
From: Related PFR Event <pfrsignificantactivitycreation@fda.hhs.gov>
To: Rotstein, David; Cleary, Michael *; HQ Pet Food Report Notification;
B6
Sent: 6/11/2019 6:08:45 PM
Subject: Taste of the Wild Sierra Mountain dry: Lisa Freeman - EON-390197
Attachments: 2068089-report.pdf; 2068089-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390197] has been created in the EON System.

A "PDF" report by name "2068089-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 "2068089-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-390197

ICSR #: 2068089

EON Title: Related PFR Event created for Taste of the Wild Sierra Mountain dry; 2068089

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

Product information

Individual Case Safety Report Number: 2068089

Product Group: Pet Food

Product Name: Taste of the Wild Sierra Mountain dry

Description: Eating Taste of the Wild Sierra Mountain since June 2018 (Acana Heritage Poultry before that). This diet was fed to multiple dogs - have not screened other dogs yet so unknown whether they are also affected. Echo showed reduced contractility and mild left atrial enlargement. BNP and troponin mildly elevated, troponin = B6 Taurine WNL B6 Changing to Pro Plan Sensitive Skin/Stomach dry 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: 7

Number of Animals Reacted With Product: 1

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

This report is linked to:

Initial EON Event Key: EON-376361

Initial ICSR: 2061171

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-390197>

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&issueId=407469&parentIssueTypeId=12>

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Report Details - EON-390197

ICSR:	2068089
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 14:02:24 EDT
Initial Report Date:	01/14/2019
Parent ICSR:	2061171
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Eating Taste of the Wild Sierra Mountain since June 2018 (Acana Heritage Poultry before that). This diet was fed to multiple dogs - have not screened other dogs yet so unknown whether they are also affected. Echo showed reduced contractility and mild left atrial enlargement. BNP and troponin mildly elevated. troponin B6 Taurine WNL B6 Changing to Pro Plan Sensitive Skin /Stomach dry and will recheck in 3 months
	Date Problem Started:	01/02/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Taste of the Wild Sierra Mountain dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	Description: See diet history for more details. TOTW fed June, 2018 to present; Acana Heritage Free Run Poultry before that
	Manufacturer /Distributor Information:	
	Purchase Location Information:	

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Female
	Reproductive Status:	Intact
	Pregnancy Status:	Not Pregnant
	Lactation Status:	Not lactating
	Weight:	30.4 Kilogram
	Age:	3 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	7
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: Yes
		Contact: Name: B6 Phone: Email:

		Address:	<div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 24pt; font-weight: bold;">B6</div> United States
Sender Information:	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
Additional Documents:	Name:	Address:	Lisa Freeman 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
		Attachment:	Follow-up medical records pt 2.pdf.pdf Description: Med records Type: Medical Records Attachment: Follow-up medical records pt 1.pdf Description: Med records Type: Medical Records

B6

Patient ID: B6

B6 Canine

B6 Female Golden Retriever
Cream

**Cardiology Appointment Report
DCM STUDY**

Date: 5/3/2019

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6

Presenting Complaint: DCM study recheck; o reports doing well at home, good energy, no other concerns.

Concurrent Diseases: None

General Medical History: On 1/2/19 was referred here by rDVM for elevated BNP (B6), rDVM prompted to check b/c of grain-free diet. Echo in January showed mild systolic dysfunction w/mild LAE. Transitioned to new diet. CBC, chem, BNP WNL.

Diet and Supplements:

Purina sensitive stomach

Cardiovascular History:

Prior CHF diagnosis? N

Prior heart murmur? N

Prior ATE? N

Prior arrhythmia? N

Monitoring respiratory rate and effort at home? N

Cough? N

Shortness of breath or difficulty breathing? N
Syncope or collapse? N
Sudden onset lameness? N
Exercise intolerance? N

Current Medications Pertinent to CV System:

Medication: Taurine
Formulation/Tab Size: 500mg capsules
Administration Frequency: 2 capsules PO BID
Need refills?

Cardiac Physical Examination:

B6

Muscle condition:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Normal | <input type="checkbox"/> Moderate cachexia |
| <input type="checkbox"/> Mild muscle loss | <input type="checkbox"/> Marked cachexia |

Cardiovascular Physical Exam:

Murmur Grade:

- | | |
|--|--------------------------------|
| <input checked="" type="checkbox"/> None | <input type="checkbox"/> IV/VI |
| <input type="checkbox"/> I/VI | <input type="checkbox"/> V/VI |
| <input type="checkbox"/> II/VI | <input type="checkbox"/> VI/VI |
| <input type="checkbox"/> III/VI | |

Murmur location/description:

Jugular vein:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Bottom 1/3 of the neck | <input type="checkbox"/> 1/2 way up the neck |
| <input type="checkbox"/> Middle 1/3 of the neck | <input type="checkbox"/> Top 2/3 of the neck |

Arterial pulses:

- | | |
|--|---|
| <input type="checkbox"/> Weak | <input type="checkbox"/> Bounding |
| <input type="checkbox"/> Fair | <input type="checkbox"/> Pulse deficits |
| <input type="checkbox"/> Good | <input type="checkbox"/> Pulsus paradoxus |
| <input checked="" type="checkbox"/> Strong | <input type="checkbox"/> Other: |

Arrhythmia:

- | | |
|---|--------------------------------------|
| <input checked="" type="checkbox"/> None | <input type="checkbox"/> Bradycardia |
| <input type="checkbox"/> Sinus arrhythmia | <input type="checkbox"/> Tachycardia |
| <input type="checkbox"/> Premature beats | |

Gallop:

- | | |
|--|-------------------------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> Pronounced |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Other: |
| <input type="checkbox"/> Intermittent | |

Pulmonary assessments:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Eupneic | <input type="checkbox"/> Pulmonary crackles |
|---|---|

- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

- Wheezes
- Upper airway stridor

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension

- Mild ascites
- Marked ascites

Problems:

Hx of asymptomatic heart disease

Differential Diagnoses:

Nutritional DCM

Diagnostic plan:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Echocardiogram | <input type="checkbox"/> Dialysis profile |
| <input type="checkbox"/> Chemistry profile | <input type="checkbox"/> Thoracic radiographs |
| <input type="checkbox"/> ECG | <input checked="" type="checkbox"/> NT-proBNP |
| <input type="checkbox"/> Renal profile | <input checked="" type="checkbox"/> Troponin I |
| <input type="checkbox"/> Blood pressure | <input type="checkbox"/> Other tests: |

B6

Doppler findings:

B6

Mitral inflow:

- | | |
|---|---------------------------------------|
| <input type="checkbox"/> Summated | <input type="checkbox"/> Pseudonormal |
| <input checked="" type="checkbox"/> Normal | <input type="checkbox"/> Restrictive |
| <input type="checkbox"/> Delayed relaxation | |

ECG findings:

B6

Assessment and recommendations:

Stable systolic function compared to previous exams, despite mild increase in LV cavity size (r/o daily variation or interobserver variation). Recommend keeping current supplementation with Taurine and recheck echocardiogram in 3 months or sooner if patient develops clinical signs consistent with worsening heart disease such as increased RR/RE, cough, exercise intolerance, or syncope.

Final Diagnosis:

Mild systolic dysfunction with mild LA enlargement - r/o early stage DCM vs. diet induced systolic dysfunction.

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM Classification:

- A
- B1
- B2
- C
- D

M-Mode

- IVSd
- LVIDd
- LVPWd
- IVSs
- LVIDs
- LVPWs
- EDV(Teich)
- ESV(Teich)
- EF(Teich)
- %FS
- SV(Teich)
- Max LA
- Time
- HR
- CO(Teich)
- CI(Teich)
- Ao Diam
- LA Diam
- LA/Ao
- TAPSE
- EPSS

M-Mode Normalized

- IVSdN
- LVIDdN
- LVPWdN
- IVSsN
- LVIDsN
- LVPWsN

2D

- IVSd
- LVIDd
- LVPWd
- EDV(Teich)



- cm
- cm
- cm
- cm
- cm
- cm
- ml
- ml
- %
- %
- ml
- cm
- ms
- BPM
- l/min
- l/minm
- cm
- cm
- cm
- cm

- (0.290 - 0.520)
- (1.350 - 1.730) !
- (0.330 - 0.530) !
- (0.430 - 0.710) !
- (0.790 - 1.140) !
- (0.530 - 0.780)

- cm
- cm
- cm
- ml

IVSs
LVIDs
LVPWs
ESV(Teich)
EF(Teich)
%FS
SV(Teich)
LV Major
LV Minor
Sphericity Index
LVld A4C
LVEDV MOD A4C
LVls A4C
LVESV MOD A4C
LVEF MOD A4C
SV MOD A4C

Doppler
MV E Vel
MV DecT
MV Dec Slope
MV A Vel
MV E/A Ratio
E'
E/E'
A'
S'
IVRT
AV Vmax
AV maxPG
PV Vmax
PV maxPG
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A'

B6

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Report Details - EON-390196

ICSR:	2068087
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 13:56:24 EDT
Initial Report Date:	02/24/2019
Parent ICSR:	2063118
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	BEG diet being fed to 7 dogs. We evaluated her other dog, B6 who had a murmur and elevated BNP, with reduced contractility and elevated troponin found on exam (see previous report - 2061171). Owner worried about this dog's breathing so we screened her and found reduced contractility, elevated troponin, but normal BNP. Changing diet on both dogs to Pro Plan Sensitive Skin/Stomach Salmon and will recheck in 3 months. Other dogs we have not screened: B6 Labrador 5 years old, B6 Golden 3 1/2 years old, B6 Golden 3 years old, B6 Golden 3 years 5 months, B6 Golden 3 years 9 months
	Date Problem Started:	01/14/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Taste of the Wild Sierra Mountain Dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	Description: Please see diet history for additional information
	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:	25.8 Kilogram		
	Age:	5 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	7		
	Number of Animals Reacted:	2		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name:	B6
			Phone:	
Email:				
Address:	B6			

B6

United States

Healthcare Professional Information:

Practice Name: Tufts Cummings School of Veterinary Medicine

Contact Name: Lisa Freeman

Phone: (508) 887-4523

Email: lisa.freeman@tufts.edu

Address: 200 Westboro Rd
North Grafton
Massachusetts
01536
United States

Sender Information:

