disease carries a
prognosis of 3-6 months given that it has progressed to the point of causing congestive heart failure. B6 will need to remain on cardiac medications for the rest of his life. As long as we can control his congestive heart failure with medications, he can have a good quality of life for his remaining time.

**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. We will use breathing rate and effort to make adjustments to drug doses.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 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 _____.
- Please do not hesitate to do so. 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.
- 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:**

We suggest that you begin feeding _____ B6 _____ a heart-safe food that is not grain-free, as a link has been found between some grain-free diets and the development of DCM. For that reason, a Taurine level has been submitted for _____ B6 _____ and you have permitted us to submit his food to the FDA for further testing. While _____ B6 _____ should be switched to a diet that is also appropriate for heart disease, we would recommend switching your other dogs at home to a different diet as well. We suggest selecting a food made by Hill’s, Purina, or Royal Canin, as these are trusted brands.

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/).

While it is generally advisable to switch diets in a slow gradual manner, we would like you to switch food immediately, as we are concerned that continuing his current grain-free diet could worsen his heart condition.

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, slightly longer walks are acceptable. However, if you find that 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. We have scheduled an appointment for you on June 12, 2018 at 11:00am. If this appointment does not work for you please call or email our liaison as soon as possible to reschedule. At this visit we will check your dog's breathing effort and heart function, do a blood test to recheck kidney values, and probably recheck a blood pressure. A recheck echocardiogram is recommended in 3-4 months.

Thank you for entrusting us with care. Please contact our Cardiology liaison or email us at cardiology@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 (617-687-4629) 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/cvm/clinical-studies

<table>
<thead>
<tr>
<th>Case</th>
<th>B6</th>
<th>Owner</th>
<th>B6</th>
<th>Discharge Instructions</th>
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</thead>
</table>

FDA-CVM-FOIA-2019-1704-012599
Discharge Instructions

Patient:
Name: B6
Species: Canine
Gray/Black Male (Neutered) Caucasian Shepherd Dog
Birthdate: B6

Owner:
Name: B6
Address: B6

Patient ID: B6

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

Cardiology Resident:
B6

Small Animal Medicine Intern:
B6
Student:
B6
Cardiology Technician:
B6

Admit Date: 6/12/2018 10:50:31 AM
Discharge Date: 6/12/2018

Thank you for bringing B6 in today for a recheck of his dilated cardiomyopathy (DCM) and congestive heart failure (CHF). He was diagnosed with DCM and CHF while at Tufts Veterinary Hospital on 5/28/18. Today we performed a physical examination to listen to his heart and watch his breathing. We also retested his blood pressure and bloodwork today to evaluate how he is tolerating the current doses of medications and make any necessary adjustments.

Clinical Findings:
B6 recheck of blood pressure showed that his blood pressure was mildly decreased. His bloodwork showed that his kidney values have increased slightly since his previous visit; these values are currently at the high end of normal. We did not hear any arrhythmias today nor any heart murmurs. He was panting throughout his examination thus making it difficult to assess his respiratory effort. He did not appear to be in any respiratory distress today.

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. We will use breathing rate and effort to make adjustments to drug doses.
○ In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 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. Please do not hesitate to do so. 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

FDA-CVM-FOIA-2019-1704-012600
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 website (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.

Diet Suggestions:
Continue to transition (______ to Royal Canin giant breed dog food. We also recommend switching your other dogs to a different diet as well (not grain free).

We have recommended that ______ be fed a heart-safe food that is not grain-free as a link has been found between some grain free diets and the development of DCM. We previously submitted a Taurine level for ______ his plasma level of Taurine was slightly below normal level. Today you provided a bag of his dog food such that we can submit his food to the FDA for further testing. Although his current diet has taurine, you may continue to supplement the taurine at this time.

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 website (http://vet.tufts.edu/heartsmart/diet/).

Exercise Recommendations:
As it appears that _______ heart failure is better controlled, slightly longer walks on a leash are acceptable. However, if you find that ______ 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.

Medications:

B6

Recheck Visits:
1. Please schedule a recheck visit in 3-4 weeks as a Tufts Cardiology technician appointment or with your primary care veterinarian to have a recheck biochemistry profile performed. This is to ensure that \_\_\_\_\_ B6 \_ is tolerating the increased \_\_\_\_\_ B6 \_ use.

2. We have scheduled a recheck visit for September 4, 2018 at 3:00pm with \_\_\_\_\_ B6 \_ . If you need to reschedule this appointment, please contact Tufts Cardiac Service as soon as possible. At this visit we will want to check breathing effort and heart function, and recheck an echocardiogram. If you move prior to this visit, please schedule an appointment with a cardiologist in \_\_\_\_\_ B6 \_ at the beginning of September.

If you are finding that \_\_\_\_\_ B6 \_ has increased respiratory rate and effort at home or if you have concerns with his exercise intolerance prior to that recheck appointment, please schedule an appointment sooner.

Tufts Emergency Service is available 24 hours a day should \_\_\_\_\_ B6 \_ ever show increased weakness or lethargy, or if you have concerns that he is having increased difficulty breathing.

Thank you for entrusting us with \_\_\_\_\_ B6 \_ care. He is such a sweet dog and pleasure to work with! Please contact our Cardiology liaison \_\_\_\_\_ B6 \_ or email us at cardiology@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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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.

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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/home/clinical-studies

<table>
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**Lab Results Report**

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<td>UREA</td>
<td>8 - 30</td>
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**COMMENTS (CHEMISTRY)**

Moderate hemolysis; Slight lipemia
## Radiology Request & Report

**Patient**
- **Name:** B6
- **Species:** Canine
- **Gray/Black Male (Neutered)**
- **Caucasian Shepherd Dog**
- **Birthdate:** B6

**Owner**
- **Name:** B6
- **Address:** B6

**Patient ID:** B6  
**Date of request:** 5/29/2018

**Attending Clinician:** B6  
(Emergency & Critical Care Resident)  
**Student:**

---

**Date of exam:** 05/29/2018

**Patient Location:** Ward/Cage: ICU R1

**Weight (kg):** 62.00

**Sedation**
- [ ] BAG
- [ ] OBAG
- [ ] 1/2 dose OBAG
- [ ] DexDormitor/Butorphanol
- [ ] Anesthesia to sedate/anesthetize

**Examination Desired:** DV and RIAT

**Presenting Complaint and Clinical Questions you wish to answer:**
- Emergency

**Pertinent History:**
- Gyn MC K9 presenting for 2wk hx of ough, presented for increased RR/RE: B6
  - [ ] B6

**Findings:**
- B6
Conclusions:
- Moderate left-sided cardiomegaly with left atrial enlargement, venous distension and cardiogenic pulmonary edema consistent with left-sided heart failure. Echocardiogram is recommended for further evaluation. Follow up radiographs are recommended to monitor response to treatment.

Radiologists
Primary: B6
Reviewing:

Dates
Reported: 5/29/18
Finalized:
From: Jones, Jennifer L <FDA/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'
Sent: 11/1/2017 5:25:22 PM
Subject: Final reports for signature

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
tax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

FDA U.S. FOOD & DRUG
ADMINISTRATION
From: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
To: Rotstein, David; Norris, Anne; Hartogensis, Martine; Jones, Jennifer L; Burkholder, William; Reimschuessel, Renate
CC: DeLancey, Siobhan
Sent: 8/13/2018 7:04:20 PM
Subject: RE: Food Safety News Query: DCM follow-up

I think that’s very good, Anne. I support your approach. J

From: Rotstein, David
Sent: Monday, August 13, 2018 3:02 PM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

That will work!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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From: Norris, Anne
Sent: Monday, August 13, 2018 3:01 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: Food Safety News Query: DCM follow-up

Went with a less is more approach. Please advise if you see anything you’d recommend changing.

Thanks,
Anne

1. Approximately how many additional reports of possible canine (or feline) DCM has FDA received since the initial investigation notice of July 12, 2018
Hi – just a few additional comments.

Added to #3.

My comments below.
My comments below.

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

From: Norris, Anne
Sent: Monday, August 13, 2018 9:34 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Delancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: Food Safety News Query: DCM follow-up

Good morning!
Thanks,
Anne

Anne Norris
Strategic Initiatives

Office of the Director
Center for Veterinary Medicine
U.S. Food & Drug Administration
O: 240-402-0132
M: 240-704-0579
Anne.Norris@fda.hhs.gov
A PFR Report has been received and PFR Event [EON-380706] has been created in the EON System.

A "PDF" report by name "2063113-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 "2063113-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380706  
**ICSR #:** 2063113  
**EON Title:** PFR Event created for Poulin Pro Form Lamb and Rice Adult Maintenance Dry; 2063113

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**Product information**  
**Individual Case Safety Report Number:** 2063113  
**Product Group:** Pet Food  
**Product Name:** Poulin Pro Form Lamb and Rice Adult Maintenance Dry  
**Description:** Had pneumonia in September 2018, re-presented in December 2018 when arrhythmias were noted. Cardiology consult identified arrhythmias and reduced contractile function (and eating BEG diet). Unclear whether this was primary problem or secondary to systemic illness. Rechecked by cardiology 2/5/19 and still had arrhythmia and reduced contractility. NT-proBNP and cTnI elevated. Owner already changed diet in January to...
Purina Pro Plan Chicken and Rice so will continue on this diet and will recheck in 3 months.

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

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<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
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<tbody>
<tr>
<td>Poulin Pro Form Lamb and Rice Adult Maintenance Dry</td>
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</tr>
</tbody>
</table>

**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:  
https://eon.fda.gov/eon/browse/EON-380706

To view the PFR Event Report, please click the link below:  
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=None&e=0&issueType=12&issueId=397715

---

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 immediately.
Report Details - EON-380706

ICSR: 2063113
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 16:24:11 EST

Reported Problem: Problem Description: Had pneumonia in September 2018, re-presented in December 2018 when arrhythmias were noted. Cardiology consult identified arrhythmias and reduced contractile function (and eating BEG diet). Unclear whether this was primary problem or secondary to systemic illness. Rechecked by cardiology 2/5/19 and still had arrhythmia and reduced contractility. NT-proBNP and cTnl elevated. Owner already changed diet in January to Purina Pro Plan Chicken and Rice so will continue on this diet and will recheck in 3 months.

Date Problem Started: 12/22/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: Pneumonia Sept and Dec 2018
Outcome to Date: Stable

Product Information:
Product Name: Poulin Pro Form Lamb and Rice Adult Maintenance Dry
Product Type: Pet Food
Lot Number: 
Package Type: BAG
Product Use Information: Description: Please see diet history form for more details
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Irish Wolfhound
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Not Pregnant
Lactation Status: Not lactating
Weight: 60.5 Kilogram
Age: 6 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: B6
Phone: 
Email: 
Address: B6
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<th>Healthcare Professional Information:</th>
<th>Practice Name: Tufts Cummings School of Veterinary Medicine</th>
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<tbody>
<tr>
<td>Contact:</td>
<td>Name: Lisa Freeman</td>
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<tr>
<td></td>
<td>Phone: (508) 887-4523</td>
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<tr>
<td></td>
<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
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| Sender Information:               | Name: Lisa Freeman                                      |
|                                   | Address: 200 Westboro Rd                                |
|                                   | North Grafton                                           |
|                                   | Massachusetts                                           |
|                                   | 01536                                                    |
|                                   | United States                                           |
|                                   | Phone: 5088874523                                       |
|                                   | Email: lisa.freeman@tufts.edu                            |

| Permission To Contact:            | Yes                                                     |
| Preferred Method Of Contact:      | Email                                                   |

| Additional Documents:             | Attachment: cbc and profile.pdf                         |
|                                   | Description: Will send by email                         |
|                                   | Type: Medical Records                                   |
A PFR Report has been received and PFR Event [EON-380848] has been created in the EON System.