Name: Lisa Freeman

Address: 200 Westboro Rd
North Grafton
Massachusetts
01536
United States

Contact Phone: 5088874523

Email: lisa.freeman@tufts.edu

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Additional Documents:

Attachment: Follow-up medical records pt 2.pdf

Description: Med records

Type: Medical Records

Attachment: Follow-up medical records pt 1.pdf

Description: Med records

Type: Medical Records

Report Details - EON-390197

ICSR:	2068089
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 14:02:24 EDT
Initial Report Date:	01/14/2019
Parent ICSR:	2061171
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Eating Taste of the Wild Sierra Mountain since June 2018 (Acana Heritage Poultry before that). This diet was fed to multiple dogs - have not screened other dogs yet so unknown whether they are also affected. Echo showed reduced contractility and mild left atrial enlargement. BNP and troponin mildly elevated. troponin = B6 Taurine WNL B6 Changing to Pro Plan Sensitive Skin /Stomach dry and will recheck in 3 months
	Date Problem Started:	01/02/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Taste of the Wild Sierra Mountain dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	Description: See diet history for more details. TOTW fed June, 2018 to present; Acana Heritage Free Run Poultry before that
	Manufacturer /Distributor Information:	
	Purchase Location Information:	

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Female
	Reproductive Status:	Intact
	Pregnancy Status:	Not Pregnant
	Lactation Status:	Not lactating
	Weight:	30.4 Kilogram
	Age:	3 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	7
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: Yes
		Contact: Name: B6 Phone: Email:

		Address: <div style="border: 1px dashed black; padding: 5px; display: inline-block;"> B6 </div> United States
Healthcare Professional Information:	Practice Name: Tufts Cummings School of Veterinary Medicine Contact:	Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu
	Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States	
Sender Information:	Name: Lisa Freeman Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States	
	Contact:	Phone: 5088874523 Email: lisa.freeman@tufts.edu
	Permission To Contact Sender: Yes	
	Preferred Method Of Contact: Email	
Additional Documents:	Attachment: Follow-up medical records pt 2.pdf.pdf Description: Med records Type: Medical Records	
	Attachment: Follow-up medical records pt 1.pdf Description: Med records Type: Medical Records	

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 2/24/2019 11:19:19 PM
Subject: B6
Attachments: rpt_medical_record_preview.pdf

Hi Jen

Sorry – only attached the dog's previous visit, not the current one. Here's the full record.

This is a housemate of a previously reported dog.

Thanks

Lisa

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

Client:

B6

Address:

All Medical Records

Patient:

B6

Breed: Labrador Retriever

DOB:

B6

Species: Canine

Sex: Female
(Spayed)

Home Phone:

Work Phone:

Cell Phone:

B6

Referring Information

B6

Client:

B6

Patient:

Initial Complaint:

Emergency

SOAP Text

B6

1:23PM

B6

B6

12:13 PM NEW VISIT (ER)

Doctor:

B6

Presenting complaint:

B6

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

HISTORY:

Signalment: 3 yo FS Labrador retriever

Current history:

B6

Prior medical history:

B6

Current medications: None

Diet: Acana, whole earth

Vaccination status/flea & tick preventative use: Ivermectin, Advantix II

B6

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

C/V: no murmurs or arrhythmias ausculted. femoral pulses strong and synchronous

B6

ASSESSMENT:

A1: **B6**

PLAN:

1) **B6**
2) **B6**
3) **B6**
4) **B6**

B6

SOAP approved (DVM to sign): **B6** MD

B6 :25:46 PM

Prescribed **B6**

Instructions - Give 1/2 tablet orally every 12 hours. Give with food. - Expires: 7/1/2018 No Refills

Initial Complaint:

Cardiology DCM study

SOAP Text Jan 16 2019 3:09PM - Rush, John

Subjective

Objective

Assessment

Plan

Disposition/Recommendations

Client:
Patient:

B6

Client: **B6**
Patient:

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

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

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

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

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units
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4/20

B6

Printed Sunday, February 24, 2019

Vitals Results

B6

Patient History

B6

2:14 PM	UserForm
2:15 PM	UserForm
2:21 PM	Vitals
2:21 PM	Vitals
2:21 PM	Vitals
2:21 PM	Vitals
2:21 PM	Vitals
01:37 PM	Prescription
01:44 PM	UserForm
01:48 PM	Purchase

B6

Client: **B6**
Patient:

Patient History

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

B6

B6

B6

Female (Spayed)

Canine Labrador Retriever Yellow

Patient ID: **B6**

STANDARD CONSENT FORM

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

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

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

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

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

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

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

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

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

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

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

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

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

Owner's name: Date:

Owner's address:

Owner's Name Signature

Date

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

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

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

B6

B6

Female (Spayed)

Canine Labrador Retriever Yellow

Patient ID: B6

STANDARD CONSENT FORM

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

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

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

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

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

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

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

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

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

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

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

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

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

Owner's name:

Date:

Owner's address:

Owner's Name Signature

Date

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

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

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City

State

Zip

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone (508) 839-5395
Fax (508) 839-8739
<http://vetmed.tufts.edu/>

Emergency & Critical Care Liaison: (508) 887-4745

Patient

Name:

B6

Signalment:

B6 Years Old Yellow Female
(Spayed) Labrador Retriever

Owner

Name:

Address:

B6

Patient ID:

B6

Emergency Clinician:

B6

VMD

ER Supervisor:

B6

Discharge Instructions

Admit Date: B6 12:13:36 PM

Check Out Date: B6

Case Summary

Diagnosis:

1. B6

General Summary:

B6

Patient Care Instructions:

B6

B6

Medications:

B6

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

Case

B6

Owner

B6

Discharge Instructions

Discharge Instructions

Patient

Name: B6

Species: Canine

Yellow Female (Spayed) Labrador

Retriever

Birthdate: B6

Owner

Name: B6

Address: B6

Patient ID: B6

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V19

Admit Date: 1/16/2019 1:29:08 PM

Discharge Date: 1/16/2019

Thank you for bringing B6 to Tufts to screen her for heart disease related to being on a "BEG" (Boutique, Exotic Ingredient, or Grain-Free) diet. On physical exam, she had no heart murmur. She had strong pulses and no arrhythmias were heard.

B6 echocardiogram showed that her heart was not contracting with normal vigor, and she had a few premature heart beats (arrhythmia - ventricular premature depolarizations). Her left atrium was also slightly enlarged, and her right heart was also slightly enlarged. These changes could perhaps be a variation of normal in athletic dogs, but we think it is more likely that she has mild heart disease, because of the premature heartbeats (arrhythmia).

We may be able to enroll B6 in our DCM study looking at heart disease associated with BEG diets today. We submitted blood tests and will contact you with the results when available. The taurine levels will take up to 2-3 weeks to come back and we would like to start taurine supplementation in the interim. If the taurine level comes back low, we'll give taurine supplementation. Either way, it's very important to change her diet, and we would have you continue with the Purina diet you are currently feeding. B6 does not require any other heart medications at this time, however if she does qualify for the study (based on an elevated NT-proBNP or an elevated troponin), we will want to follow up with another echo in 3 months, now that her diet has been changed.

If her NT-proBNP and troponin are normal then she does not qualify for the study, but we would recommend a repeat echo in 8 to 10 months, because of the changes we saw today with the heart and the premature heart beats.

Medications and supplements:

None at this time.

Monitoring at Home:

B6 does not appear to have any significant heart disease at this time. However, please monitor for any weakness or collapse, exercise intolerance, cough or distension of the belly. If you notice any abnormalities we would like to see her for a recheck exam.

Diet Suggestions:

Please continue the Purina diet that B6 is now eating.

Recheck Visits and Follow Up: The taurine levels will take 2-3 weeks so we'll let you know when we get these back. If she does qualify for the study (based on an elevated NT-proBNP or an elevated troponin), we will want to follow up with another echo in 3 months and in 6 months. If she does not qualify then a recheck cardiac exam is recommended in 8 to 10 months.

Thank you for entrusting us with B6 care - she is a sweet, beautiful girl and we loved meeting her today!

Please contact our Cardiology liaison at (508) 887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

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

Prescription Refill Disclaimer:

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

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

Clinical Trials:

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

Case: B6

Owner: B6

Discharge Instructions

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID: B6

B6 Canine
Years Old Female (Spayed) Labrador Retriever
Yellow

Cardiology Appointment Report ENROLLED IN DCM STUDY

Date: 1/16/2019

Attending Cardiologist:

John E. Rush DVM, MS, DACVM (Cardiology), DACVECC (primary)

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: **B6**, V19

Presenting Complaint:

Possible exercise intolerance, eats grain free food

Exercise intolerance start at about one year - breathes loudly, more hard, will sometimes lay down; same all year, been at a stable state since noticing at one year old

Concurrent Diseases: **B6**

General Medical History:

Overall good at home, good appetite, no coughing

Diet and Supplements:

Taste of the wild, has had Acana in the past

On purina pro plan switched about 1 week ago

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? no

Shortness of breath or difficulty breathing? yes but since a puppy

Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? yes but since dog is a puppy

Current Medications Pertinent to CV System:

None

Cardiac Physical Examination:

B6

Murmur location/description:

None heard

Jugular vein:

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

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:

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

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension

- Mild ascites
- Marked ascites

Problems: Exercise intolerance

Differential Diagnoses:

DCM vs pain related (hx TPLO x2) vs congenital

Diagnostic plan:

- | | |
|--|---|
| <input checked="" type="checkbox"/> Echocardiogram | <input type="checkbox"/> Dialysis profile |
| <input type="checkbox"/> Chemistry profile | <input type="checkbox"/> Thoracic radiographs |
| <input type="checkbox"/> ECG | <input type="checkbox"/> NT-proBNP |
| <input type="checkbox"/> Renal profile | <input type="checkbox"/> Troponin I |
| <input type="checkbox"/> Blood pressure | <input type="checkbox"/> Other tests: |

Echocardiogram Findings:



Assessment and recommendations:

Overall the LV cavity has slightly reduced contractile function and the LA looks to be mildly enlarged.

Final Diagnosis:

Mildly reduced LV contractile function R/O diet related vs variation of normal.

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM Classification:

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

M-Mode

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

EDV(Teich)

ESV(Teich)

EF(Teich)

%FS

SV(Teich)

Ao Diam

LA Diam

LA/Ao

Max LA

EPSS

cm
cm
cm
cm
cm
cm
ml
ml
%
%
ml
cm
cm
cm
cm

B6

M-Mode Normalized

IVSdN

LVIDdN

LVPWdN

IVSsN

LVIDsN

LVPWsN

Ao Diam N

LA Diam N

{0.290 - 0.520}
{1.350 - 1.730}
{0.330 - 0.530}
{0.430 - 0.710}
{0.790 - 1.140} !
{0.530 - 0.780}
{0.680 - 0.890}
{0.640 - 0.900}

B6

2D

SA LA

Ao Diam

SA LA / Ao Diam

IVSd

LVIDd

LVPWd

EDV(Teich)

IVSs

LVIDs

LVPWs

ESV(Teich)

EF(Teich)

%FS

SV(Teich)

LV Major

LV Minor

Sphericity Index

LVld IAX

LVAd IAX

LVEDV A-L IAX

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B6

LVEDV MOD LAX
LVLs LAX
LVA's 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
R-R
HR
CO A-L LAX
CO MOD LAX

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

B6

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B6

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mmHg

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

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

B6 Female (Spayed)
Canine Labrador Retriever Yellow
B6

B6

Dear **B6**

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

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

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; B6
Sent: 2/24/2019 11:24:38 PM
Subject: Taste of the Wild Sierra Mountain Dry: Lisa Freeman - EON-380714
Attachments: 2063118-report.pdf; 2063118-attachments.zip

A PFR Report has been received and PFR Event [EON-380714] has been created in the EON System.

A "PDF" report by name "2063118-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 "2063118-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380714

ICSR #: 2063118

EON Title: PFR Event created for Taste of the Wild Sierra Mountain Dry; 2063118

AE Date	01/14/2019	Number Fed/Exposed	7
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Golden		
Age	5 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063118

Product Group: Pet Food

Product Name: Taste of the Wild Sierra Mountain Dry

Description: BEG diet being fed to 7 dogs. We evaluated her other dog, B6 who had a murmur and elevated BNP, with reduced contractility and elevated troponin found on exam (see previous report - 2061171). Owner worried about this dog's breathing so we screened her and found reduced contractility, elevated troponin, but normal BNP. Changing diet on both dogs to Pro Plan Sensitive Skin/Stomach Salmon and will recheck in 3 months Other dogs we have not screened: Max Labrador 5 years old B6 Golden 3 1/2 years old B6 Golden 3 years old B6 Golden 3 years 5 months B6 Golden 3 years 9 months

Submission Type: Initial

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

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

Number of Animals Treated With Product: 7

Number of Animals Reacted With Product: 2

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

<https://eon.fda.gov/eon//browse/EON-380714>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=397723>

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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-380714

ICSR: 2063118
 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 18:16:40 EST

Reported Problem:
Problem Description: BEG diet being fed to 7 dogs. We evaluated her other dog **B6** who had a murmur and elevated BNP, with reduced contractility and elevated troponin found on exam (see previous report - 2061171). Owner worried about this dog's breathing so we screened her and found reduced contractility, elevated troponin, but normal BNP. Changing diet on both dogs to Pro Plan Sensitive Skin/Stomach Salmon and will recheck in 3 months Other dogs we have not screened: **B6** Labrador 5 years old **B6** Golden 3 1/2 years old **B6** Golden 3 years old **B6** Golden 3 years 5 months **B6** Golden 3 years 9 months
Date Problem Started: 01/14/2019
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Taste of the Wild Sierra Mountain Dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** Please see diet history for additional information
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: 25.8 Kilogram
Age: 5 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 7
Number of Animals Reacted: 2
Owner Information: **Owner Information provided:** Yes
Contact: **Name:** **B6**
Phone: **B6**
Email:
Address: **B6**
 United States
Healthcare Professional Practice Name: Tufts Cummings School of Veterinary Medicine

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

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

Additional Documents:	Attachment: rpt_medical_record_preview.pdf
	Description: Medical records
	Type: Medical Records

Report Details - EON-376363

ICSR: 2061172
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-01-14 17:14:59 EST

Reported Problem:
Problem Description: Eating BEG diet; developed DCM and CHF 4/11/18 Owner changed diet to Royal Canin Early Cardiac and dog has improved significantly. Will recheck again in 3 months. Have not gotten approval for you to contact owner but sent an email today
Date Problem Started: 04/11/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Zignature kangaroo dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** See diet history for more details. Zignature Sept 2017-April 2017 Acana Pork/Squash before that
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Female
Reproductive Status: Neutered
Weight: 26.3 Kilogram
Age: B6 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** Yes
Contact: **Name:** B6
Phone: B6
Email: B6
Address: B6
 United States
Healthcare Professional Information: **Practice Name:** Tufts Cummings School of Veterinary Medicine
Contact: **Name:** Lisa Freeman
Phone: (508) 887-4523
Email: lisa.freeman@tufts.edu

Address: 200 Westboro Rd
North Grafton
Massachusetts
01536
United States

Sender Information:

Name: Lisa Freeman

Address: 200 Westboro Rd
North Grafton
Massachusetts
01536
United States

Contact: **Phone:** 5088874523
Email: lisa.freeman@tufts.edu

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Additional Documents:

Attachment: rpt_medical_record_preview **B6** pdf

Description: Records

Type: Medical Records

From: PFR Event <pfpreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification [B6]
Sent: 10/8/2018 7:28:33 PM
Subject: Pro Plan Savory dry - chicken: Lisa Freeman - EON-367850
Attachments: 2055797-report.pdf; 2055797-attachments.zip

A PFR Report has been received and PFR Event [EON-367850] has been created in the EON System.

A "PDF" report by name "2055797-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 "2055797-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367850
ICSR #: 2055797
EON Title: PFR Event created for Pro Plan Savory dry - chicken beef or lamb (1 cup TID); 2055797

AE Date	[B6]	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Labrador		
Age	7 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2055797

Product Group: Pet Food

Product Name: Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)

Description: Presented to ER of [B6] for CHF and DCM (had rads at RDVM for cough). Full echo on 8/28/18. Unlikely to be associated with diet but reporting because he is sometimes fed the lamb formula Pro Plan. Taurine WNL

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)		

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-367850>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=384772>

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-367850

ICSR: 2055797
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-10-08 15:17:24 EDT

Reported Problem:
Problem Description: Presented to ER on [B6] for CHF and DCM (had rads at RDVM for cough). Full echo on 8/28/18. Unlikely to be associated with diet but reporting because he is sometimes fed the lamb formula Pro Plan. Taurine WNL
Date Problem Started: [B6]
Concurrent Medical Problem: Yes
Pre Existing Conditions: [B6]
Outcome to Date: Stable

Product Information:
Product Name: Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)
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: Retriever - Labrador
Gender: Male
Reproductive Status: Neutered
Weight: 37.7 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: Yes
Contact: Name: [B6]
Phone: [B6]
Email: [B6]
Address: [B6]
United States
Healthcare Professional Information: Practice Name: Tufts Cummings School of Veterinary Medicine
Contact: Name: Lisa Freeman
Phone: (508) 887-4523

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

Client:

B6

Address:

All Medical Records

Patient: B6

Breed: Labrador Retriever

DOB: B6

Species: Canine

Sex: Male
(Neutered)

Home Phone: B6

Work Phone: () -

Cell Phone: B6

Referring Information

B6

Client:

B6

Patient:

Initial Complaint:

Emergency

SOAP Text B6 :54PM - Clinician, Unassigned FHSA

NEW VISIT (ER)

Doctor: B6

Presenting complaint: cardiomegaly

Referral visit? yes

Diagnostics completed prior to visit: CXR (on disk), cardiomegaly, B6

HISTORY:

Signalment: 7yo NM lab

Current history: Presented for cardiomegaly diagnosed at rDVM. Developed cough and went to rDVM on Tuesday, where was put on B6 with presumptive diagnosis of kennel cough (was boarded last week). Better for about a day. However, last night was coughing a lot and seemed uncomfortable. Restless last night and this morning. Seems to have increased effort breathing. Productive cough this am. Took to rDVM this am where they took chest rads and saw cardiogenic pulmonary edema and cardiomegaly. Non-febrile at that time. Was coughing quite a bit previously at rDVM. No prior c/s/v/d/PU/PD. This past week had decreased appetite and lethargic.

Prior medical history: Hx of kennel cough last year. Was boarded again last week. Other dog doesnt show any signs. Hx of B6 Takes B6 from June throughout summer B6

Current medications: B6 Got B6 this morning.

Diet: Purina ProPlan.

Vaccination status/flea & tick preventative use: UTD. Flea/tick and heartworm preventative. Just had heartworm test

Client
Patient:

B6

(negative)

Travel history: None

EXAM:

B6

C/V: grade IV-V/VI L systolic heart murmur, thready pulse quality, no arrhythmia ausculted

B6

ASSESSMENT:

A1: Heart murmur, cardiomegaly, r/o DCM, CHF

A2:

B6

A3:

PLAN:

B6

Diagnostics completed: NOVA

Diagnostics pending: CBC/Chem, cardio consult

Client communication:

Told O that gave **B6**. Also told them that he had significant heart murmur today. On rads he has enlarged heart and pulmonary edema. Gave **B6** to draw fluid out of lungs. On triage US also has decreased contractility. This is seen with DCM, which can be seen with genetics and age. Gave diuretic because heart is being inefficient and have fluid back-up into lungs. Told O that should be admitted to hospital, get recheck rads tomorrow, and likely will need repeat of **B6**. Needs cardio consult and an echo-likely wont get until Monday. Also may need oxygen supplementation. O asked if common to see acute signs with DCM. Told O that likely had minor progressive changes culminating in breathing difficulty. O asked if fluid could be related to pneumonia. Told O that unlikely, but also why we do recheck rads (looking to see improvement with **B6** if it is CHF). O asked about treatment for DCM. Informed O that will be diuretic to make them urinate out his retained fluid. O asked if will drink more. Told will need free choice water while on diuretic. O asked what other drugs he might be on. Discussed **B6** which will help

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

with contractility. Also informed O that with DCM are at risk for arrhythmia, which we havent noticed yet but he may need medication for if he develops it. O asked if drugs might shrink his heart. Told it likely won't make a significant difference in heart size. However, may shrink heart enough to relieve any compression on trachea and may help with relieving cough. rDVM was worried that cardiomegaly was contributing to his coughing. Told O that coughing is likely related to pulmonary edema. O asked about prognosis and told them that the goal is 6 months without another episode of failure. Some dogs may live longer than that, but on average they generally come back in failure in 6 months. O asked when they might be able to take him home, told them likely Monday. O was very distressed about 6 month timeline, was very surprised and upset. Told O that we frequently have dogs live past the 6 months, but it is hard for us to tell beyond that. Told O that he will need to be on medications and have follow-up with Cardio. O asked if he can go back to his normal acitivity levels. Told O that he will need to have pretty strict exercise restriction and that Cardio will guide them further.