A "PDF" report by name "2063189-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 "2063189-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380848  
**ICS R #:** 2063189  
**EON Title:** PFR Event created for Wellness Complete Health Fish and Sweet Potato dry; 2063189

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<th>02/22/2019</th>
<th>Number Fed/Exposed</th>
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<tbody>
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<td>Number Reacted</td>
<td>1</td>
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<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Boxer (German Boxer)</td>
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<td></td>
</tr>
<tr>
<td>Age</td>
<td>B6 Years</td>
<td>District Involved</td>
<td>PFR-New England DO</td>
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</table>

**Product Information**

**Individual Case Safety Report Number:** 2063189  
**Product Group:** Pet Food  
**Product Name:** Wellness Complete Health Fish and Sweet Potato dry  
**Description:** Arrhythmia dx July 2018 (had been "wheezing") Started wheezing again 1 week before admission. Diagnosed with DCM, CHF, and ventricular tachycardia 2/22/19. Was fed Wellness diet until 6/2018 then changed to Royal Canin Boxer (current diet). Taurine and troponin pending. Owner has another Boxer eating same diets - has not been screened. Enrolled in DCM study. Changing to different diet (although Boxer diet
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Wellness Complete Health Fish and Sweet Potato dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:
https://eon.fda.gov/eon/browse/EON-380848

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=397857

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 immediately.
**Report Details - EON-380848**

**ICSR:** 2063189

**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 19:07:14 EST

**Reported Problem:**

<table>
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<tr>
<th>Problem Description</th>
<th>Date Problem Started</th>
<th>Concurrent Medical Problem</th>
<th>Outcome to Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrhythmia dx at ___ July 2018 (had been &quot;wheezing&quot;) started wheezing again 1 week before admission. Diagnosed with DCM, CHF, and ventricular tachycardia. 2/22/19 was fed Wellness diet until 6/2018 then changed to Royal Canin Boxer (current diet). Taurine and troponin pending. Owner has another Boxer eating same diets - has not been screened. Enrolled in DCM study. Changing to different diet (although Boxer diet is probably fine) and will recheck in 7 days and 3 months.</td>
<td>02/22/2019</td>
<td>No</td>
<td>Stable</td>
</tr>
</tbody>
</table>

**Product Information:**

<table>
<thead>
<tr>
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<th>Product Type</th>
<th>Lot Number</th>
<th>Product Use Information</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wellness Complete Health Fish and Sweet Potato dry</td>
<td>Pet Food</td>
<td></td>
<td></td>
<td>Fed this diet 2012 - June, 2018 currently, fed Royal Canin Boxer. See diet history</td>
</tr>
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</table>

**Animal Information:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Type Of Species</th>
<th>Type Of Breed</th>
<th>Gender</th>
<th>Reproductive Status</th>
<th>Weight</th>
<th>Age</th>
<th>Number of Animals Given the Product</th>
<th>Number of Animals Reacted</th>
<th>Owner Information Provided</th>
<th>Owner Information</th>
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</thead>
<tbody>
<tr>
<td>B6</td>
<td>Dog</td>
<td>Boxer (German Boxer)</td>
<td>Male</td>
<td>Neutered</td>
<td>23.3</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>Yes</td>
<td>Name: B6</td>
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</table>

**Healthcare Professional Information:**

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tufts Cummings School of Veterinary Medicine</td>
<td>Name: Lisa Freeman</td>
</tr>
<tr>
<td></td>
<td>Phone: (508) 887-4523</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
</tbody>
</table>

**Address:**

United States
<table>
<thead>
<tr>
<th>Sender Information:</th>
<th>Lisa Freeman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>200 Westboro Rd</td>
<td></td>
</tr>
<tr>
<td>North Grafton</td>
<td></td>
</tr>
<tr>
<td>Massachusetts</td>
<td></td>
</tr>
<tr>
<td>01536</td>
<td></td>
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<tr>
<td>United States</td>
<td></td>
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<tr>
<td>Contact:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td>508-887-4523</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
<tr>
<td>Permission To Contact Sender:</td>
<td>Yes</td>
</tr>
<tr>
<td>Preferred Method Of Contact:</td>
<td>Email</td>
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<tr>
<td>Additional Documents:</td>
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<tr>
<td>Attachment:</td>
<td>rpt_medical_record_preview_small.pdf</td>
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<td>Description:</td>
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<td>Type:</td>
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A PFR Report has been received and PFR Event [EON-364577] has been created in the EON System.

A "PDF" report by name "2054750-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 "2054750-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-364577  
**ICSR #:** 2054750  
**EON Title:** PFR Event created for Honest Kitchen Whole Grain Turkey Beef or CHicken, Ziwi Peak (recently started); 2054750

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<td>Animal Species</td>
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<td>Outcome to Date</td>
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<tr>
<td>Breed</td>
<td>Retriever - Golden</td>
<td>Stable</td>
</tr>
<tr>
<td>Age</td>
<td>6 years</td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
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</tbody>
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**Product information**

**Individual Case Safety Report Number:** 2054750  
**Product Group:** Pet Food  
**Product Name:** Honest Kitchen Whole Grain Turkey, Beef, or CHicken, Ziwi Peak (recently started)  
**Description:** Not true DCM but reduced contractility [B6] taurine (whole blood)  
**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 Reacted With Product: 1

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<tr>
<td>Honest Kitchen Whole Grain Turkey, Beef, or Chicken</td>
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<td></td>
</tr>
</tbody>
</table>

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:
https://eon.fda.gov/eon//browse/EON-364577

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction/viewReport.jspa?decorator=none&e=0&issueType=12&issueId=381311

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<td>2054750</td>
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<tr>
<td><strong>Type Of Submission:</strong></td>
<td>Initial</td>
</tr>
<tr>
<td><strong>Report Version:</strong></td>
<td>FPSR.FDA.PETF.V.V1</td>
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<td><strong>Type Of Report:</strong></td>
<td>Adverse Event (a symptom, reaction or disease associated with the product)</td>
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<td><strong>Reporting Type:</strong></td>
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<tr>
<td><strong>Report Submission Date:</strong></td>
<td>2018-09-07 17:16:09 EDT</td>
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<tr>
<td><strong>Reported Problem:</strong></td>
<td>Problem Description: Not true DCM but reduced contractility, jaundice (whole blood)</td>
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<tr>
<td><strong>Date Problem Started:</strong></td>
<td>09/05/2018</td>
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<tr>
<td><strong>Concurrent Medical Problem:</strong></td>
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<td><strong>Outcome to Date:</strong></td>
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<td><strong>Purchase Location Information:</strong></td>
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<tr>
<td><strong>Animal Information:</strong></td>
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<tr>
<td><strong>Name:</strong></td>
<td>B6</td>
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<tr>
<td><strong>Type Of Species:</strong></td>
<td>Dog</td>
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<tr>
<td><strong>Type Of Breed:</strong></td>
<td>Retriever - Golden</td>
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<td><strong>Gender:</strong></td>
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<td><strong>Reproductive Status:</strong></td>
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<td><strong>Weight:</strong></td>
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<td><strong>Assessment of Prior Health:</strong></td>
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<td><strong>Number of Animals Reacted:</strong></td>
<td>1</td>
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<td><strong>Owner Information:</strong></td>
<td></td>
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<tr>
<td><strong>Owner Information provided:</strong></td>
<td>Yes</td>
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<tr>
<td><strong>Contact:</strong></td>
<td>Name: B6</td>
</tr>
<tr>
<td><strong>Address:</strong></td>
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</tr>
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<td><strong>Phone:</strong></td>
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<tr>
<td>Healthcare Professional Information:</td>
<td>Practice Name: Tufts Cummings School of Veterinary Medicine</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-----------------------------------------------------------</td>
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<td>Name: Lisa Freeman</td>
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<td>Contact:</td>
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| Permission to Release Records to FDA: Yes |

<table>
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<tr>
<th>Sender Information:</th>
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<tbody>
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<table>
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<tr>
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<td>Type: Medical Records</td>
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<tr>
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<td>Attachment: rdvm records.pdf</td>
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<td>Type: Medical Records</td>
</tr>
<tr>
<td>Description: Cardio report</td>
</tr>
<tr>
<td>Type: Medical Records</td>
</tr>
</tbody>
</table>
Discharge Instructions

Patient: B6

Species: Canine
Gold Male (Neutered) Golden Retriever

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

Cardiology Resident: B6
Cardiology Technician: B6

Date: 9/5/18

Diagnoses:
Mild reduced contractile function, normal cardiac size
Low blood taurine levels

Clinical Findings: Thank you for bringing B6 in for evaluation of his heart. His heart is normal in size, but his contractile function is not quite as vigorous as some dogs. This could be a variation of normal for him, but it is also possible that it could be related to low taurine. We have submitted an NTproBNP test to gather more information about heart health. We also submitted a total T4 to assess thyroid on his current level of medication. We will call you with these results within the next few days.

Monitoring at Home: Please watch for any exercise intolerance, weakness, or collapse.

Diet Suggestions: We recommend a change in B6 diet. If you would like to pursue a mix of home cooking and new kibble we recommend scheduling a Nutrition consultation with Dr Lisa Freeman. If you would like to feed primarily home cooked diet then please schedule an appointment with B6

Exercise Recommendations: B6 can have normal exercise.

Recommended Medications:
Taurine supplement: Give 1000mg by mouth twice daily
We recommend Swanson, NOW, or GNC brands.

Recheck Visits: We will want to do a recheck echocardiogram in around 6-12 months, but we will decide based on his NTproBNP results.

Thank you for entrusting us with B6 care. He is such a good boy! Please contact our Cardiology liaison at...
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/cvm/clinical-studies
Cardiology Appointment Report

Date: 9/5/2018

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Presenting Complaint: Low taurine level [B6]. On facebook page with UC Davis. Dr Stem recommended getting an echo. Tested positive for lyme but is not symptomatic. Has been treated in the past. Has noticed in the last year that he gets out of the pool sooner than usual. Slowing down on hikes, but no breathing difficulties or coughing. May breathe faster than other dog (34 bpm).

Owner sent out whole blood taurine test after reading about low taurine on line.

Concurrent Diseases:

B6

Diet and Supplements:
ZiwiPeak grain free, air dried; home cooked. Switched to honest kitchen about 3 years ago. Bravo canned rotates food, got treats will grains. Sardines.

Cardiovascular History:
Prior CHF diagnosis? no
Prior heart murmur? no
Prior ATE? no
Prior arrhythmia? no
Monitoring respiratory rate and effort at home? no
Cough? after swimming
Shortness of breath or difficulty breathing? no
Syncpe or collapse? no
Sudden onset lameness? no
Exercise intolerance? starting last year started leaving the pool sooner, coughs to clear throat

Current Medications Pertinent to CV System:

B6

Muscle condition:
- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:
Murmur Grade:
- None
- 1/VI
- II/VI
- III/VI

Jugular vein:
- Bottom 1/3 of the neck
- Middle 1/3 of the neck
- 1/3 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

FDA-CVM-FOIA-2019-1704-012764
Assessment and recommendations:
Echocardiogram reveals mildly reduced contractile function with no evidence of chamber enlargement or wall thinning. It is possible that these mild changes are related to taurine deficiency/diet, but other mild cardiomyopathy, age related change, or variation for this individual cannot be ruled out. An NTproBNP level was submitted for additional information. Patient is receiving thyroid supplementation and T4 has not been checked recently, so T4 was also submitted today (6 hours post pill). Recommend taurine.
supplementation and diet change. Owner will likely pursue nutrition consultation for diet options. Recheck echo in ~6 months, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance, or if NTproBNP is markedly elevated.

Final Diagnosis:
Mildly reduced LV contractile function
<table>
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<th>Unit</th>
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<td>IVS</td>
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<td>LVDS</td>
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**Doppler**

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A PFR Report has been received and PFR Event [EON-365022] has been created in the EON System.

A "PDF" report by name "2054861-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 "2054861-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-365022
ICSR #: 2054861
EON Title: PFR Event created for Nature's Variety Instinct Raw Boost Chicken dry, Rachel Ray Nutrish Chicken and Veggie dry; 2054861

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<td>Dog</td>
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Breed: Great Dane
Age: 6 Years
District Involved: PFR-New England DO

Product information
Individual Case Safety Report Number: 2054861
Product Group: Pet Food
Product Name: Nature's Variety Instinct Raw Boost Chicken dry, Rachel Ray Nutrish Chicken and Veggie dry
Description: DCM and CHF. Owner was feeding Natures Variety until ~1/8/18 then switched to Rachel Ray. Presented to ER for coughing. DCM and CHF diagnosed (with atrial fibrillation). Taurine not measured and diet not changed. Re-evaluated 9/10/18 and no improvement. Whole blood taurine pending and owner is switching diet. Owner does not have the Nature's Variety but will hold onto the Rachel Ray. She is happy to
answer any additional questions

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

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<tr>
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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:
https://eon.fda.gov/eon/browse/EON-365022

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=381781

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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through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.
Report Details - EON-365022
ICSR: 2054861
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: 2018-09-12 08:00:29 EDT

Reported Problem:
Problem Description: DCM and CHF. Owner was feeding Natures Variety until ~1/8/18 then switched to Rachel Ray. Presented to ER for coughing. DCM and CHF diagnosed (with atrial fibrillation). Taurine not measured and diet not changed. Re-evaluated 9/10/18 and no improvement. Whole blood taurine pending and owner is switching diet. Owner does not have the Nature's Variety but will hold onto the Rachel Ray. She is happy to answer any additional questions.

Date Problem Started: B6
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Rachel Ray Nutrish Chicken and Veggie dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: Description: Fed from 1/8/18 to present.
First Exposure Date: 01/08/2018
Last Exposure Date: 09/12/2018

Manufacturer/Distributor Information:
Purchase Location Information:
Product Name: Nature's Variety Instinct Raw Boost Chicken dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Opened Product: No
Product Use Information: Description: Fed from 14 months of age until ~1/8/'18
Perceived Possibly related
Relatedness to Adverse Event:

Manufacturer/Distributor Information:
Purchase Location Information:
Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Great Dane
Gender: Male
Reproductive Status: Neutered
Weight: 71 Kilogram
Age: 6 Years
Assessment of Prior Health: Excellent
| Number of Animals Given the Product: | 1 |
| Number of Animals Reacted: | 1 |
| Owner Information: | Yes |
| Contact: Name: | B6 |
| Contact: Phone: | B6 |
| Contact: Email: | B6 |
| Address: | B6 |
| United States |
| Healthcare Professional Information: |
| Practice Name: | Tufts Cummings School of Veterinary Medicine |
| Contact: Name: | Lisa Freeman |
| Contact: Phone: | (508) 887-4523 |
| Contact: 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 |
| Contact: Email: | lisa.freeman@tufts.edu |
| Permission To Contact Sender: | Yes |
| Preferred Method Of Contact: | Email |
| Additional Documents: |
| Attachment: cardio report B6 pdf |
| Description: Cardio report |
| Type: Echocardiogram |
| Attachment: discharge report B6 pdf |
| Description: Discharge report |
| Type: Medical Records |
| Attachment: diet history B6 pdf |
| Description: Diet history |
| Type: Medical Records |
| Attachment: cardiology report 9-10-18.pdf |
| Description: Cardio report |
| Type: Echocardiogram |
| Attachment: bnp.pdf |
| Description: NT-proBNP |
| Type: Laboratory Report |
Patient ID: B6
Canine
B6 Years Old Male (Neutered) Great Dane
Black BW: Weight(lbs) 0.00

Cardiology Inpatient

Date: B6
Weight: Weight(lbs) 0.00

Attending Cardiologist:

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

Cardiology Resident:

[ ] B6

Thoracic radiographs available for review?

[ ] Yes - in SS
[ ] Yes - in PACS
[ ] No

Presenting complaint and important concurrent diseases:
History of gagging/coughing. Tachycardia and irregular heart rhythm appreciated at referring veterinarian. No history of exercise intolerance or syncope.

Current medications and doses: Salmon oil

Key indication for consultation: Irregular heart rhythm, pulse deficits, tachycardia

Questions to be answered from the Consult:
Evidence of DCM vs other? Evidence of CHF?

Is your consult time-sensitive? (e.g., anesthesia today, owner waiting, trying to get biopsy today)

[ ] Yes (explain)
[ ] No

*STOP - remainder of form to be filled out by Cardiology*

Physical Examination
Muscle condition:
- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam
Murmur Grades:
- None
- I/VI
- II/VI
- III/VI
- IV/VI
- V/VI
- VI/VI

Murmur location/description: systolic left apical

Jugular vein:
- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3 of neck

Arterial pulses:
- Weak
- Fair
- Good
- Strong
- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other (describe):

Arrhythmia:
- None
- Sinus arrhythmia
- Premature beats
- Bradycardia
- Tachycardia, irregular

Gallop:
- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds
- Pulmonary Crackles
- Wheezes
- Upper airway stridor
- Other auscultatory findings:

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

Echocardiogram Findings:
B6

FDA-CVM-FOIA-2019-1704-012809
Assessment and recommendations:
Echocardiogram reveals severe DCM with moderate secondary IAE, and EKG reveals atrial fibrillation with rapid ventricular response rate. Changes are consistent with CHF being the cause for reported cough. Recommend treating with B6 and B6, and consider addition of an ACE inhibitor and low dose of B6. Recommend B6. Recommend B6. Recheck renal function level 6-8 hours post pill, and ECG in 7-10 days. Recheck echo/fluid check in ~3 months, or sooner if clinical sign occur such as increased RR/RE, cough, collapse, or exercise intolerance.

Addendum: Overnight telemetry showed relatively frequent VPCs, couplets with Ron T morphology, and occasional non sustained ventricular tachycardia. Recommend stopping B6 and adding B6 at 400 mg PO BID for 7 days, then 510.

Treatment plan:

Final Diagnosis:
DCM, CHF
Atrial fibrillation with rapid ventricular response rate

Heart Failure Classification Score:
ISACHC Classification:
- Ia
- Ib
- II
- IIIa
- IIIb
Cardiology Appointment Report

Date: 9/10/2018

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVECC

B6

Cardiology Resident:

Cardiology Technician:

Student: B6

Presenting Complaint: Recheck for DCM & atrial fibrillation diagnosed Feb 2018

Concurrent Diseases:
None

General Medical History:
Diagnosed DCM Feb 2018
Doing well in general, good energy level, seems to have good tolerance for exercise. Eating well, drinking well. Some diarrhea in car on way over, other than that nothing.
Cough has diminished over time, but coughs approximately once or twice a day. Rarely gives an extra dose of... (maybe "once a month")

Diet and Supplements:
Rachel Ray Nutrish "Real Chicken & Veggies" flavor 3 cups BID
1/3 cup + 1/2 cup chicken broth +/- chicken a day

Salmon Oil

Cardiovascular History:
Prior CHF diagnosis? yes
Prior heart murmur? yes
Prior ATE? no
Prior arrhythmia? yes
Monitoring respiratory rate and effort at home? yes
Cough? yes
Shortness of breath or difficulty breathing? yes
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? mild

**Current Medications Pertinent to CV System:**

- Normal
- Mild muscle loss
- Moderate cachexia
- Severe cachexia

**Cardiovascular Physical Exam:**

- **Murmur Grade:**
  - None
  - I/VI
  - II/VI
  - III/VI
  - IV/VI
  - V/VI

- **Murmur location/description:** Holosystolic
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
- Pulsum paradoxus
- Other:

Arrhythmias:
- None
- Sinus arrhythmia
- Irregularly irregular
- Bradycardia
- Tachycardia

Gallop:
- Yes
- No
- Intermittent
- Pronounced
- Other:

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

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:
Prior diagnosis DCM, Atrial fibrillation

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

Echoendoscopy

B6
Assessment and recommendations:

Echocardiogram reveals DCM with similar LA size and progression in LV cavity size (r/o disease progression with contribution from slower heart rate today compared to last exam). Ventricular arrhythmia appears well controlled, but atrial fibrillation ventricular response rate was rapid today. Recommend

Final Diagnosis:

DCM, history of CHF
Atrial fibrillation with rapid ventricular response rate

Heart Failure Classification Score:

ISACHC Classification:
- □ Ia
- □ Ib
- □ II

ACVIM Classification:
- □ A
- □ B1
- □ B2

M-Mode

IVSd  cm
LVIDd  cm
LVPWd  cm
IVSs  cm
LVIDs  cm
LVPWs  cm
%FS  %
Ao Diam  cm
LA Diam  cm
LA/Ao  cm
Max LA  cm

M-Mode Normalized

IVSdN  (0.29 - 0.52)
LVIDdN  (1.35 - 1.73)
LVPWdN  (0.33 - 0.53)
IVSsN  (0.43 - 0.71)
LVIDsN  (0.79 - 1.14)
LVPWsN  (0.53 - 0.78)
Ao Diam N  (0.68 - 0.89)
LA Diam N
2D
SA LA
Ao Diam
SA LA / Ao Diam
IVSd
LVIDd
LVPWd
EDV (Teich)
IVSs
LVIDs
LVPWs
ESV (Teich)
EF (Teich)
%FS
SV (Teich)
LVot LAX
LVAd LAX
LVEDV A-L LAX
LVEDV MOD LAX
LVls LAX
LVAs LAX
LVESV A-L LAX
LVESV MOD LAX
HR
EF A-L LAX
LVEF MOD LAX
SV A-L LAX
SV MOD LAX
CO A-L LAX
CO MOD LAX
Doppler
MR Vmax
MR maxPG
PV Vmax
PV maxPG
AV Vmax
AV maxPG

B6

(0.64 - 0.90) l

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mmHg
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mmHg
m/s
mmHg

FDA-CVM-FOIA-2019-1704-012816
Discharge Instructions

Patient
Name: B6
Species: Canine
Sex: Male (Neutered)
Date of Birth: 86

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
John E. Rush DVM, MS, DACVIM (Cardiology), DACVIM (Cardiology)

B6

Cardiology Resident:
B6

Cardiology Technician:
B6

Admit Date: 86 11:16:58 AM
Discharge Dates: B6

Diagnoses:
Dilated cardiomyopathy (DCM) with congestive heart failure
Atrial fibrillation and ventricular arrhythmias

Case summary:
Thank you for bringing B6 to Tufts for evaluation of his coughing and irregular heart rhythm. 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. The heart enlargement has now progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs and causing cough. 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 B6 comfortable and have him breathing easier.

Diagnostic test results and findings:
Chest radiograph (x-ray) findings: The heart was enlarged and there was fluid in the lungs.
Echocardiogram findings: All chambers of the heart are enlarged and the contractile function is reduced.
ECG findings: The ECG showed atrial fibrillation with rapid ventricular response rate. Additionally there were some ventricular arrhythmias (ventricular premature beats and ventricular tachycardia).
Laboratory findings: The kidney values and urinalysis are within normal limits. He has slightly elevated bilirubin, and elevated AST but the rest of his liver values are normal and these values have decreased during his stay.
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 \[ \text{B6} \]
  If difficulty breathing is not improved by within 30-60 minutes after giving extra \[ \text{B6} \], 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.
- You may want to explore the option of purchasing an Aliveto/Kardia at home ECG monitoring device. This would allow you to get an ECG and send it to us via email.

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 website (http://vet.tufts.edu/heartsmart/diet/)

Your dog’s usual diet may also have more sodium than recommended - we want him to continue to eat his 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.). Hopefully you can find a diet on the list that your dog likes to eat. Alternatively, you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

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.

Recheck Visits:
A recheck visit is recommended in 1-2 weeks to check kidney values, electrolytes, and liver values. An ECG is also recommended at that time. This can be done with us or with your primary care veterinarian. If you have any concerns about how things are going then we would prefer for [B6] to come here for that recheck.

A recheck echocardiogram is recommended in 3-4 months, or sooner if you have any concerns. Please call or email to schedule this appointment.

Thank you for entrusting us with [B6] care. He is such a sweet boy. Please contact our Cardiology liaison, [B6] or email us at cardiology@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 (508-827-4629) 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/cme/clinical-studies

A PFR Report has been received and PFR Event [EON-364568] has been created in the EON System.

A "PDF" report by name "2054744-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 "2054744-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-364568  
**ICSR #:** 2054744  
**EON Title:** PFR Event created for Rachel Ray Nutrish real beef and brown rice (barcode 7119000095); 2054744

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**Product information**

**Individual Case Safety Report Number:** 2054744  
**Product Group:** Pet Food  
**Product Name:** Rachel Ray Nutrish real beef and brown rice (barcode 7119000095)  
**Description:** Diagnosed with DCM and CHF  
**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 Reacted With Product: 1

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<td>Rachel Ray Nutrish real beef and brown rice (barcode 7119000095)</td>
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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:
https://eon.fda.gov/eon//browse/EON-364568

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction/viewReport.jspa?decorator=none&e=0&issueType=12&issueId=381302

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

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAREportableFoods@fda.hhs.gov immediately.
**Report Details - EON-364568**

**ICSR:** 2054744

**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 16:24:16 EDT

**Reported Problem:**

<table>
<thead>
<tr>
<th>Problem Description</th>
<th>Diagnosed with DCM and CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Problem Started</td>
<td>08/06/2018</td>
</tr>
<tr>
<td>Concurrent Medical Problem</td>
<td>No</td>
</tr>
<tr>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
</tbody>
</table>

**Product Information:**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Rachel Ray Nutrish real beef and brown rice (barcode 7119000095)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type</td>
<td>Pet Food</td>
</tr>
<tr>
<td>Lot Number</td>
<td></td>
</tr>
<tr>
<td>Package Type</td>
<td>BAG</td>
</tr>
<tr>
<td>Product Use Information</td>
<td>First Exposure Date: 01/02/2017</td>
</tr>
</tbody>
</table>

**Animal Information:**

<table>
<thead>
<tr>
<th>Name</th>
<th>B6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type Of Species</td>
<td>Dog</td>
</tr>
<tr>
<td>Type Of Breed</td>
<td>Mixed (Dog)</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
</tr>
<tr>
<td>Reproductive Status</td>
<td>Neutered</td>
</tr>
<tr>
<td>Weight</td>
<td>25.6 Kilogram</td>
</tr>
<tr>
<td>Age</td>
<td>6 Years</td>
</tr>
<tr>
<td>Assessment of Prior Health</td>
<td>Excellent</td>
</tr>
<tr>
<td>Number of Animals Reacted</td>
<td>1</td>
</tr>
</tbody>
</table>

**Owner Information:**

<table>
<thead>
<tr>
<th>Name</th>
<th>B6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone</td>
<td></td>
</tr>
</tbody>
</table>

**Address:**

United States

**Healthcare Professional Information:**

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Tufts Cummings School of Veterinary Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Name</td>
<td>Lisa Freeman</td>
</tr>
<tr>
<td>Phone</td>
<td>(508) 887-4523</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
<tr>
<td>Address</td>
<td>200 Westboro Rd North Grafton Massachusetts 01536 United States</td>
</tr>
<tr>
<td>Attachment</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>cardio report.pdf</td>
<td>Cardio report</td>
</tr>
<tr>
<td>diet history.pdf</td>
<td>Diet history</td>
</tr>
<tr>
<td>discharge.pdf</td>
<td>Discharge</td>
</tr>
<tr>
<td>chem profile.pdf</td>
<td>Chem profile</td>
</tr>
<tr>
<td>taurine.pdf</td>
<td>Taurine</td>
</tr>
</tbody>
</table>
Withheld in Full as B5, B6
DOCUMENT PRODUCED IN NATIVE
DOCUMENT PRODUCED IN NATIVE
Withheld in Full as B4, B5, B6
A PFR Report has been received and PFR Event [EON-372652] has been created in the EON System.