Deposit & estimate status: **B6**

Resuscitation code (if admitting to ICU) **B6**

SOAP approved (DVM to sign): **B6** DVM ECC Resident

SOAP Text **B6** 9:40AM - **B6**

7 yo MN LRT

- Presented **B6** for cardiomegally and suspected cardiogenic edema (rDVM rads)
- Coughing since start of the week, initially received doxy b/c boarded at week; not febrile at rDVM

Subjective:

- BAR, friendly, lovely dog

Objective:

B6
CVS: 3-4/6 systolic left murmur, crt normal, pulses SS, mمبر PM, peripheral limbs warm

B6

Assessment:

1. CHF, suspected secondary to DCM

Plan:

B6

Client:
Patient:

B6

B6

Initial Complaint:

New - **B6** - presumed DCM from ICU

SOAP Text Aug 28 2018 5:23PM - **B6**

Disposition/Recommendations

Client:
Patient:

B6

Client: **B6**
 Patient:



Foster Hospital for Small Animals

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

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

Patient:	B6
Species:	Canine
Breed:	Labrador Retriever
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Nova Full Panel-ICU **B6** 9:58:25 PM Accession ID: **B6**

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE	0 - 0		



6/27

B6

Printed Monday, October 08, 2018

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

FiO2	B6	0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

Nova Full Panel-ICU **B6** 10:02:12 PM Accession ID: **B6**

Test	Results	Reference Range	Units
WBC (ADVIA)	B6	4.4 - 15.1	K/uL
RBC(ADVIA)		5.8 - 8.5	M/uL
HGB(ADVIA)		13.3 - 20.5	g/dL
HCT(ADVIA)		39 - 55	%
MCV(ADVIA)		64.5 - 77.5	fL
MCH(ADVIA)		21.3 - 25.9	pg
MCHC(ADVIA)		31.9 - 34.3	g/dL
RDW (ADVIA)		11.9 - 15.2	
PLT(ADVIA)		173 - 486	K/uL
MPV (ADVIA)		8.29 - 13.2	fL
PLTCRT		0.129 - 0.403	%
RETIC(ADVIA)		0.2 - 1.6	%
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL

Nova Full Panel-ICU **B6** 10:02:28 PM Accession ID: **B6**

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
ICO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	



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

T BILIRUBIN	B6	0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE		409 - 1250	U/L
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
COMMENTS (CHEMISTRY)		0 - 0	

Nova Full Panel-ICU **B6** 10:02:07 PM Accession ID: **B6**

Test	Results	Reference Range	Units
SEGS%	B6	43 - 86	%
LYMPHS%		7 - 47	%
MONOS%		1 - 15	%
SEGS (AB)AD VIA		2.8 - 11.5	K/uL
LYMPHS (ABS)AD VIA		1 - 4.8	K/uL
MONOS (ABS)AD VIA		0.1 - 1.5	K/uL
WBC MORPHOLOGY		0 - 0	
No Morphologic Abnormalities			
RBC MORPHOLOGY		0 - 0	
No morphologic abnormalities			

Nova Full Panel-ICU **B6** 10:49:36 PM Accession ID: **B6**

Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU **B6** 11:42:25 AM Accession ID: **B6**

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L
CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L



8/27

B6

Printed Monday, October 08, 2018

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

GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	
FiO2		0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

B6

Nova Full Panel-ICU **B6** 11:47:47 AM **Accession ID: B6**

Test	Results	Reference Range	Units
TS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%
TS (FHSA)		0 - 0	g/dl

Nova Full Panel-ICU 8/28/2018 5:24:21 PM **Accession ID: B6**

Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	

B6



B6

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

T BILIRUBIN	B6	0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
COMMENTS (CHEMISTRY)		0 - 0	
Slight hemolysis; Slight lipemia			

Nova Full Panel-ICU		8/28/2018 5:27:40 PM	Accession ID: B6
Test	Results	Reference Range	Units
TS (FHSA)	B6	0 - 0	g/dl
PCV **		0 - 0	%
TS (FHSA)		0 - 0	g/dl



10/27

B6

Printed Monday, October 08, 2018

Client: **B6**
Patient:

RDVM **B6** referral **B6**



REFERRAL FORM

TUFTS UNIVERSITY
Cummings School of Veterinary Medicine
Henry and Lois Foster Hospital for Small Animals
Hospital for Large Animals
200 Westboro Road, Room 30
North Grafton, MA 01556
603-882-1200

Service to Which Referred: Emergency Appointment Date: _____ Time: _____

OWNER INFORMATION:

B6

PATIENT INFORMATION:

Registered Name/ID: **B6**
Species: Dog Breed: Lab Sex: M Age: 7

CASE HISTORY:

Chief Concern/Provisional Diagnosis: Non-productive cough
Intermittent vomiting

Vaccination History: Current - rabies, distemper (DAP)

Other History: Intermittent coughs with a cough spasm
No response to doxycycline and amoxicillin

Diagnostic Test Results (if possible, please attach results): None

Are Radiographs enclosed? Yes

Current Therapy & Medications (include dosages): **B6**

Special Comments/Requests: Some dog cough R/O cardiac

REFERRING VETERINARIAN INFORMATION:

B6

Address: _____ City: _____ State: _____ Zip Code: _____

If an animal is being referred which has had lab work done at TVDL, please include copies of the lab results or the TVDL accession number. If you are faxing us information about a clinical case which has been referred, please use fax number (508) 839-7951.

Client:
Patient:

B6

Taurine Level

20881

Sample Submission Form

Amino Acid Laboratory
University of California, Davis
3020 Ste Med Bld
3089 Veterinary Medicine Drive
Davis, CA 95616
Tel: (530)752-5058, Fax: (530)752-4998

UC CUSTOMERS ONLY:
Non-Federal Funds ID/Account Number
to bill: _____

<https://www.vetmed.ucdavis.edu/vmb/aal/aal.html>

Vet/Tech Contact: **B6**
Company Name: Tufts Cummings School of Vet Med - Clinical Pathology Laboratory
Address: 300 Westboro Road
North Grafton, MA 01536
Email: clnpath@tufts.edu; carlowet@tufts.edu
Tel: 508-887-4669 Fax: 508-839-7906

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

Patient Name: **B6**
Species: *canine* **B6**
Owner's Name: **B6**

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

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

Reference Ranges (nmol/ml)

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

Client:
Patient:

B6

Amino Acid Labs Taurine results 8/28/18

20881

Sample Submission Form

Amino Acid Laboratory
University of California, Davis
1020 Vet Med Bldg
1009 Veterinary Medicine Center
Davis, CA 95616
Tel: (530)752-8268 Fax: (530)752-8268

UC CUSTOMERS ONLY
Non-Animal Health ID/Account Number
AN#

<http://www.ucdavis.edu/vetmed/ahla/submit.html>

Vet/Tech Contact: **B6**

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

Address: 200 Western Road
North Andover, MA 01855

Email: ahla@ucdavis.edu / aminoacids@ucdavis.edu

Tel: 508-850-4808 Fax: 508-850-7508

Billing Contact: **B6**

TAX ID:

Email: **B6**

Tel: **B6**

Patient Name: **B6**

Species: **B6**

Owner's Name: **B6**

Sample Type: Plasma Whole Blood Urine Food Other _____
Test Name: Taurine Complete Amino Acid Other _____

Taurine Results (nmol/mol)

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

Reference Ranges (nmol/mol)

	Plasma		Whole Blood	
	Normal Range	No known risk for Taurine Deficiency	Normal Range	No known risk for Taurine Deficiency
Cat	80-120	>80	200-600	>200
Dog	80-120	>80	100-150	>150

B6

B6

Client: **B6**
Taurine (nmol/mol) 81,000
Citation: NRC 1981

UNIVERSITY OF CALIFORNIA, DAVIS



STERN CARDIAC GENETICS LABORATORY
JOHN A. STERN, DVM, PhD, DACVIM (CARDIOLOGY)
stern@ucdavis.edu August 8, 2018

FREQUENTLY REQUESTED INFORMATION REGARDING TAURINE & RELATED
CARDIOMYOPATHY IN GOLDEN RETRIEVERS

Taurine reference ranges for Golden Retrievers: The Stern Lab suggests that the following (Human) reference ranges be used for Golden Retrievers and be considered for other known taurine-sensitive breeds such as Newfoundland or American Cocker Spaniels. This is primarily based on 3 observations:

1. Golden Retrievers with marginal taurine levels (defined below) have been diagnosed with dilated cardiomyopathy and have demonstrated disease reversal after taurine supplementation and diet change.
2. Previously published work demonstrates taurine insufficiency in Golden Retrievers.
3. The most recently published reference on normal blood taurine values shows higher levels than previously reported.