A "PDF" report by name "2059566-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 "2059566-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-372652  
**ICSR #:** 2059566  
**EON Title:** PFR Event created for Blue Buffalo Wilderness Large Breed Grain free dry; 2059566

<table>
<thead>
<tr>
<th>AE Date</th>
<th>09/18/2018</th>
<th>Number Fed/Exposed</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Best By Date</td>
<td></td>
<td>Number Reacted</td>
<td>1</td>
</tr>
<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Great Dane</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>6 Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**

**Individual Case Safety Report Number:** 2059566  
**Product Group:** Pet Food  
**Product Name:** Blue Buffalo Wilderness Large Breed Grain free dry  
**Description:** Evaluated for exercise intolerance; identified ventricular arrhythmia and mildly reduced contractile function. Plasma taurine [B6] WB not evaluated. We will be rechecking dog in a 3-4 months. Was eating BEG diet (Blue Buffalo) at time of diagnosis then switched to Fromm Lg Breed after diagnosis but now transitioning to Pro Plan Weight Management  
**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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Buffalo Wilderness Large Breed Grain free dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:
https://eon.fda.gov/eon/browse/EON-372652

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=12&issueId=389621

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**Report Details - EON-372652**

**ICSR:** 2059566

**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:** 2018-12-03 14:40:10 EST

**Reported Problem:**

<table>
<thead>
<tr>
<th>Problem Description</th>
<th>Evaluated for exercise intolerance, identified ventricular arrhythmia and mildly reduced contractile function. Plasma taurine [B6] (WB not evaluated). We will be rechecking dog in a 3-4 months. Was eating BEG diet (Blue Buffalo) at time of diagnosis then switched to Fromm Lg Breed after diagnosis but now transitioning to Pro Plan Weight Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Problem Started</td>
<td>09/18/2018</td>
</tr>
<tr>
<td>Concurrent Medical Problem</td>
<td>No</td>
</tr>
<tr>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
</tbody>
</table>

**Product Information:**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Blue Buffalo Wilderness Large Breed Grain free dry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type</td>
<td>Pet Food</td>
</tr>
<tr>
<td>Lot Number</td>
<td></td>
</tr>
<tr>
<td>Package Type</td>
<td>BAG</td>
</tr>
<tr>
<td>Product Use Information</td>
<td></td>
</tr>
<tr>
<td>Manufacturer /Distributor Information</td>
<td></td>
</tr>
<tr>
<td>Purchase Location Information</td>
<td></td>
</tr>
</tbody>
</table>

**Animal Information:**

<table>
<thead>
<tr>
<th>Name</th>
<th>B6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type Of Species</td>
<td>Dog</td>
</tr>
<tr>
<td>Type Of Breed</td>
<td>Great Dane</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td>Reproductive Status</td>
<td>Neutered</td>
</tr>
<tr>
<td>Weight</td>
<td>97.8 Kilogram</td>
</tr>
<tr>
<td>Age</td>
<td>6 Years</td>
</tr>
<tr>
<td>Assessment of Prior Health</td>
<td>Excellent</td>
</tr>
<tr>
<td>Number of Animals</td>
<td>1</td>
</tr>
<tr>
<td>Given the Product</td>
<td>1</td>
</tr>
<tr>
<td>Number of Animals Reacted</td>
<td>1</td>
</tr>
</tbody>
</table>

**Owner Information:**

<table>
<thead>
<tr>
<th>Owner Information provided</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact</td>
<td>Name: B6</td>
</tr>
<tr>
<td>Phone</td>
<td>B6</td>
</tr>
<tr>
<td>Email</td>
<td>B6</td>
</tr>
<tr>
<td>Address</td>
<td>B6 United States</td>
</tr>
<tr>
<td>Healthcare Professional Information</td>
<td>Practice Name: Tufts Cummings School of Veterinary Medicine</td>
</tr>
<tr>
<td>Contact</td>
<td>Name: Lisa Freeman</td>
</tr>
<tr>
<td>Phone</td>
<td>(508) 887-4523</td>
</tr>
<tr>
<td><strong>Sender Information:</strong></td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td><strong>Name:</strong></td>
<td>Lisa Freeman</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
<td>Phone: 5088874523</td>
</tr>
<tr>
<td><strong>Permission To Contact:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Additional Documents:</strong></td>
<td>Attachment: records B6 pdf</td>
</tr>
<tr>
<td></td>
<td>Description: Records</td>
</tr>
<tr>
<td></td>
<td>Type: Medical Records</td>
</tr>
</tbody>
</table>
**Report Details - EON-372831**

**ICSR:** 2059622

**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:** 2018-12-04 18:08:14 EST

**Reported Problem:**

<table>
<thead>
<tr>
<th>Problem Description</th>
<th>Date Problem Started</th>
<th>Concurrent Medical Problem</th>
<th>Outcome to Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daughter diagnosed with reduced cardiac contractility</td>
<td>11/15/2018</td>
<td>No</td>
<td>Stable</td>
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</table>

**Product Information:**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Type</th>
<th>Lot Number</th>
<th>Package Type</th>
<th>Product Use Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earthborn Meadow Feast dry</td>
<td>Pet Food</td>
<td></td>
<td>BAG</td>
<td>Description: See diet history in medical record for more info</td>
</tr>
</tbody>
</table>

**Animal Information:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Type Of Species</th>
<th>Type Of Breed</th>
<th>Gender</th>
<th>Reproductive Status</th>
<th>Pregnancy Status</th>
<th>Lactation Status</th>
<th>Weight</th>
<th>Age</th>
<th>Assessment of Prior Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>B6</td>
<td>Dog</td>
<td>Boxer (German Boxer)</td>
<td>Female</td>
<td>Intact</td>
<td>Not pregnant</td>
<td>Not lactating</td>
<td>29.1 Kilogram</td>
<td>3 Years</td>
<td>Excellent</td>
</tr>
</tbody>
</table>

**Number of Animals Given the Product:** 5

**Number of Animals Reacted:** 4

**Owner Information:**

<table>
<thead>
<tr>
<th>Owner Information</th>
<th>Owner Information provided</th>
<th>Contact</th>
<th>Name</th>
<th>Phone</th>
<th>Email</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td></td>
<td>B6</td>
<td>B6</td>
<td>B6</td>
<td>B6 United States</td>
</tr>
</tbody>
</table>

**Healthcare Professional Information:**

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Contact</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tufts Cummings School of Veterinary Medicine</td>
<td>Lisa Freeman</td>
<td></td>
</tr>
<tr>
<td>Sender Information:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>Name:</td>
<td>Lisa Freeman</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>200 Westboro Rd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>North Grafton</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Massachusetts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>01536</td>
<td></td>
</tr>
<tr>
<td></td>
<td>United States</td>
<td></td>
</tr>
<tr>
<td>Contact:</td>
<td>Phone: (508) 887-4523</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
<td></td>
</tr>
<tr>
<td>Permission To Contact:</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Preferred Method Of Contact:</td>
<td>Email</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Documents:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment:</td>
<td>rpt_medical_record_preview_B6.pdf</td>
</tr>
<tr>
<td>Description:</td>
<td>Medical records</td>
</tr>
<tr>
<td>Type:</td>
<td>Medical Records</td>
</tr>
</tbody>
</table>
**Foster Hospital for Small Animals**
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

---

**All Medical Records**

<table>
<thead>
<tr>
<th>Client:</th>
<th>B6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
</tbody>
</table>

| Patient: | B6 |
| Breed: | Golden Retriever Cross |
| DOB: | B6 |
| Species: | Canine |
| Sex: | Male (Neutered) |

| Home Phone: | B6 |
| Work Phone: | |
| Cell Phone: | B6 |

---

**Referring Information**

| Client: | B6 |
| Patient: | |

---

**Initial Complaint:**

**New, DCM**

**SOAP Text**

12:07PM

---

**Disposition/Recommendations**
Client: B6
Veterinarian: 
Patient ID: B6
Visit ID: 

**Lab Results Report**

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>Reference Range</th>
<th>Units</th>
</tr>
</thead>
</table>

**Accession ID:**

B6

3/23

Printed Thursday, December 27, 2018
Client: B6

Patient: B6

Referral, labs, echo

**Chief Concern/Provisional Diagnosis:** Dilated Cardiomyopathy

**Other History:** Dilated Cardiomyopathy

**Diagnostic Test Results (please attach if possible):**

Echo 2017, 2018

**Are Radiographs Enclosed?** [ ]

**Preferred means of communicating with you about this case?** Phone [ ] Fax [ ] Email [ ]
**Client:**

**Patient:**

---

**Index of N, 1+, 2+ exhibits no significant effect on chemistry values.**

**LIPEMIA INDEX**

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALB</td>
<td>3.5 - 5.0 g/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>0.2 - 1.0 mg/dL</td>
</tr>
<tr>
<td>ALT</td>
<td>10 - 45 IU/L</td>
</tr>
<tr>
<td>AST</td>
<td>10 - 45 IU/L</td>
</tr>
<tr>
<td>BUN</td>
<td>10 - 25 mg/dL</td>
</tr>
<tr>
<td>Creatinine</td>
<td>1.0 - 2.0 mg/dL</td>
</tr>
</tbody>
</table>

**AMMONIA**

<table>
<thead>
<tr>
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<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALTU</td>
<td>10 - 45 IU/L</td>
</tr>
<tr>
<td>ASTU</td>
<td>10 - 45 IU/L</td>
</tr>
<tr>
<td>BUNU</td>
<td>10 - 25 mg/dL</td>
</tr>
<tr>
<td>Creatinine</td>
<td>1.0 - 2.0 mg/dL</td>
</tr>
</tbody>
</table>

**BLOOD GLUCOSE**

<table>
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<tr>
<th>Test</th>
<th>Result</th>
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</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>60 - 110 mg/dL</td>
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</table>

**BLOOD UREA**

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
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</thead>
<tbody>
<tr>
<td>Urea</td>
<td>10 - 25 mg/dL</td>
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</table>

**C/COMPREHENSIVE**

<table>
<thead>
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<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>4.0 - 17.0 x 10^9/L</td>
</tr>
<tr>
<td>HGB</td>
<td>13.4 - 25.7 g/dL</td>
</tr>
<tr>
<td>HCT</td>
<td>36.0 - 55.0 %</td>
</tr>
<tr>
<td>MCV</td>
<td>80 - 95 fL</td>
</tr>
<tr>
<td>MCH</td>
<td>27.0 - 32.0 pg</td>
</tr>
<tr>
<td>MCHC</td>
<td>32.8 - 36.8 g/dL</td>
</tr>
<tr>
<td>% RETICULOCYTE</td>
<td>0 - 1.5 %</td>
</tr>
<tr>
<td>% NEUTROPHIL</td>
<td>20 - 50 %</td>
</tr>
<tr>
<td>%LYMPHOCYTE</td>
<td>20 - 40 %</td>
</tr>
<tr>
<td>% MONOCYTE</td>
<td>1 - 8 %</td>
</tr>
<tr>
<td>% EOSINOPHIL</td>
<td>0 - 5 %</td>
</tr>
<tr>
<td>% BASOPHIL</td>
<td>0 - 1 %</td>
</tr>
<tr>
<td>PLATELET</td>
<td>150,000 - 400,000</td>
</tr>
<tr>
<td>REMARKS</td>
<td>Blistered redness microscopically. No parasites seen.</td>
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**COLLECTION METHOD**

<table>
<thead>
<tr>
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<th>Result</th>
</tr>
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<tbody>
<tr>
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**COLOR**

<table>
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<th>Result</th>
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<tbody>
<tr>
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</table>

**CLARITY**

<table>
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**FINAL REPORT - CONTINUED ON NEXT PAGE**

---

Page 8/23
Client: B6
Patient: B6

Referral, labs, echo

Final Report
Page 9 of 3
**ECG CARDIOGRAM REPORT**

<table>
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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>Pet Name</td>
<td>B6</td>
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<tr>
<td>Hospital</td>
<td>B6</td>
</tr>
<tr>
<td>Species: Canine</td>
<td>Breed: Goldenoodle</td>
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<tr>
<td>DOB: 8 y</td>
<td>Sex: M</td>
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<tr>
<td>Weight: 69.1 lb</td>
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</tbody>
</table>


Blood Pressure: 161/83, 105/63, 96/58.
Page 2

B6 echocardiogram report, continued.