- Normal whole blood taurine: >250nmol/L
- Normal plasma taurine: >75nmol/L
- Marginal whole blood taurine: 100-250nmol/L
- Marginal plasma taurine: 40-75nmol/L
- Low whole blood taurine: <200nmol/L
- Low plasma taurine: <40nmol/L

References:

Albery CA, Williams AB, Pitt JF, Lawler J, Pitt JF. Packed serum concentrations and normal range and its range with fresh plasma. *J Vet Invest* 1991; 5:222-226

Rehder MC, Mueller B, Grotzer G, Knauss W. Taurine deficiency disease: occurrence in a family of golden retrievers with acute dog food. *J Vet Intern Med* 2011; 35:294-297

Williams AB, Albery CA, Pitt JF, Lawler J, Pitt JF. Investigation of the relationship between taurine (TAU) levels and echocardiographic dilated cardiomyopathy in American Cocker Spaniels with decreased plasma taurine concentrations. *J Vet Intern Med* 2017; 31:284-291

Rehder MC, Albery CA, Pitt JF, Lawler J, Pitt JF, Grotzer G, Knauss W. Taurine deficiency in Newfoundland Retrievers: a genetic complex and familial disease. *J Am Vet Med Assoc* 2003; 223:1236-1238

Stewart BJ, Reid JL, Rogers JK, Rankin BJ. Taurine deficiency in dog diets based on commercial. *J Anim Sci* 1997; 85:1122-1126. *J Am Vet Med Assoc* 2003; 223:1237-1241

Winters LA, Ward BE, Brown W, August PA, Hovde CE, Reynolds H, Reynolds H, Kover WB, Reid JL. Alimentary dilated cardiomyopathy in German Shepherds. *J Vet Intern Med* 1995; 9: 345-349. *J Am Vet Med Assoc* 1996; 209:1272-1276

Stewart BJ, Reid JL, Rogers JK, Rankin BJ. Taurine and whole blood taurine in normal dogs of varying genetic backgrounds. *Proceedings of the 1st International Conference on Animal Health* 2004; 107:226-228

Plasma vs. whole blood taurine testing

If at all possible, we recommend that paired (plasma and whole blood) taurine samples be submitted for analysis. A low value on either or both tests is clinically relevant. If your dog is diagnosed with HCM, submitting paired taurine samples (plasma and whole blood) is imperative. We recommend that the UC Davis Amino Acid Laboratory be used for taurine testing, as this is where the literature cited for our reference ranges was generated. <http://www.vetermed.ucdavis.edu/labs/amino-acid-lab/index.html>. If a single test is submitted the Stern Lab recommends that whole blood be submitted preferentially. This is due to the false elevation of taurine levels that is possible in plasma samples due to sample handling issues. This is an area of some debate between clinicians and conflicting information on preference for plasma vs. whole blood exists. This underlines the value of paired sampling.

Amino Acid Labs Taurine results 8/28/18

Clinical Recommendations for Golden Retrievers based on taurine levels:

Taurine level less than 200 - 250nmol/L or whole blood or plasma (nmol/L) in plasma

- An echocardiogram by a board-certified veterinary cardiologist is recommended.
- After echocardiogram has been completed, a diet change is recommended.
 - If HCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
 - If HCM is diagnosed, prescribed supplementation with oral taurine and L-carnitine is recommended.
 - Reevaluation of taurine levels is suggested after three months of diet change and supplementation.
 - Cardiology reevaluation schedule will be recommended by the attending clinician pending echocardiographic findings.
 - Many Golden Retrievers with cardiac-deficient HCM do not show clinical signs and steady improvement over a period of 6-12 months.

Taurine level less than 200 - 250nmol/L or whole blood or plasma (nmol/L) in plasma

- An echocardiogram by a board-certified cardiologist is recommended.
- After echocardiogram has been completed, a diet change is recommended.
- We recognize that many dogs in this category may have normal echocardiograms, and that the value of screening should be carefully considered. If the dog is eating within the limits within the FDA warning or other labels with the diets identified in our study (see diets of concern section below), we encourage echocardiographic screening with greater enthusiasm.
- If an echocardiogram is not performed, a diet change is still recommended and a taurine level reevaluation after three months as the owner should be considered.
- If HCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
 - If HCM is diagnosed, prescribed supplementation with oral taurine and L-carnitine is recommended.
 - Reevaluation of taurine levels is suggested after three months of diet change and supplementation.
 - Cardiology reevaluation schedule will be recommended by the attending clinician pending echocardiographic findings.
 - Many Golden Retrievers with cardiac-deficient HCM do not show clinical signs and steady improvement over a period of 6-12 months.

Taurine level less than 200 - 250nmol/L or whole blood or plasma (nmol/L) in plasma

- Diet change is recommended if you are feeding a diet that falls within the FDA warning or other labels with the diets identified in our study (see diets of concern section below)
- If your pet shows any signs of cardiac disease (rattling breathing, extreme tiredness, fainting/collapse, coughing) we recommend your veterinarian evaluate your pet.

Effect of Corn and Changing a Diet

The FDA alert called attention to several dietary ingredients that should be considered when evaluating whether your pet is at risk (for example, because the pet's diet lacks, or has too much, of these nutrients). These findings were largely recapitulated in our current study of Golden Retrievers with low taurine levels and HCM. Our lab considers these ingredients to be of greatest concern when present within the first 5 listed ingredients on the dog food bag. Additionally, we noted a high percent of diets in our study were using protein sources other than chicken or beef and labeled as grain-free.

Points to consider when making a diet change:

- Choose a diet that does not contain the concerning components listed above.
- Choose a diet that meets the WSAVA Global Nutrition Assessment Guidelines published or approved by veterinary organizations from around the world:
<http://www.wsava.org/WSAVA/media/42/pdfs/and-Global-nutritional-requirements-for-Dog-Food-for-pet.pdf>
- FDA alert listed here:
<http://www.fda.gov/animal/animalproducts/foodandnutrition/CMV101618a/ucm162004.htm>

Choosing a source of L-taurine supplement:

Selecting supplements should be performed based upon diets that match their stated contents and are readily available for absorption. Ideally, a previous publication called multiple taurine and L-carnitine supplements. Based upon this publication our laboratory recommends the following supplements to those meeting our quality criteria. (Bough et al. 2009) *Am J Vet Res* 70:1242-1247

Taurine 500 mg supplements that are within 5% of stated contents and if applicable, disintegrates within 30 minutes:

- Taurine 500 mg by Tetrakis (100mg tablets)
- Taurine by Sarnova Health Products (100mg capsules)
- Taurine by NOW Foods (100mg capsules)
- Taurine 500 by GNC (100mg tablets)

Taurine L-carnitine supplements that are within 5% of stated contents and if applicable, disintegrates within 30 minutes:

- L-carnitine 500 by Jarrow Formulas (100mg capsules)
- L-carnitine 500 by Lascary Labs (100mg capsules)
- Meat L-carnitine by Solgar Vitamins and Herbs (100mg tablets)
- L-carnitine by Pharmacia's Vitals (100mg tablets)

The above list does not recommend the combined supplementation of taurine or L-carnitine to dogs without evidence of HCM and/or significant deficiency. If HCM is diagnosed we typically recommend dogs under 50lbs receive 1000mg of taurine every 12hrs and dogs under 50lbs receive 500mg of taurine every 12hrs. We recommend L-carnitine at a dose of ~50mg/kg orally with food every 8hrs. Your veterinary cardiologist or family veterinarian should be consulted for promoting the best dose for your dog.

Reporting to the FDA:

Understanding the basis of this condition requires a great deal of research and investigation. Owners with affected dogs can contribute their data to help propel this research forward. You can report cases of taurine deficiency, dilated cardiomyopathy, sudden cardiac death, or any combination of these events to the FDA by following the information found here:

<http://www.fda.gov/animal/animalproducts/foodandnutrition/CMV101618a/ucm162004.htm>

Additional questions or comments:
Dr. [Name]
This document last updated Aug. 28, 2018



CARDIOLOGY SERVICE UPDATE: DOG FOOD & RELATED CARDIOMYOPATHY

The Cardiology Service has developed this document in response to the alerts from the FDA. These alerts identify an increased risk for some grain-free diets containing certain ingredients (especially rice bran, pea, chickpeas, lentils, white potatoes, sweet potatoes) and a diagnosis of dilated cardiomyopathy (DCM). The links provided throughout this document can be copied and pasted to obtain additional information.

FDA Alerts found here:

<https://www.fda.gov/animal/veterinary/ucdavis/ucdaviscardiology/DCM.html>
<https://www.fda.gov/animal/veterinary/ucdavis/ucdaviscardiology/your-grain-free-diet-may-harm-your-dogs-heart.html>

What is Dilated Cardiomyopathy (DCM)?

DCM is a heart muscle disease that results in a weak pump function and heart chamber enlargement. In the early stages of this disease dogs may appear totally healthy with no apparent clinical signs. Later in the course of the disease, dogs may have a heart murmur, an arrhythmia (irregular heart beat), collapse episodes, weakness or tiredness with exercise, and even acute breathing from congestive heart failure. While there are some breeds of dogs (like Doberman) that have a genetic predisposition to development of DCM, there are also nutritional factors that may result in this disease.

What should I do?

If you are feeding a diet of concern listed upon the FDA alert we recommend that you consult with your veterinarian or veterinary cardiologist. We provide 4 general points for guidance below:

1. An initial step is to consider whether you are willing or interested in performing additional testing to assess whether your pet is affected with DCM. If you believe your dog is at risk, showing any of the aforementioned clinical signs or would prefer to simply rule out any heart disease, we recommend that you first have your pet's taurine levels tested (both whole blood and plasma levels) as well as seek an echocardiogram by a board-certified veterinary cardiologist. Low taurine levels are associated with development of DCM in dogs and are sometimes a component of this current issue.

Additional information regarding testing can be found here: <https://www.ucdavis.edu/ucdaviscardiology/your-grain-free-diet-may-harm-your-dogs-heart.html>

2. At the time, diet change is recommended where possible and should be considered regardless of the results obtained from any testing. You can consult with your veterinarian in selecting a new diet that avoids the ingredients of concern listed by the FDA. When selecting this diet, we recommend that you choose a diet that is manufactured with rigorous quality control measures and research behind the formulation. A way to ensure that your diet meets these recommendations is to follow the following guidelines that were generated by a large number of the world's leading experts in veterinary nutrition:

Food selection guidelines found here:

<https://www.ucdavis.edu/ucdaviscardiology/your-grain-free-diet-may-harm-your-dogs-heart.html>

3. If your pet is identified through testing to have a low blood taurine level in evidence of DCM by a cardiologist, we urge you to report this information to the FDA.