Assessment:

1. Dilated Cardiomyopathy - Myopathic

Recommendations: There is a degree of progression since the last study with progressive systolic dysfunction and the development of mild enlargement of the left atrium. These findings remain consistent with occult Dilated Cardiomyopathy. This patient may continue to remain asymptomatic for an extended period of time, however he is at risk for exercise intolerance, weakness, lethargy, syncope, ventricular and atrial arrhythmias, development of congestive heart failure, and even passing away suddenly.

Interpret by: B6 DVM, DACVM (Cardiology)
Performed by: B6 RDCC

If you have any further questions or concerns regarding this case, please contact B6 at:
Client: B6
Patient: B6

rDVM B6 referral, labs, echo

ECHOCARDIOGRAM REPORT

Date: B6
Pet Name: B6
Species: Canine
Breed: Golden Doodle
DOB: (7 y)
Sex: MN
Weight: 03.1 lb

History/Clinical presentation: New grade IV systolic murmur noted on PE. ECG?
Dog needs dental cleaning, FIK for anesthesia
Blood pressure: 166/83 (106); 161/61 (95); 145/80 (107)

Continued on page 2.
Page 3

ASSESSMENT:
1. Dilated Cardiomyopathy – Idiopathic

RECOMMENDATIONS: Unfortunately, this patient’s has myocardial failure of both the LV and RV enlargement. These findings are consistent with occult Dilated Cardiomyopathy. This patient may continue to remain asymptomatic for an extended period of time; however, he does have risk for exercise intolerance, weakness, lethargy, syncope, ventricular and atrial arrhythmias, development of congestive heart failure, and even passing away suddenly.

Interpreted by: 

FDA-CVM-FOIA-2019-1704-012935
### Cardiology Diet History Form

#### Pet's Name: [Client: B6] [Patient: B6]

**Owner's Name:**

1. How would you assess your pet's appetite? (Mark the position on the line that best represents your pet's appetite.)
   - Poor
   - Good
   - 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
   - Eats to prefer different foods than usual
   - Other

3. Over the last few weeks, has your pet:
   - Lost weight
   - Gained weight
   - Stayed about the same weight
   - Don't know

4. Please list below ALL pet foods, people food, treats, snacks, 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.

<table>
<thead>
<tr>
<th>Food/brand-specific product and flavor</th>
<th>Form</th>
<th>Amount</th>
<th>How often?</th>
<th>Feeding notes</th>
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<tbody>
<tr>
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</table>

Any additional diet information can be filled out 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 intense and amount.

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 regular food
   - [ ] I put them in a Pill Pouch or similar pouch
   - [ ] I put them in food (list food): [ ]

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Page 15/23

FDA-CVM-FOIA-2019-1704-012937
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ECG from Cardio
### Patient History

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<tr>
<td>10:00 AM</td>
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<td>10:15 AM</td>
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<td>11:11 AM</td>
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<tr>
<td>03:13 PM</td>
<td>Email</td>
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</table>
Dear B6

Thank you for referring B6 with their pet B6.

Would we be able to see the echo images for the patient? The images can be emailed to us at carelovet@tufts.edu

If you have any questions, or concerns, please contact us at 508-822-4988.

Thank you,

B6

[ורי, DACVIM (Cardiology)]
Initial Complaint:
New cruciate evaluation, possibly sx at rDVM

History: 7 yo CM Dobie presenting for his right hind limb lameness. 2 weeks ago he became acutely lame on his RH after running around. He was taken to the DVM who suspected a \underline{B6} rupture. Hx of \underline{B6} for 6 years. rDVM did bloodwork, showed increase of ALT and started him on \underline{B6} ALT decreased after 2 weeks.

Exam:
Subjective Nervous. BAR-H. MM pink, moist. CRT<2s
Plan
RH CCL repair with Lateral Suture

Initial Complaint:
Drop Off Chief Surgery, admit to B ward

SOAP Text

Subjective

Objective

Assessment

Plan

SOAP Text

History: 7 yo CM Dobie presenting for right hind limb lameness. He became acutely lame on his RH after running around 3-4 weeks ago. He was taken to the DVM who suspected a B6 rupture. Hx of B6 for 6 years. DVM did bloodwork, showed increase of ALT and started him on B6. ALT decreased after 2 weeks of B6.

Subjective (S): BAR-H. Very anxious. MM pink, moist CRT<2s
Patient did well overnight. He ate prior to drop off. Drinking and urinating normally. No stool produced.

Objective (O)
Assessment (A)
A1: Torn Cranial cruciate ligament - RH

Plan (P)

SOAP completed by: B6
SOAP reviewed by:

Addendum:
Patient vWF is 41%. Minimal risk of bleeding. B6 explained vWF protocol with owner. She wants to proceed with surgery and use the protocol. Patient received 2 units of B6 was blood typed, and given DDAVP 30 minutes prior to surgery.

Anesthesia Notes - 0.00 Rough recovery - extubated fine then had loud vocalization with head thrashing. Gave 0.5mcg dexmedetomidine IV. Relaxed quickly - stopped panting and RR returned to 28/m. Recovering in ICU - likely to be moved to B ward overnight. Gave B6 2:44PM. T= 99F. Rounded with ICU technicians during tech rounds
History: 7 yo CM Dobie presenting for right hind limb lameness. He became acutely lame on his RH after running around 3-4 weeks ago. He was taken to the DVM who suspected a rupture. Hx of for 6 years. rDVM did bloodwork, showed increase of ALT and started him on ALT decreased after 2 weeks on  

Subjective (S): BAR-H. Very anxious. MM pink, moist CRT<2s 1 day post op lateral suture. Patient did well overnight. He ripped out his T-set. E collar was placed. He is eating and urinating. No stools noted overnight, but he produced a large stool during recovery.

Objective (O)  
H/L: NMA, NSR, fPSS, Normal BVs bilaterally. Eupneic.

Assessment (A)  

Plan (P)  

SOAP completed by SOAP reviewed by: 
Subjective (S): BAR-H. Very anxious. MM pink, moist CRT<2s
2 days post op lateral suture RH. Patient did well over night. Catheter intact as is his E collar. He is eating and urinating. Still has yet to defecate, but he produced a large stool during recovery. He was misbehaving re his catheter last night so was switched to oral

Bandage removed today, incision looks very well apposed with minimal discharge. Nonpainful on palpation. Ready to be discharged today.

Objective (O)


Plan (P)

P1: Discharge today

Initial Complaint:
Chief Recheck No Xrays

Recheck examination:
Client: B6

Patient: B6

SOAP created by: B6 V16

SOAP reviewed by:

Initial Complaint:
New B6 DCM/arrhythmia (poss DCM study)

Initial Complaint:
Emergency

Initial Complaint:
Chief New Soft Tissue B6 on gums - CT on hold 12/11 @ 3PM
Hx VW and heart disease (cardio appt 12/5)

Initial Complaint:
Drop Off Chief Surgery, Admit to B, mandible mass

Subjective
EXAM, GENERAL

Subjective (S)

10 yo CM Doberman

B6 is presenting today for resection. Owner noticed an oral mass on right side of mouth around mid-May of this year. It reportably started as an abscess, and about a month ago the owner noticed the mass triple in size, still has a good appetite and is on a home cooked soft food diet. The mass has been bleeding and has a significant odor. B6 was on a two week course of B6 which helped with the odor, and it has since discontinued and the odor has returned. B6 has a history of DCM which he is on medications to help manage.

Subjective (S)

B6
Objective (O)

H/L: NMA, NSR, FPSS, Normal BVS in all lung fields, no crackles or wheezes ausculted. Eupnic.

Diagnostics Completed:

- vWF: 68%
- Big 4: PCV 47, TS 7.6, BG 88, Azo 0

Assessment (A)

A2: History of DCM

Plan (P)

P1: Mandibular mass resection

SOAP completed by: B6 V'19
SOAP reviewed by:
Foster Hospital for Small Animals  
55 Willard Street  
North Grafton, MA 01536  
(508) 839-5395

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Report Details - EON-374789

ICSR: 2060600
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 10:47:28 EST

Reported Problem:

Problem Description: Arrhythmia identified at primary care vet on 11/15/18. Evaluated at Tufts and diagnosed DCM with VPCs and APCs. Eating unbalanced homecooked diet WB taurine plasma not measured because owner had started taurine supplementation. Owner was recommended to change diet and we will recheck in 3 months.

Date Problem Started: 11/15/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:

Product Name: Homecooked diet - see diet history in medical record
Product Type: Other
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:

Name: B6
Type Of Species: Dog
Type Of Breed: Doberman Pinscher
Gender: Male
Reproductive Status: Neutered
Weight: 40.9 Kilogram
Age: B6 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1

Owner Information:

Owner Information provided: Yes
Name: B6
Phone: B6
Email: B6
Address: B6

Healthcare Professional Information:

Practice Name: Tufts Cummings School of Veterinary Medicine
Contact: Lisa Freeman
Phone: (508) 887-4523
Email: lisa.freeman@tufts.edu

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

<table>
<thead>
<tr>
<th>Name:</th>
<th>Lisa Freeman</th>
</tr>
</thead>
</table>
| **Address:** | 200 Westboro Rd  
North Grafton  
Massachusetts  
01536  
United States |
| **Contact:** | Phone: 5088874523 |
| **Email:** | lisa.freeman@tufts.edu |

**Permission To Contact:** Yes

**Preferred Method Of Contact:** Email

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

FOUO- For Official Use Only

FDA-CVM-FOIA-2019-1704-013441
Report Details - EON-376363

ICSR: 2061172

Type Of Submission: Initial

Report Version: FPSR.FDA.PETF.V.V1

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

Reporting Type: Voluntary

Report Submission Date: 2019-01-14 17:14:59 EST

Reported Problem: Problem Description: Eating BEG diet; developed DCM and CHF 4/11/18 Owner changed diet to Royal Canin Early Cardiac and dog has improved significantly. Will recheck again in 3 months. Have not gotten approval for you to contact owner but sent an email today

Date Problem Started: 04/11/2018

Concurrent Medical Problem: No

Outcome to Date: Better/Improved/Recovering

Product Information: Product Name: Zignature kangaroo dry

Product Type: Pet Food

Lot Number: 

Package Type: BAG

Product Use Information: Description: See diet history for more details. Zignature Sept 2017-April 2017 Acana Pork/Squash before that

Manufacturer/Distributor Information: 

Purchase Location Information: 

Animal Information: Name: B6

Type Of Species: Dog

Type Of Breed: Retriever - Golden

Gender: Female

Reproductive Status: Neutered

Weight: 26.3 Kilogram

Age: B6 Years

Assessment of Prior Health: Excellent

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information: Owner Information provided: Yes

Contact: Name: B6

Phone: B6

Email: 

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

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

Sent: 3/21/2019 3:41:24 PM

Subject: Homecooked diet - see diet history in medical record: Lisa Freeman - EON-382947

Attachments: 2064359-report.pdf; 2064359-attachments.zip

A PFR Report has been received and Related PFR Event [EON-382947] has been created in the EON System.

A "PDF" report by name "2064359-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 "2064359-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-382947  
**ICSR #:** 2064359  
**EON Title:** Related PFR Event created for Homecooked diet - see diet history in medical record; 2064359

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**Product information**

**Individual Case Safety Report Number:** 2064359  
**Product Group:** Other  
**Product Name:** Homecooked diet - see diet history in medical record  
**Description:** Arrhythmia identified at primary care vet on 11/15/18. Evaluated at Tufts 12/5/18 and diagnosed DCM with VPCs and APCs. Eating unbalanced homecooked diet. WB taurine [B6] (plasma not measured because owner had started taurine supplementation). Owner was recommended to change diet and we will recheck in 3 months.
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

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<th>Product Name</th>
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This report is linked to:
Initial EON Event Key: EON-374789
Initial ICSR: 2060600

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:
https://eon.fda.gov/eon//browse/EON-382947

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=10100&issueId=400045&parentIssueTypeId=12

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through your local district FDA office.

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Report Details - EON-382947

- **ICSR:** 2064359
- **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 11:28:27 EDT
- **Initial Report Date:** 12/27/2018
- **Parent ICSR:** 2060600
- **Follow-up Report to FDA Request:** Yes

**Reported Problem:**

- **Problem Description:** Arrhythmia identified at primary care vet on 11/15/18. Evaluated at Tufts 12/5/18 and diagnosed DCM with VPCs and APCs. Eating unbalanced homecooked diet with B6 (plasma not measured because owner had started taurine supplementation). Owner was recommended to change diet and we will recheck in 3 months

- **Date Problem Started:** 11/15/2018
- **Concurrent Medical Problem:** Yes
- **Pre Existing Conditions:**

- **Outcome to Date:** Stable

**Product Information:**

- **Product Name:** Homecooked diet - see diet history in medical record
- **Product Type:** Other
- **Lot Number:**
- **Product Use Information:**
- **Manufacturer/Distributor Information:**
- **Purchase Location Information:**

**Animal Information:**

- **Name:** B6
- **Type Of Species:** Dog
- **Type Of Breed:** Doberman Pinscher
- **Gender:** Male
- **Reproductive Status:** Neutered
- **Weight:** 40.9 Kilogram
- **Age:** 6 Years
- **Assessment of Prior Health:** Good
- **Number of Animals Given the Product:** 1
- **Number of Animals Reacted:** 1
- **Owner Information:** Yes

**Contact:**

- **Name:** B6
- **Phone:** B6
- **Email:** B6
- **Address:** B6
<table>
<thead>
<tr>
<th>Healthcare Professional Information:</th>
<th>Practice Name: Tufts Cummings School of Veterinary Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact:</td>
<td>Name: Lisa Freeman</td>
</tr>
<tr>
<td></td>
<td>Phone: (508) 887-4523</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
<tr>
<td></td>
<td>Address: 200 Westboro Rd North Grafton Massachusetts 01536</td>
</tr>
<tr>
<td></td>
<td>United States</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Sender Information:</th>
<th>Name: Lisa Freeman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
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</tr>
<tr>
<td></td>
<td>North Grafton</td>
</tr>
<tr>
<td></td>
<td>Massachusetts</td>
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<tr>
<td>Contact:</td>
<td>Phone: 5088874523</td>
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<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
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<tr>
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<td>Preferred Method Of Contact:</td>
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<tr>
<td>Reported to Other Parties:</td>
<td>None</td>
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<table>
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<tr>
<th>Additional Documents:</th>
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<tbody>
<tr>
<td>Description: Medical record Dec 2018-March 2019</td>
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<tr>
<td>Type: Medical Records</td>
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<tr>
<td>Attachment: Medical record 12-2018-3-2019 2.pdf</td>
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<td>Type: Medical Records</td>
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FOUO- For Official Use Only
A PFR Report has been received and PFR Event [EON-374789] has been created in the EON System.

A "PDF" report by name "2060600-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 "2060600-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-374789
ICSR #: 2060600
EON Title: PFR Event created for Homecooked diet - see diet history in medical record: 2060600

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<td>Best By Date</td>
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<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Doberman Pinscher</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>6 Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product information
Individual Case Safety Report Number: 2060600
Product Group: Other
Product Name: Homecooked diet - see diet history in medical record
Description: Arrhythmia identified at primary care vet on 11/15/18. Evaluated at Tufts and diagnosed DCM with VPCs and APCs. Eating unbalanced homecooked diet. WB taurine plasma not measured because owner had started taurine supplementation). Owner was recommended to change diet and we will recheck in 3 months
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
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<tbody>
<tr>
<td>Homecooked diet - see diet history in medical record</td>
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</tbody>
</table>

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:
https://eon.fda.gov/eon/browse/EON-374789

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction/viewReport.jsa?decorator=none&e=0&issueType=12&issueId=391798

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

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

Below is the summary of the report:

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

<table>
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<th>AE Date</th>
<th>04/11/2018</th>
<th>Number Fed/Exposed</th>
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<td>Number Reacted</td>
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<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Better/Improved/Recovering</td>
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<tr>
<td>Breed</td>
<td>Retriever - Golden</td>
<td></td>
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<tr>
<td>Age</td>
<td>[B6] Years</td>
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<td></td>
</tr>
</tbody>
</table>

**District Involved:** PFR-New England DO

**Product information**  
**Individual Case Safety Report Number:** 2061172  
**Product Group:** Pet Food  
**Product Name:** Zignature kangaroo dry  
**Description:** Eating BEG diet; developed DCM and CHF 4/11/18 Owner changed diet to Royal Canin Early Cardiac and dog has improved significantly. Will recheck again in 3 months. Have not gotten approval for you to contact owner but sent an email today  
**Submission Type:** Initial  
**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)  
**Outcome of reaction/event at the time of last observation:** Better/Improved/Recovering
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Zignature kangaroo dry</td>
<td></td>
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</table>

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:
https://eon.fda.gov/eon/browse/EON-376363

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorate=none&e=0&issueType=12&issuel=393372

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**Report Details - EON-376446**

**ICSR:** 2061214  
**Type Of Submission:** Initial  
**Report Version:** FPSR.FDA.PETF.V.V1  
**Type Of Report:** Adverse Event (a symptom, reaction or disease associated with the product)  
**Reporting Type:** Voluntary  
**Report Submission Date:** 2019-01-15 15:49:52 EST

**Reported Problem:**  
**Problem Description:** 2 syncopal episodes in summer got echo in October 2018 and arrhythmia identified. Feeding BEG diets all of her life (Zignature) DCM and VPCs identified 1/9/19. Owner changing to Purina EN Fiber and we will recheck in 3 months. BNP elevated, troponin and taurine pending.

**Date Problem Started:** 01/09/2019  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** Boxer as young dog. Successfully treated.  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Zignature - various flavors (venison, goat, kangaroo, lamb, turkey, pork)  
**Product Type:** Pet Food  
**Lot Number:**   
**Product Use Information:** Description: Rotated proteins/flavors of Zignature for past 8-9 years

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Boxer (German Boxer)  
**Gender:** Female  
**Reproductive Status:** Neutered  
**Weight:** 21 Kilogram  
**Age:** 1 Years  
**Assessment of Prior Health:** Good  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1

**Owner Information:**  
**Owner Information provided:** Yes  
**Contact:** Name: B6  
**Phone:** B6  
**Email:**  
**Address:** United States

**Healthcare Professional Information:**  
**Practice Name:** Tufts Cummings School of Veterinary Medicine  
**Contact:** Name: Lisa Freeman  
**Phone:** (508) 887-4523
**Sender Information:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Lisa Freeman</th>
</tr>
</thead>
</table>
| 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:**

<table>
<thead>
<tr>
<th>Attachment</th>
<th>rpt_medical_record_preview.pdf</th>
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</thead>
<tbody>
<tr>
<td>Description</td>
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<tr>
<td>Type</td>
<td>Medical Records</td>
</tr>
</tbody>
</table>
A PFR Report has been received and PFR Event [EON-380706] has been created in the EON System.

A "PDF" report by name "2063113-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 "2063113-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380706  
**ICSR #:** 2063113  
**EON Title:** PFR Event created for Poulin Pro Form Lamb and Rice Adult Maintenance Dry; 2063113

<table>
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<th>AE Date</th>
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<tr>
<td>Best By Date</td>
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<td>Number Reacted</td>
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<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Irish Wolfhound</td>
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</tr>
<tr>
<td>Age</td>
<td>6 Years</td>
<td></td>
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</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**  
**Individual Case Safety Report Number:** 2063113  
**Product Group:** Pet Food  
**Product Name:** Poulin Pro Form Lamb and Rice Adult Maintenance Dry  
**Description:** Had arrhythmias in September 2018; re-presented in December 2018 when arrhythmias were noted. Cardiologist consulted identified arrhythmias and reduced contractile function (and eating BEG diet). Unclear whether this was primary problem or secondary to systemic illness. Rechecked by cardiology 2/5/19 and still had arrhythmia and reduced contractility. NT-proBNP and cTnl elevated. Owner already changed diet in January to Purina Pro Plan Chicken and Rice so will continue on this diet and will recheck in 3 months.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Poulin Pro Form Lamb and Rice Adult Maintenance Dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:
https://eon.fda.gov/eon/browse/EON-380706

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=397715

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you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.
Report Details - EON-380706

ICSR: 2063113
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 16:24:11 EST

Reported Problem:
Problem Description: Had B6 in September 2018; re-presented in December 2018 when arrhythmias were noted. Cardiology consult identified arrhythmias and reduced contractile function (and eating BEG diet). Unclear whether this was primary problem or secondary to systemic illness. Rechecked by cardiology 2/5/19 and still had arrhythmia and reduced contractility. NT-proBNP and cTnl elevated. Owner already changed diet in January to Purina Pro Plan Chicken and Rice so will continue on this diet and will recheck in 3 months.

Date Problem Started: 12/22/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6 Sept and Dec 2018
Outcome to Date: Stable

Product Information:
Product Name: Poulin Pro Form Lamb and Rice Adult Maintenance Dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: Description: Please see diet history form for more details
Manufacturer/Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Irish Wolfhound
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Not Pregnant
Lactation Status: Not lactating
Weight: 60.5 Kilogram
Age: 6 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: B6
Phone: B6
Email: B6
Address: B6
<table>
<thead>
<tr>
<th>Healthcare Professional Information:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice Name:</td>
<td>Tufts Cummings School of Veterinary Medicine</td>
</tr>
<tr>
<td>Contact:</td>
<td></td>
</tr>
<tr>
<td>Name:</td>
<td>Lisa Freeman</td>
</tr>
<tr>
<td>Phone:</td>
<td>(508) 887-4523</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
</tbody>
</table>
| Address: | 200 Westboro Rd  
North Grafton  
Massachusetts  
01536  
United States |

<table>
<thead>
<tr>
<th>Sender Information:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Lisa Freeman</td>
</tr>
</tbody>
</table>
| Address: | 200 Westboro Rd  
North Grafton  
Massachusetts  
01536  
United States |
| Contact: |  |
| Phone: | 5088874523 |
| Email: | lisa.freeman@tufts.edu |

<table>
<thead>
<tr>
<th>Permission To Contact</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sender:</td>
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<tr>
<td>Preferred Method Of Contact:</td>
<td>Email</td>
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<tr>
<td>Type:</td>
<td>Medical Records</td>
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</table>
A PFR Report has been received and Related PFR Event [EON-390164] has been created in the EON System.

A "PDF" report by name "2068069-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 "2068069-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390164  
**ICSR #:** 2068069  
**EON Title:** Related PFR Event created for Poulin Pro Form Lamb and Rice Adult Maintenance Dry; 2068069

<table>
<thead>
<tr>
<th>AE Date</th>
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<tbody>
<tr>
<td>12/22/2018</td>
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<td>Dog</td>
</tr>
</tbody>
</table>

- **Best By Date**: 
- **Number Reacted**: 1
- **Animal Species**: Dog  
- **Outcome to Date**: Stable  
- **Breed**: Irish Wolfhound  
- **Age**: 6 Years  
- **District Involved**: PFR-New England DO

**Product information**

**Individual Case Safety Report Number:** 2068069  
**Product Group:** Pet Food  
**Product Name:** Poulin Pro Form Lamb and Rice Adult Maintenance Dry  
**Description:** Had \( \text{BEG} \) in September 2018; re-presented in December 2018 when arrhythmias were noted. Cardiology consult identified arrhythmias and reduced contractile function (and eating BEG diet). Unclear whether this was primary problem or secondary to systemic illness. Rechecked by cardiology 2/5/19 and still had arrhythmia and reduced contractility. NT-proBNP and cTnl elevated. Owner already changed diet in January to...
Purina Pro Plan Chicken and Rice so will continue on this diet and will recheck in 3 months.

**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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<td></td>
<td></td>
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</tbody>
</table>

This report is linked to:

**Initial EON Event Key:** EON-380706

**Initial ICSR:** 2063113

**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:
https://eon.fda.gov/eon/browse/EON-390164

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=10100&issueId=407436&parentIssueTypeId=12

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**Report Details - EON-390164**

**ICSR:** 2068069  
**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 11:03:06 EDT  
**Initial Report Date:** 02/24/2019  
**Parent ICSR:** 2063113  
**Follow-up Report to FDA Request:** Yes

**Reported Problem:**  
**Problem Description:** Had arrhythmias in September 2018; re-presented in December 2018 when arrhythmias were noted. Cardiology consult identified arrhythmias and reduced contractile function (and eating BEG diet). Unclear whether this was primary problem or secondary to systemic illness. Rechecked by cardiology 2/5/19 and still had arrhythmia and reduced contractility. NT-proBNP and cTnl elevated. Owner already changed diet in January to Purina Pro Plan Chicken and Rice so will continue on this diet and will recheck in 3 months.