FDA reporting guidelines found here: <https://www.fda.gov/animal/veterinary/ucdavis/ucdaviscardiology/your-grain-free-diet-may-harm-your-dogs-heart.html>

4. Work with your veterinarian(s) to determine the best course of action and medical treatments if indicated. In the case of a DCM diagnosis, diet change alone may not be sufficient and additional medications may be prescribed.

Please continue to monitor the FDA website and the UC Davis School of Veterinary Medicine Newsletters for updates and recommendations regarding this issue.

Client:
Patient:

B6

Vitals Results

7:19:38 PM	Heart Rate (/min)
7:19:39 PM	Respiratory Rate
7:19:40 PM	Temperature (F)
7:19:41 PM	Lasix treatment note
8:01:18 PM	Nursing note
10:51:29 PM	Cardiac rhythm
10:51:30 PM	Heart Rate (/min)
10:52:15 PM	Respiratory Rate
10:55:36 PM	Lasix treatment note
11:11:46 PM	Respiratory Rate
11:15:36 PM	Eliminations
11:59:29 PM	Cardiac rhythm
11:59:30 PM	Heart Rate (/min)
1:06:28 AM	Respiratory Rate
1:06:38 AM	Cardiac rhythm
1:06:39 AM	Heart Rate (/min)
1:07:29 AM	Respiratory Rate
1:16:20 AM	Catheter Assessment
1:16:30 AM	Temperature (F)
1:16:40 AM	Amount eaten
1:24:55 AM	Eliminations
1:59:16 AM	Cardiac rhythm
1:59:17 AM	Heart Rate (/min)
2:00:45 AM	Nursing note
3:07:42 AM	Cardiac rhythm
3:07:43 AM	Heart Rate (/min)
3:08:14 AM	Respiratory Rate
3:51:34 AM	Respiratory Rate
3:51:49 AM	Cardiac rhythm
3:51:50 AM	Heart Rate (/min)
3:56:33 AM	Eliminations
4:53:31 AM	Respiratory Rate
4:53:41 AM	Cardiac rhythm
4:53:42 AM	Heart Rate (/min)
5:05:59 AM	Catheter Assessment
5:47:32 AM	Cardiac rhythm
5:47:33 AM	Heart Rate (/min)
5:47:43 AM	Respiratory Rate
6:58:01 AM	Cardiac rhythm
6:58:02 AM	Heart Rate (/min)

B6

B6

Client:
Patient:

B6

Vitals Results

B6

6:58:10 AM	Respiratory Rate
7:36:37 AM	Weight (kg)
7:36:43 AM	Eliminations
7:36:58 AM	Respiratory Rate
7:40:41 AM	Amount eaten
7:40:57 AM	Cardiac rhythm
7:40:58 AM	Heart Rate (/min)
8:15:42 AM	Lasix treatment note
8:57:02 AM	Cardiac rhythm
8:57:03 AM	Heart Rate (/min)
8:57:12 AM	Respiratory Rate
9:02:45 AM	Catheter Assessment
9:02:59 AM	Eliminations
9:58:29 AM	Respiratory Rate
11:03:50 AM	Respiratory Rate
11:36:45 AM	Respiratory Rate
11:36:53 AM	Heart Rate (/min)
11:42:00 AM	Eliminations
12:53:35 PM	Respiratory Rate
1:51:27 PM	Amount eaten
2:11:08 PM	Respiratory Rate
2:32:31 PM	Lasix treatment note
2:32:41 PM	Catheter Assessment
2:46:00 PM	Respiratory Rate
2:50:43 PM	Eliminations
4:29:41 PM	Weight (kg)

B6

Client:
Patient:

B6

RDVM

B6

Rad

B6

B6

Study Date

B6

B6

Client: **B6**
Patient:

RDVM **B6** Rads **B6**

ID **B6** Study Date **B6**

B6

Client:
Patient:

B6

Patient History

06:37 PM	UserForm
07:19 PM	Vitals
07:19 PM	Vitals
07:19 PM	Vitals
07:19 PM	Vitals
07:19 PM	Vitals
08:01 PM	Vitals
08:13 PM	Prescription
09:00 PM	UserForm
09:24 PM	Purchase
09:24 PM	Purchase
09:25 PM	Purchase
09:25 PM	Purchase
09:25 PM	Purchase
09:58 PM	Purchase
10:02 PM	Purchase
10:02 PM	Purchase
10:06 PM	Purchase
10:06 PM	Purchase
10:49 PM	Labwork
10:51 PM	Treatment
10:51 PM	Vitals
10:51 PM	Vitals
10:52 PM	Treatment
10:52 PM	Vitals
10:55 PM	Vitals
10:55 PM	Treatment
11:11 PM	Treatment
11:11 PM	Vitals
11:11 PM	Treatment
11:15 PM	Treatment
11:15 PM	Vitals
11:59 PM	Treatment
11:59 PM	Vitals
11:59 PM	Vitals
01:06 AM	Treatment
01:06 AM	Vitals
01:06 AM	Treatment
01:06 AM	Vitals
01:06 AM	Vitals
01:07 AM	Treatment
01:07 AM	Vitals
01:16 AM	Treatment
01:16 AM	Vitals

B6

B6

Client:
Patient:

B6

Patient History

01:16 AM	Treatment
01:16 AM	Vitals
01:16 AM	Treatment
01:16 AM	Vitals
01:24 AM	Treatment
01:24 AM	Vitals
01:59 AM	Treatment
01:59 AM	Vitals
01:59 AM	Vitals
02:00 AM	Vitals
03:07 AM	Treatment
03:07 AM	Vitals
03:07 AM	Vitals
03:08 AM	Treatment
03:08 AM	Vitals
03:51 AM	Treatment
03:51 AM	Vitals
03:51 AM	Treatment
03:51 AM	Vitals
03:51 AM	Vitals
03:56 AM	Treatment
03:56 AM	Vitals
04:53 AM	Treatment
04:53 AM	Vitals
04:53 AM	Treatment
04:53 AM	Vitals
04:53 AM	Vitals
05:05 AM	Treatment
05:05 AM	Vitals
05:06 AM	Treatment
05:47 AM	Treatment
05:47 AM	Vitals
05:47 AM	Vitals
05:47 AM	Treatment
05:47 AM	Vitals
06:58 AM	Treatment
06:58 AM	Vitals
06:58 AM	Vitals
06:58 AM	Treatment
06:58 AM	Vitals
07:36 AM	Treatment
07:36 AM	Vitals
07:36 AM	Treatment

B6

B6

Client:
Patient:

B6

Patient History

07:36 AM	Vitals
07:36 AM	Treatment
07:36 AM	Vitals
07:40 AM	Treatment
07:40 AM	Treatment
07:40 AM	Vitals
07:40 AM	Treatment
07:40 AM	Vitals
07:40 AM	Vitals
08:15 AM	Vitals
08:16 AM	Treatment
08:57 AM	Treatment
08:57 AM	Vitals
08:57 AM	Vitals
08:57 AM	Treatment
08:57 AM	Vitals
09:02 AM	Treatment
09:02 AM	Vitals
09:02 AM	Treatment
09:02 AM	Vitals
09:11 AM	Purchase
09:22 AM	Purchase
09:52 AM	UserForm
09:58 AM	Treatment
09:58 AM	Treatment
09:58 AM	Vitals
10:04 AM	Deleted Reason
11:03 AM	Treatment
11:03 AM	Vitals
11:29 AM	Treatment
11:31 AM	Purchase
11:36 AM	Treatment
11:36 AM	Vitals
11:36 AM	Treatment
11:36 AM	Vitals
11:42 AM	Treatment
11:42 AM	Vitals
11:42 AM	Treatment
11:42 AM	Purchase
11:47 AM	Labwork
12:53 PM	Treatment

B6

B6

Client:
Patient:

B6

Patient History

B6

12:53 PM	Vitals
01:51 PM	Treatment
01:51 PM	Treatment
01:51 PM	Vitals
02:11 PM	Treatment
02:11 PM	Vitals
02:30 PM	Prescription
02:31 PM	Prescription
02:32 PM	Vitals
02:32 PM	Treatment
02:32 PM	Treatment
02:32 PM	Vitals
02:34 PM	Purchase
02:46 PM	Treatment
02:46 PM	Vitals
02:50 PM	Treatment
02:50 PM	Vitals
03:05 PM	UserForm
12:25 PM	Appointment
04:00 PM	UserForm
04:00 PM	Purchase
04:04 PM	Treatment
04:29 PM	Vitals
04:49 PM	Purchase
05:24 PM	Purchase
05:27 PM	Labwork
06:02 PM	UserForm
06:17 PM	Prescription
06:19 PM	Purchase
09:54 AM	Prescription
09:54 AM	Purchase

B6

Cardio Discharge - DCM CHF Form Saved to Record

B6

Report Details - EON-380716

ICSR: 2063119
 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 18:45:24 EST

Reported Problem:
Problem Description: Has been regularly rechecked after [B6] Progressive reduction in left ventricular contractile function noted on most recent echo. Eating BEG diet. Owner changed to Royal Canin Early Cardiac diet and we will recheck in April
Date Problem Started: 01/02/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: [B6]
Outcome to Date: Stable

Product Information:
Product Name: Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** 1/4 cup kibble (divided into 2 meals) 1 tbsp cooked chicken BID Owner switched to Weight Control version of same diet (salmon, lentil, green bean) just a few days before visit
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: [B6]
Type Of Species: Dog
Type Of Breed: Chihuahua
Gender: Female
Reproductive Status: Neutered
Weight: 3.72 Kilogram
Age: 9 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]
 United States
Healthcare Professional Information: **Practice Name:** Tufts Cummings School of Veterinary Medicine
Contact: **Name:** Lisa Freeman

		Phone: (508) 887-4523
		Email: lisa.freeman@tufts.edu
		Address: 200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:	Lisa Freeman
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	Phone: 5088874523 Email: lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
Additional Documents:	Attachment:	T_26346.pdf
	Description:	Taurine - will send rest of records by email (too large)
	Type:	Laboratory Report

Report Details - EON-390030

ICSR:	2067990
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-06-10 10:42:47 EDT
Initial Report Date:	02/24/2019
Parent ICSR:	2063119
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Has been regularly rechecked after [B6] Progressive reduction in left ventricular contractile function noted on most recent echo. Eating BEG diet. Owner changed to Royal Canin Early Cardiac diet and we will recheck in April April cardiology recheck - echo measurements improved overall - eating Royal Canin Cardiac diet, no additional medications prescribed. [B6] remains occluded. Patient has purposefully lost weight.
	Date Problem Started:	01/02/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	Description:	1/4 cup kibble (divided into 2 meals) 1 tbsp cooked chicken BID Owner switched to Weight Control version of same diet (salmon, lentil, green bean) just a few days before visit	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			

Animal Information:	Name:	[B6]
	Type Of Species:	Dog
	Type Of Breed:	Chihuahua
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	3.72 Kilogram
	Age:	9 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided:
	Contact:	Name: [B6]
		Phone: [B6]
		Email: [B6]

		Address: B6 United States
Healthcare Professional Information:	Practice Name:	Tufts Cummings School of Veterinary Medicine
	Contact:	Name: Lisa Freeman Phone: (508) 887-4523 Email: lisa.freeman@tufts.edu
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
Sender Information:	Name:	Lisa Freeman
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States
	Contact:	Phone: 5088874523 Email: lisa.freeman@tufts.edu
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:	Attachment:	NT-proBNP & Diet Hx 4-5-19.pdf
	Description:	lab work
	Type:	Laboratory Report
	Attachment:	B6 -2019-01-03-1008 NT-proBNP - Copy.pdf
	Description:	lab work
	Type:	Laboratory Report
	Attachment:	troponin 5-30-2019.pdf
	Description:	lab work results
	Type:	Laboratory Report

B6

PET OWNER: **B6**
SPECIES: Canine
BREED: Chihuahua
GENDER: Unknown
AGE: 9 Years
PATIENT ID:

Tufts University Attn: Lisa Freeman
200 Westboro Rd.
North Grafton, MA 01536
508-839-5395
ACCOUNT #: **B6**
ATTENDING VET: **B6**

LAB ID: 2303280698
ORDER ID: 338315
COLLECTION DATE: **1/1/19**
DATE OF RECEIPT: **1/2/19**
DATE OF RESULT: **1/3/19**

IDEXX Services:

Chemistry



1/2/19 (Order Received)
1/3/19 10:08 AM (Last Updated)

TEST	RESULT	REFERENCE VALUE
Cardiopet proBNP (Canine)	B6	0 - 900 pmol/L

a **B6**

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

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 3/12/2019 11:00:00 AM
Subject: RE: GILab Results

Thanks, Lisa!

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Sunday, March 10, 2019 2:48 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: FW: GILab Results

Hi Jen,
Troponin results on a bunch of the dogs that I've already reported. The 4 B6 boxers are recheck values –

B5

Lisa

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

From: Tufts Veterinary Cardiology Service
Sent: Friday, March 08, 2019 10:40 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>; B6
Subject: FW: GILab Results

I can put into SS.

From: Clinical Pathology Lab <clinpath@tufts.edu>
Sent: Friday, March 8, 2019 8:28 AM
To: Tufts Veterinary Cardiology Service <cardiovet@tufts.edu>; B6
Subject: FW: GILab Results

Forwarding Troponin Results that I think were sent through Cardio service.

B6

Clinical Pathology Laboratory

B6

From: gilab@cvm.tamu.edu [gilab@cvm.tamu.edu]

Sent: Wednesday, March 06, 2019 6:21 PM

To: Clinical Pathology Lab

Cc: **B6**

Subject: GILab Results

Greetings:

Please see the attachment for updated results for your patient(s).

To obtain results faster, you can also login to our website at <http://vetmed.tamu.edu/gilab/service/clinic-login> to view results immediately when they become available.

Your username is **B6**

Thank you for using the GI Lab

The GI Lab - Promoting gastrointestinal health in companion animals
(979) 862 2861; FAX (979) 862 2864; <http://vetmed.tamu.edu/gilab>

=====
Accession: **B6**
Patient: **B6**
=====

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

Report Comments:

=====
Accession: **B6**
Patient: **B6**
=====

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

Report Comments:

=====
Accession: **B6**

Patient: **B6**
=====

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

Report Comments:

=====
Accession: **B6**

Patient: **B6**
=====

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

B6

Report Comments:

=====
=====
Accession: **B6**

Patient: **B6**
=====
=====

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

Report Comments:

=====
=====
Accession: **B6**

Patient: **B6**
=====
=====

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

Report Comments:

Accession: **B6**

Patient: **B6**

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

Report Comments:

Accession: **B6**

Patient: **B6**

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

Report Comments:

Accession: **B6**

Patient: **B6**

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

Report Comments:

=====
Accession: **B6**

Patient: **B6**
=====

Ultra-Sensitive Troponin I Fasting

Timing: Fasting

Result: **B6**

Range: 0 - 0.06

B6

Report Comments:

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 11/11/2018 1:56:12 AM
Subject: DCM (not Lisa Freeman and/or Tufts) 11/10/2018 2055
Attachments: Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food **B6** EON-370755

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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Report Details - EON-370755

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

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

Attachment: **B6** echo.pdf

Description: Echocardiogram report

Type: Echocardiogram

CARDIOLOGY SERVICE UPDATES: DOG FOOD & DILATED CARDIOMYOPATHY

The Cardiology Service has developed this document in response to the alerts from the FDA. These alerts identify an associated risk for some grain-free diets containing certain ingredients (legumes like peas, pea components, lentils; white potatoes, sweet potatoes) and a diagnosis of dilated cardiomyopathy (DCM). The links provided throughout this document can be copied and pasted to obtain additional information.

FDA Alerts found here:

<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm>

<https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm616279.htm>

What is Dilated Cardiomyopathy (DCM)?

DCM is a heart muscle disorder that results in a weak pump function and heart chamber enlargement. In the early stages of this disease pets may appear totally healthy with no apparent clinical signs. Later in the course of this disease, dogs may have a heart murmur, an arrhythmia (irregular heart beat), collapse episodes, weakness or tiredness with exercise, and even trouble breathing from congestive heart failure. While there are some breeds of dogs (like Dobermans) that have a genetic predisposition to development of DCM, there are also nutritional factors that may result in this disease.

What should I do?

If you are feeding a diet of concern based upon the FDA alert we recommend that you consult with your veterinarian or veterinary cardiologist. We provide 4 general points for guidance below:

1. An initial step is to **consider whether you are willing or interested in performing additional testing** to assess whether your pet is affected with DCM. If you believe your dog is at risk, showing any of the aforementioned clinical signs or would prefer to simply rule out any heart disease, we recommend that you first have your pet's taurine levels tested (both whole blood and plasma levels) as well as seek an echocardiogram by a board-certified veterinary cardiologist. Low taurine levels are associated with development of DCM in dogs and are sometimes a component of this current issue.

Information on taurine testing can be found here: <https://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory>

2. At this time, **diet change is recommended when possible** and should be considered regardless of the results obtained from any testing. You can consult with your veterinarian in selecting a new diet that avoids the ingredients of concern listed by the FDA. When selecting this diet, we recommend that you choose a diet that is manufactured with rigorous quality control measures and research behind the formulation. A way to ensure that your diet meets these recommendations is to follow the following guidelines that were generated by a large number of the world's leading experts in veterinary nutrition.

Food selection guidelines found here:

<https://www.wsava.org/WSAVA/media/Arpita-and-Emma-editorial/Selecting-the-Best-Food-for-your-Pet.pdf>

3. If your pet is identified through testing to have a low blood taurine level or evidence of DCM by echocardiogram, we urge you to **report this information to the FDA**.

FDA reporting guidelines found here: <https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

4. **Work with your veterinarian(s)** to determine the best course of action and medical treatments if indicated. In the case of a DCM diagnosis, diet change alone may not be sufficient and additional medications may be prescribed.

Please continue to monitor the FDA website and the UC Davis School of Veterinary Medicine Newsfeeds for updates and recommendations regarding this issue.

From: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah; Jones, Jennifer L; Peloquin, Sarah
CC: Rotstein, David; Carey, Lauren; Hartogensis, Martine
Sent: 8/1/2018 12:11:35 PM
Subject: RE: 800.267-FDA Case Investigation for [REDACTED] EON-359970

Thanks – I have been following a FB page from my home computer (without commenting in any way, of course). I wonder if it's the same – many had been working with Josh Stern at UC Davis. Hopefully some will report to us as well.

From: Reimschuessel, Renate
Sent: Wednesday, August 1, 2018 8:01 AM
To: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
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Subject: FW: 800.267-FDA Case Investigation for [REDACTED] EON-359970

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This morning I received the file, and again suggested she advise owners to submit to FDA through the portal.

I'm sharing the file for your additional information.

rr

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

Phone 1-240-402-5404

Fax 301-210-4685

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

From: Reimschuessel, Renate
Sent: Wednesday, August 1, 2018 7:54 AM
To: [REDACTED]
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Thank you for the information.

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Phone 1-240-402-5404

Fax 301-210-4685

From: [REDACTED] **B6**
Sent: Tuesday, July 31, 2018 10:57 PM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: Re: 800.267-FDA Case Investigation for [REDACTED] **B6** EON-359970

Hi Dr. Reimschuessel,

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Please let me know when you receive this.