**Date Problem Started:** 12/22/2018  
**Concurrent Medical Problem:** Yes  
**Pre Existing Conditions:** B6 Sept and Dec 2018  
**Outcome to Date:** Stable

**Product Information:**  
**Product Name:** Poulin Pro Form Lamb and Rice Adult Maintenance Dry  
**Product Type:** Pet Food  
**Package Type:** BAG  
**Lot Number:**  
**Product Use Information:** Description: Please see diet history form for more details

**Manufacturer/Distributor Information:**

**Purchase Location Information:**

**Animal Information:**  
**Name:** B6  
**Type Of Species:** Dog  
**Type Of Breed:** Irish Wolfhound  
**Gender:** Female  
**Reproductive Status:** Intact  
**Pregnancy Status:** Not Pregnant  
**Lactation Status:** Not lactating  
**Weight:** 60.5 Kilogram  
**Age:** 6 Years  
**Assessment of Prior Health:** Good  
**Number of Animals Given the Product:** 1  
**Number of Animals Reacted:** 1

**Owner Information:** Yes  
**Information provided:**

**Contact:**  
**Name:** B6  
**Phone:** B6
<table>
<thead>
<tr>
<th>Healthcare Professional Information:</th>
<th>Practice Name: Tufts Cummings School of Veterinary Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact:</td>
<td>Name: Lisa Freeman</td>
</tr>
<tr>
<td></td>
<td>Phone: (508) 887-4523</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
<tr>
<td>Address:</td>
<td>200 Westboro Rd</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td>01536</td>
</tr>
<tr>
<td></td>
<td>United States</td>
</tr>
</tbody>
</table>

| 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:             | Yes                                                         |
| Preferred Method Of Contact:       | Email                                                       |

| Additional Documents:              | Attachment: Follow-up med records pt 2.pdf                   |
|                                   | Description: Med Records                                     |
|                                   | Type: Medical Records                                        |
|                                   | Attachment: Follow-up med records pt 1.pdf                   |
|                                   | Description: Med Records                                     |
|                                   | Type: Medical Records                                        |
|                                   | Attachment: ECG 5-9-2019.pdf                                 |
|                                   | Description: ECG                                             |
|                                   | Type: Medical Records                                        |
ECG from cardio
Discharge Instructions

Patient
Name: B6
Species: Canine
Gray Female Irish Wolfhound
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:
☐ John E. Rush DVM, MS, DACVIM (Cardiology), DACVCP

Cardioflow Resident: B6
Cardiology Technician: B6

Student: B6
Date: B6

Diagnoses:
Slightly decreased cardiac contractility - stable to a bit improved
History of single ventricular premature contractions (VPCs) - none seen today
Suspected geriatric onset laryngeal paralysis and paresis (GLPP) with recurrent B6

Clinical Findings:
Thank you for bringing B6 to the Tufts Cardiology Service for a recheck thought the DCM study.

You report that B6 is doing much better at home, and her breathing has improved since started B6. You did note that she had a laceration of the foot pad on her right hind foot, which appears to be healing well today B6.

Echocardiogram today demonstrated that the contractility of her heart is still slightly abnormal, but appears to be a bit better than on her previous exam. The chambers in her heart are normal sized and the walls of the chambers are normal thickness. Her ECG (electrocardiogram) did not show any arrhythmias (irregular heart beats).

B6 did not show any signs of worsening cardiac disease on examination today. We submitted blood today to recheck these tests, and will call or email you when we get the results.

Monitoring at Home:
Please monitor B6 for changes in appetite, vomiting, diarrhea, coughing, difficulty breathing, exercise intolerance, lethargy, or any other changes. If you note any of these, please contact us or bring her to see a veterinarian as soon as possible.

Diet Suggestions:
Please continue feeding the Purina Proplan food.

Exercise Recommendations:
B6 does not need any exercise restriction at this time. If you notice that she is not tolerating exercise, stop and contact a veterinarian.

Medications:
Continue as previously directed.

Recheck Visits: We have scheduled for a recheck examination and echo on August 12th at 11:30am.

Thank you for entrusting us with care. she is such a great patient! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiology@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/cvm/cclinical-studies

<table>
<thead>
<tr>
<th>Case</th>
<th>B6</th>
<th>Owner</th>
<th>B6</th>
<th>Discharge Instructions</th>
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</table>

FDA-CVM-FOIA-2019-1704-013594
Patient ID: B6

Canine

6 years old Female Irish Wolfhound

Gray

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 3m recheck

Concurrent Diseases: Recurrent aspiration B6 hindlimb weakness (suspect GOLPP)

General Medical History: 1st evaluated in 12/18 for acute resp distress B6 Echo showed mildly decomp contractile fn, no cardiomegaly. Has occasional VPCs.

Had bronchoscopy, TTW, chest rads and course of ABX in April for B6

Resp fn has improved since starting simplicef, breathing much better, no coughing

Drags 1 foot

Diet and Supplements:

Purina ProPlan - 2c BID
No supplements

Cardiovascular History:

Prior CHF diagnosis? n
Prior heart murmur? n
Prior ATE? n
Prior arrhythmia? y VPCs

Monitoring respiratory rate and effort at home? n - but usually very slow RR - "has to check if still breathing"
Cough? no
Shortness of breath or difficulty breathing? no
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? no

Current Medications Pertinent to CV System:

Cardiac Physical Examination:

Muscle condition:
- Normal
- Mild muscle loss
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:
- None
- I/VI
- II/VI
- III/VI

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 - possible rare, only heard by one person
- Bradycardia
- Tachycardia

Gallup:
- Yes
- No
- Pronounced
- Other:
Pulmonary assessments:
- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal LV sounds
- Pulmonary crackles
- Wheezes
- Upper airway stridor

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites
- Marked ascites

Problems:
- DCM-like changes
- Arrhythmias

Diagnostic plan:
- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests: DCM study

Assessment and recommendations:
Echocardiogram reveals mildly reduced contractile function, but there may be slight improvement in vigor of contraction today. No arrhythmia was observed compared to relatively frequent VPCs last time. It is unclear whether these improvements are related to daily variation, better control of pneumonia, or actual improvement in cardiac status. Blood work submitted for DCM study. Recheck in 3 months for echo and blood work +/- EKG for study.

Final Diagnosis:
Mild decreased of the contractile function r/o variant of normal vs. DCM (diet related vs. breed related)
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LVEESV MOD A4C
LVEF MOD A4C
SV MOD A4C

Doppler
MV E Vel
MV DecT
MV Dec Slope
MV A Vel
MV E/A Ratio
E'
E/E'
A'
S'
AV Vmax
AV maxPG
PV Vmax
PV maxPG

ml
cm
ml
%
ml
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ms
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m/s
m/s
m/s
m/s
mmHg
m/s
mmHg
A PFR Report has been received and PFR Event [EON-385697] has been created in the EON System.

A "PDF" report by name "2066104-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 "2066104-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-385697  
**ICSR #:** 2066104  
**EON Title:** PFR Event created for Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food Natural Chicken & Brown Rice; 2066104

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<th>AE Date</th>
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<th>Number Fed/Exposed</th>
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<td>Age</td>
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<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
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**Product information**  
**Individual Case Safety Report Number:** 2066104  
**Product Group:** Pet Food  
**Product Name:** Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice  
**Description:** Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd and referred to Tufts

FDA-CVM-FOIA-2019-1704-013601
for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF

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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Buffalo Life Protection Adult Dog Food, Natural Chicken &amp; Brown Rice</td>
<td></td>
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<tr>
<td>Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food</td>
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</table>

Sender information

B6
USA

Owner information

B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-385697

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=402825

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

This email message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential. Any dissemination, distribution, or copying is strictly prohibited.
The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.
Report Details - EON-385697

ICSR: 2066104
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: 2019-04-22 13:04:20 EDT

Reported Problem:

| Problem Description | Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. OD suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx'd pimobendan and referred to Tufts for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF. |
| Date Problem Started | 03/17/2019 |
| Concurrent Medical Problem | No |
| Outcome to Date | Stable |

Product Information:

| Product Name | Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice |
| Lot Number | |
| Package Type | BAG |
| Manufacturer/Distributor Information | |

| Product Name | Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food |
| Lot Number | |
| Package Type | BAG |
| Manufacturer/Distributor Information | |

Animal Information:

<p>| Name | |
| Type Of Species | Dog |
| Type Of Breed | Retriever - Golden |
| Gender | Male |
| Reproductive Status | Neutered |
| Weight | 38 Kilogram |
| Age | 12 Years |
| Assessment of Prior Health | Excellent |
| Number of Animals Given the Product | 1 |
| Number of Animals Reacted | 1 |
| Owner Information | Owner Yes |</p>
<table>
<thead>
<tr>
<th><strong>Information provided:</strong></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Contact:</strong></td>
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<tr>
<td>Name:</td>
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<td><strong>Address:</strong></td>
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**Healthcare Professional Information:**

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<td>Name:</td>
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<td>Phone:</td>
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</table>

**Permission to Release Records to FDA:**

- Yes

**Sender Information:**

<table>
<thead>
<tr>
<th><strong>Name:</strong></th>
<th>B6</th>
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<tbody>
<tr>
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<td><strong>Reported to Other Parties:</strong></td>
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**Additional Documents:**

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<tr>
<th><strong>Attachment:</strong></th>
<th>Tufts Medical record.pdf</th>
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<td>Medical records</td>
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<td><strong>Type:</strong></td>
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A PFR Report has been received and Related PFR Event [EON-390198] has been created in the EON System.

A "PDF" report by name "2068091-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 "2068091-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390198  
**ICSR #:** 2068091  
**EON Title:** Related PFR Event created for Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food Natural Chicken & Brown Rice; 2068091

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**Product information**  
**Individual Case Safety Report Number:** 2068091  
**Product Group:** Pet Food  
**Product Name:** Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food, Blue Buffalo Life Protection Adult Dog Food, Natural Chicken & Brown Rice  
**Description:** Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O
suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was rx’d [B6] and referred to Tufts for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF Normal plasma and whole blood taurine levels

**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

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</table>

This report is linked to:

**Initial EON Event Key:** EON-385697

**Initial ICSR:** 2066104

**Sender information**

B6

USA

**Owner information**

B6

USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-390198

To view the Related PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=10100&issuelld=407470&parentIssueTypeId=12

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Report Details - EON-390198

ICSR: 2068091
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
Initial Report Date: 04/22/2019
Parent ICSR: 2066104
Follow-up Report to FDA Request: Yes

Reported Problem: Presented to rDVM 4/15 and 4/16 for a non-productive cough x 1 month and decreased appetite. O suspected cough was due to seasonal allergies as patient has a hx of allergies. RDVM was suspicious of pericardial effusion vs DCM. Enlarged heart on radiograph. Patient was x'd 86 and referred to Tufts for further evaluation. Diet history: Blue Buffalo chicken limited ingredient x 1 year. Previously eating Blue Buffalo chicken grain-free since 2010. Echo revealed 3+ MR, reduced contractile function, trace pericardial effusion, ruptured chordae, no obvious heart base mass, no obvious RAA mass. Suspect CHF Normal plasma and whole blood taurine levels

Date Problem Started: 03/17/2019
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:

<table>
<thead>
<tr>
<th>Product Name: Blue Buffalo Life Protection Adult Dog Food, Natural Chicken &amp; Brown Rice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type: Pet Food</td>
</tr>
<tr>
<td>Lot Number:</td>
</tr>
<tr>
<td>Package Type: BAG</td>
</tr>
<tr>
<td>Product Use Information:</td>
</tr>
<tr>
<td>Manufacturer /Distributor Information:</td>
</tr>
<tr>
<td>Purchase Location Information:</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Name: Blue Buffalo Life Protection Formula Adult Chicken Recipe Grain-Free Dry Dog Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Type: Pet Food</td>
</tr>
<tr>
<td>Lot Number:</td>
</tr>
<tr>
<td>Package Type: BAG</td>
</tr>
<tr>
<td>Product Use Information:</td>
</tr>
<tr>
<td>Manufacturer /Distributor Information:</td>
</tr>
<tr>
<td>Purchase Location Information:</td>
</tr>
</tbody>
</table>

Animal Information:

<table>
<thead>
<tr>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type Of Species: Dog</td>
</tr>
<tr>
<td>Type Of Breed: Retriever - Golden</td>
</tr>
<tr>
<td>Gender: Male</td>
</tr>
<tr>
<td>Reproductive Status: Neutered</td>
</tr>
<tr>
<td>Weight: 38 Kilogram</td>
</tr>
<tr>
<td>Age: 12 Years</td>
</tr>
<tr>
<td>Assessment of Prior Health: Excellent</td>
</tr>
</tbody>
</table>

FOUO- For Official Use Only
<table>
<thead>
<tr>
<th>Number of Animals Given the Product:</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Animals Reacted:</td>
<td>1</td>
</tr>
</tbody>
</table>

**Owner Information:**
- **Yes**
- **Name:** B6
- **Phone:** B6
- **Email:** B6
- **Address:** B6 United States

**Healthcare Professional Information:**
- **Practice Name:** Tufts Cummings School of Veterinary Medicine
- **Contact:**
  - **Name:** B6
  - **Phone:** B6
  - **Email:** B6
- **Address:**
  - 200 Westboro Road
  - North Grafton
  - Massachusetts
  - 01536
  - United States

- **Practice Name:** Tufts University
- **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:** B6
- **Address:**
  - 200 Westboro Road
  - North Grafton
  - Massachusetts
  - 01536
  - United States
- **Contact:**
  - **Phone:** B6
  - **Email:** B6
- **Permission To Contact Sender:** Yes
- **Preferred Method Of Contact:** Email
- **Reported to Other Parties:** None

**Additional Documents:**
- **Attachment:** At home ECG readings.pdf
- **Description:** ECGs
- **Type:** Medical Records
Patient: B6
Breed/Species: Golden / Canine
Recorded: Wednesday
Heart Rate: 85 bpm
Time: 9:07:06 PM
Client: [Client Name]
Patient: B6

Alivecor ECG

Patient: B6
Breed/Species: Golden Retriever
Recorded: Thursday, 8/8/19 at 1:03:43 PM
Heart Rate: 95 bpm Duration: 38 s

AliveCor Heart Rate: 95 bpm Duration: 38 s
alivecor ECG

Patient: B6
Breed/Species: Golden/Labradoodle
Recorded: Friday, B6 at 10:00:45 PM
Heart Rate: 84 bpm
Duration: 28 s
Client: B6

Patient: B6

Breed/Species: Golden Canine

Recorded: Sunday, June 28, 2020, at 8:06:46 PM

Heart Rate: 86 bpm

Duration: 40 s
Patient: B6
Breed/Species: Golden Lab
Recorded: Sunday, B6, at 8:06:45 PM
Heart Rate: 81 bpm  Duration: 40 s
**Alivecor ECG**

**Patient:** B6

**Breed/Species:** Canine

**Recorded:** Monday, 8:43:21 PM

**Heart Rate:** 96 bpm  
**Duration:** 43 s
<table>
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<tr>
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<th>B6</th>
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</thead>
<tbody>
<tr>
<td>Breed/Species:</td>
<td>Golden / Canine</td>
</tr>
<tr>
<td>Recorded:</td>
<td>Monday, 8/4/21 PM</td>
</tr>
<tr>
<td>Heart Rate:</td>
<td>98 bpm</td>
</tr>
<tr>
<td>Duration:</td>
<td>43 s</td>
</tr>
</tbody>
</table>

Alivecor ECG
Client: B6
Patient: B6

Alivecor ECG

Patient: B6
Breed/Species: Golden / Canine
Recorded: Wednesday, B6 at 9:34:29 PM
Heart Rate: 95 bpm Duration: 39 s
Patient: B6
Breed/Species: Golden Retriever
Recorded: Wednesday, B6 at 9:34:29 PM
Heart Rate: 95 bpm
Duration: 39 s
Client: B6
Patient: B6

Alivecor ECG

Patient: B6
Breed/Species: [G~]
Recorded: Sunday B6 at 8:36:16 PM
Heart Rate: 100 bpm Duration: 32 s
<table>
<thead>
<tr>
<th>Client:</th>
<th>B6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient:</td>
<td>B6</td>
</tr>
</tbody>
</table>

**Alivecor ECG**

| Patient: | B6 |
| Breed/Species: | Canine |
| Recorded: | Monday, B6, 9/141, 45 PM |
| Heart Rate: | 95 bpm |
| Duration: | 36 s |

| AliveCor ECG Version 2.17, Report v2.0.0, UNID: 7C1F538E4595-4956-A539-447D0F505828 |

Page 28/34
B6

Alivecor ECG

Patient: B6
Breed/Species: Cat
Recorded: Monday, B6, 9:41:45 PM
Heart Rate: 95 bpm
Duration: 36 s
| Patient: | B6 |
| Brood/Species: | G606h |
| Recorded: | Sunday, B6, at 9:45:27 PM |
| Heart Rate: | 92 bpm |
| Duration: | 32 s |

Alivecor ECG

AliveCor

B6
Client: B6
Patient: B6

Alivecor ECG

Patient: B6
Breed/Species: Golden Retriever
Recorded: Sunday, B6, 9:45:27 PM
Heart Rate: 92 bpm, Duration: 32 s
Discharge Instructions
Cardiology Technician Appointment - ENROLLED IN DCM DIET STUDY

Patient
Name: B6
Species: Canine
Gender: Male (Neutered)
Address: [Redacted]
Birthdate: [Redacted]

Owner
Name: [Redacted]
Address: [Redacted]

Patient ID: B6

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

Cardiology Resident:

Cardiology Technician:

Discharge Date: B6

Clinical Findings:
B6 came in today to recheck bloodwork and an ECG. His bloodwork looked great and seems to be tolerating the medications well. The ECG still showed [B6]. We discussed a few options of the next steps [B6] [B6] [B6]

At this time, it was decided to purchase the [B6] We went over the device and how to use it in the room. There are also directions attached to the discharge. I will send the readings to Dr. Rush for review when he is back next week and if he feels an additional medication is needed, then I will call or email you with what he recommends.

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 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 of [B6]. If difficulty breathing is not improved within 30-60 minutes after giving [B6] then we recommend that a recheck exam be scheduled and/or that [B6] 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 notice an episode of collapse, it is okay to help the dog get back up; however, most dogs will get up on their own in about 20 minutes. If an episode of collapse occurs, we would like to know about it right away.

Medications:

B6

Redcheck Visits:

A recheck has been scheduled for Thursday, B6 at 1:00pm with Dr. John Rush

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508) 887-4696 or email us at cardiology@tufts.edu for scheduling and non-emergent questions or concerns.

B6 was such a good boy today.

Kind Regards

B6 MT, VTS (Cardiology)

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/cvm/cclinical-studies

Case B6 Owner B6 Discharge Instructions
ECG from cardio
ECG from cardio
ECG from cardio
ECG from cardio
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

<table>
<thead>
<tr>
<th>AE Date</th>
<th>Number Fed/Exposed</th>
<th>Best By Date</th>
<th>Number Reacted</th>
<th>Animal Species</th>
<th>Outcome to Date</th>
<th>Breed</th>
<th>Age</th>
<th>District Involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>B6</td>
<td>1</td>
<td></td>
<td>1</td>
<td>Dog</td>
<td>Died, Euthanized</td>
<td>Doberman Pinscher</td>
<td>Years</td>
<td>PFR-New England DO</td>
</tr>
</tbody>
</table>

**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. 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 whole blood. Patient was humanely euthanized 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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earthborn grain free weight management dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:  
https://eon.fda.gov/eon//browse/EON-390207

To view the Related PFR Event Report, please click the link below:  
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=10100&issueId=407479&parentIssueTypeId=12

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through your local district FDA office.

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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

**Reported Problem:**

Problem Description: Diagnosed with DCM, CHF, and atrial fibrillation. 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 2016. Genetic testing - negative for DCM1 & DCM2 Normal taurine levels - plasma [B6] whole blood. Patient was humanely euthanized due to worsening CHF. Specimens were not collected for evaluation per owner.

Date Problem Started:  
Concurrent Medical Problem: No  
Outcome to Date: Died Euthanized  
Date of Death: B6

**Product Information:**

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

**Animal Information:**

Name: B6  
Type Of Species: Dog  
Type Of Breed: Doberman Pinscher  
Gender: Male  
Reproductive Status: Neutered  
Weight: 45.2 Kilogram  
Age: B6 years  
Assessment of Prior Health: Excellent  
Number of Animals Given the Product:  
Number of Animals Reacted:  
Owner Information: Yes  
Owner Information provided:  
Contact: Name: B6  
Phone: B6  
Email: B6  
Address: B6
Healthcare Professional Information:

Practice Name: Tufts Cummings School of Veterinary Medicine

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

Sender Information:

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

Permission To Contact Sender: Yes
Preferred Method Of Contact: Email

Additional Documents:

Attachment: Follow-up med records pt 4.pdf
Description: Med records
Type: Medical Records

Attachment: Follow-up med records pt 2.pdf
Description: Med records
Type: Medical Records

Attachment: Follow-up med records pt 3.pdf
Description: Med records
Type: Medical Records

Attachment: Follow-up med records pt 1.pdf
Description: Med records
Type: Medical Records
ECG from Cardio
Client: B6

Patient: B6

ECG from Cardio
ECG from Cardio
ECG from Cardio

B6

Page 38/71
A PFR Report has been received and PFR Event [EON-380706] has been created in the EON System.

A "PDF" report by name "2063113-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 "2063113-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380706  
**ICSR #:** 2063113  
**EON Title:** PFR Event created for Poulin Pro Form Lamb and Rice Adult Maintenance Dry; 2063113

<table>
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<th>12/22/2018</th>
<th>Number Fed/Exposed</th>
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<td>Number Reacted</td>
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<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Irish Wolfhound</td>
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</tr>
<tr>
<td>Age</td>
<td>6 Years</td>
<td></td>
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</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**  
**Individual Case Safety Report Number:** 2063113  
**Product Group:** Pet Food  
**Product Name:** Poulin Pro Form Lamb and Rice Adult Maintenance Dry  
**Description:** Had [B6] in September 2018; re-presented in December 2018 when arrhythmias were noted. Cardiology consult identified arrhythmias and reduced contractile function (and eating B6G diet). Unclear whether this was primary problem or secondary to systemic illness. Rechecked by cardiology 2/5/19 and still had arrhythmia and reduced contractility. NT-proBNP and cTnl elevated. Owner already changed diet in January to Purina Pro Plan Chicken and Rice so will continue on this diet and will recheck in 3 months.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poulin Pro Form Lamb and Rice Adult Maintenance Dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:
https://eon.fda.gov/eon/browse/EON-380706

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=397715

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you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.
Report Details - EON-380706

ICSR: 2063113
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 16:24:11 EST

Reported Problem:
Problem Description: Had in September 2018; re-presented in December 2018 when arrhythmias were noted. Cardiology consult identified arrhythmias and reduced contractile function (and eating BEG diet). Unclear whether this was primary problem or secondary to systemic illness. Rechecked by cardiology 2/5/19 and still had arrhythmia and reduced contractility. NT-proBNP and cTnl elevated. Owner already changed diet in January to Purina Pro Plan Chicken and Rice so will continue on this diet and will recheck in 3 months.

Date Problem Started: 12/22/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: Sept and Dec 2018
Outcome to Date: Stable

Product Information:
Product Name: Poulin Pro Form Lamb and Rice Adult Maintenance Dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: Description: Please see diet history form for more details
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: [Redacted]
Type Of Species: Dog
Type Of Breed: Irish Wolfhound
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Not Pregnant
Lactation Status: Not lactating
Weight: 60.5 Kilogram
Age: 6 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: [Redacted]
Phone: [Redacted]
Email: [Redacted]
Address: [Redacted]
<table>
<thead>
<tr>
<th>Healthcare Professional Information:</th>
<th>Practice Name: Tufts Cummings School of Veterinary Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact:</td>
<td>Name: Lisa Freeman</td>
</tr>
<tr>
<td></td>
<td>Phone: (508) 887-4523</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:lisa.freeman@tufts.edu">lisa.freeman@tufts.edu</a></td>
</tr>
<tr>
<td>Address:</td>
<td>200 Westboro Rd</td>
</tr>
<tr>
<td></td>
<td>North Grafton</td>
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<tr>
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<td>Massachusetts</td>
</tr>
<tr>
<td></td>
<td>01536</td>
</tr>
<tr>
<td></td>
<td>United States</td>
</tr>
</tbody>
</table>

| 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:             | Yes                                                      |
| Sender:                             |                                                          |
| Preferred Method Of Contact:       | Email                                                    |

| Additional Documents:              | Attachment: cbc and profile.pdf                         |
|                                   | Description: Will send by email                         |
|                                   | Type: Medical Records                                   |

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