Thank you,

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To: Hartogensis, Martine; Reimschuessel, Renate; Ceric, Olgica; Nemser, Sarah; Jones, Jennifer L; Peloquin, Sarah
CC: Rotstein, David; Carey, Lauren
Sent: 8/1/2018 12:16:19 PM
Subject: RE: 800.267-FDA Case Investigation for [B6] EON-359970

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Phone 1-240-402-5404

Fax 301-210-4685

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

From: Reimschuessel, Renate
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To: Palmer, Lee Anne; Hartogensis, Martine; Ceric, Olgica; Nemser, Sarah; Jones, Jennifer L; Peloquin, Sarah
CC: Rotstein, David; Carey, Lauren
Sent: 8/1/2018 12:19:56 PM
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Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Subject: FW: 800.267-FDA Case Investigation for [B6] EON-359970

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Fax 301-210-4685

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

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Sent: Wednesday, August 1, 2018 7:54 AM

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To: Reimschuessel, Renate; Palmer, Lee Anne; Hartogensis, Martine; Ceric, Olgica; Nemser, Sarah; Peloquin, Sarah
CC: Rotstein, David; Carey, Lauren
Sent: 8/1/2018 12:25:18 PM
Subject: RE: 800.267-FDA Case Investigation for [REDACTED] EON-359970

Yes-Josh was in a group we spoke with. He mentioned his cases all involved Acana. After speaking w/ Andrea Fascetti at Davis, [REDACTED] B5

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



From: Reimschuessel, Renate
Sent: Wednesday, August 01, 2018 8:20 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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From: Palmer, Lee Anne
Sent: Wednesday, August 1, 2018 8:16 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
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To: 'Darcy Adin'
CC: [REDACTED] B6
Sent: 1/30/2019 4:37:05 PM
Subject: RE: Sample?

Hi Darcy,

Thank you for the kind words. [REDACTED] B6 I apologize for the delay.

We are definitely interested in the case. We'd just need a complaint submitted through the Safety Reporting Portal found here: <https://www.safetyreporting.hhs.gov/>

After you submit the report, please send me the ICSR number (confirmation of report submission). We can send you a box to collect the tissue. Was there also a full necropsy report with medical records you could share as well? Those can be attached to the report you submit.

Please let me know if you have questions.

Thank you again for your help,

Jen

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

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

From: Darcy Adin <dbadin@ncsu.edu>
Sent: Friday, January 25, 2019 5:01 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: [REDACTED] B6
Subject: Sample?

Hi Jen,

I hope you are doing well - not sure how the partial government shutdown is impacting your area specifically?

[REDACTED] B6 was able to collect fresh frozen myocardium from one of our presumed diet induced DCM cases and we are wondering if we should hang on to this in a -80 freezer or send you the sample for testing? This is an almost 2yr MI Yorkie mix that was diagnosed in April 2018 and was eating Castor and Pollux Organic GF Small Breed. The owners tried to change the diet to a grain based Royal canin diet but because of lack of interest he was changed to Primal (raw and grain free). He represented in September 2018 for CHF and was then changed to Fromm Adult Gold Small breed, grain-based supplemented with boiled chicken and rice. Progressive disease was noted at each exam echocardiographically with no improvement in systolic function. His whole blood taurine was [REDACTED] B6 but he was still supplemented with taurine.

Thanks for your thoughts!

Take care

Darcy

From: [REDACTED] B6
To: Jones, Jennifer L; [REDACTED] B6 ADIN,DARCY BRITTAIN
Sent: 1/31/2019 4:47:01 PM
Subject: Fwd: Safety Report ID 252600 Submission Confirmation

Hi Jennifer,

Here is the Safety Report Confirmation. Please contact me if you need any additional information.

[REDACTED] B6

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

From: <noreply.safetyreporting@hhs.gov>
Date: Thu, Jan 31, 2019 at 11:37 AM
Subject: Safety Report ID 252600 Submission Confirmation
To: [REDACTED] B6

Your initial Pet Food Safety Report, ID 252600, was successfully submitted on 1/31/2019 11:24:47 AM EST to the FDA, and it was issued an Individual Case Safety Report Number (ICSR) of 2062004.

Thank you for using the Safety Reporting Portal.

Please do not reply to this message. Replies to this message are routed to an unmonitored mailbox. If you have questions please refer to the Portal's Contact Us page for further instructions.

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6 ADIN,DARCY BRITTAIN
CC: Peloquin, Sarah
Sent: 2/1/2019 3:16:52 PM
Subject: RE: 800.267-cc-212- Safety Report ID 252600 Submission Confirmation

Thank you for submitting the report.

We will send you a box to collect the frozen heart tissue. You'll reuse the box, package the sample, use the prepaid shipping label we provide, and call UPS for the pick-up. Please return ship the box to us on a Monday through Wednesday.

***If for some reason we are furloughed again mid-February, please do not ship during the government shutdown. ***

Thank you again for your help,
Jen

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



From: [REDACTED] B6
Sent: Thursday, January 31, 2019 11:47 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> [REDACTED] B6
ADIN,DARCY BRITTAIN <adind@ufl.edu>
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Thank you for using the Safety Reporting Portal.

Please do not reply to this message. Replies to this message are routed to an unmonitored mailbox. If you have questions please refer to the Portal's Contact Us page for further instructions.

From: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-RREIMSCH>
To: Jones, Jennifer L; Nemser, Sarah
Sent: [REDACTED] 12:17:41 PM
Subject: FW: Nutritionally-mediated DCM case necropsy recommendations
Attachments: 800.267-Vet-LIRN Rapid Necropsy-DCM-v7.pdf

fyi

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

Phone 1-240-402-5404

Fax 301-210-4685

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

From: Joshua A Stern <jstern@ucdavis.edu>
Sent: [REDACTED] 10:39 PM
To: [REDACTED]
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: Nutritionally-mediated DCM case necropsy recommendations

Hi [REDACTED] - Although I wasn't on clinic I heard about [REDACTED]. This is such a sad case. For what it is worth for future cases we have seen some dogs take 9-12 months to show improvement after diet change and taurine + carnation supplementation (regardless of measured taurine levels). I'm so glad to hear the owner had a positive experience and wish this case wasn't ending this way for everyone!

The FDA can really use the help with tissue samples. Please ensure that you report the case to the FDA and if you are able to use the attached protocol to obtain samples for them they would greatly appreciate it. I believe they will pay necropsy costs and cover shipping for you. The person to contact (Renate Reimschuessel) at the FDA is CC'd on this email. Your willingness to help us get to the bottom of this horrible disease is greatly appreciated.

Best

Josh

Joshua Stern, DVM, PhD, DACVIM (Cardiology)
Associate Professor & Chief of Service: Cardiology

Interim Small Animal Clinic Director
Department of Medicine & Epidemiology

University of California Davis; CCAH Room 258
(614) 390.1516 cell (530) 752.2475 office
jstern@ucdavis.edu

Associate Editor - Journal of Veterinary Cardiology
www.journals.elsevier.com/journal-of-veterinary-cardiology

Rapid necropsy for Vet-LIRN's Case Investigation into Canine Dilated Cardiomyopathy (DCM) 2018

Prior to Necropsy:

1. Contact Vet-LIRN if you think you have a case of DCM to request authorization for payment to conduct a necropsy.
2. Submit a pet food report through the FDA Safety Reporting Portal. (<https://www.safetyreporting.hhs.gov>)
3. Refrigerate the body if the necropsy can be done in 1 day, otherwise freeze the body.

Necropsy

4. Photograph any lesions – place a tag with the dog's name in each picture.
5. Record any gross findings in detail
 - a. Describe location, number, size, color, and texture.
 - b. Photograph the heart *in situ*.
6. Sampling and **FIXING** (10% neutral buffered formalin, 10:1 NBF to tissue):
 - a. Heart – Weigh it (remove clots first) – place in NBF without cutting
 - b. Eye (#1, record OD or OS) inject with NBF, and place in NBF
 - c. Lungs – Weigh lungs, then fix the perihilar region and caudo-dorsal
 - d. Muscles – sample gastrocnemius and abdominal muscle, labelling each.
 - e. Organs sample:
 - i. Ileum
 - ii. Pancreas
 - iii. Liver
 - iv. Gall bladder
 - v. Spleen
 - vi. Kidney (1/2 of each)
 - vii. Adrenal
 - viii. Thyroid
 - f. Sample any tissues with gross lesions.
7. Sampling for **FROZEN TISSUES**
 - a. Eye (#2, record OD or OS)
 - b. Liver (4x4 cm section – state size or weight)
 - c. Skeletal muscle-gastrocnemius and abdominal muscle
 - d. Kidney (1/2 of each)
 - e. Fat (abdominal)

If available:

- f. small intestinal contents and feces (for bile acids)
- g. Whole blood and/or Plasma
- h. Urine

Sample Shipping to Vet-LIRN:

8. Vet-LIRN will send you 2 boxes – one for fixed samples, one for frozen samples.
 - a. The boxes will contain packaging instructions and a prepaid shipping label.
 - b. Vet-LIRN will need to know the final weights of both the collective frozen and fixed tissues, separately.
 - c. Call UPS to schedule box pick-up ONLY FOR Monday through Wednesday.

Reimbursement:

9. Submit an invoice (email or fax: 301-210-4685) for the necropsy charges.

Histopathology-**to be done by FDA:**

10. Vet-LIRN will send histopathology results to the veterinarian to share with the owner.

From: [redacted] B6
To: Jones, Jennifer L
Sent: [redacted] B6 4:32:34 PM
Subject: Necropsy authorization

Dear Dr. Jones,

I left a message on your number this morning but figured I would also follow up with an email. Dr. Josh Stern gave us your contact information – I reached out to both Renate and Sarah but both appear out of the office today. We have a nutrition mediated DCM case, diagnosed at UC Davis that will be euthanized [redacted] B6 [redacted] B6 is in CHF and isn't responding to treatment. She is a 3.5yr old, FS, Golden Retriever. The owner is willing to submit the body/tissues towards research on this condition. Please give me a call at your earliest convenience to discuss next steps [redacted] B6

Sincerely,

[redacted] B6

[redacted] B6

[redacted] B6

Tel [redacted] B6
Fax [redacted]

[redacted] B6



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6
CC: 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)'; Peloquin, Sarah
Sent: [REDACTED] B6 5:40:43 PM
Subject: 800.267-cc-295-RE: Necropsy authorization
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 03-Vet-LIRN-NetworkProceduresOwners-12.22.2015.pdf

Good afternoon [REDACTED] B6

Thank you for contacting us about your case. As we discussed on the phone, for me to send you a box to collect the samples, I'll need an official report. You can mention in the report, that I recommended you submit a complaint. Can you please submit a consumer complaint here?

<https://www.safetyreporting.hhs.gov/>

- Please send me the ICSR number (confirmation code) from the report.

We will send you 2 boxes with the materials to collect the fixed and frozen samples, including jars with formalin. You will reuse the boxes we send and package the samples per the instructions in the box.

- Please send me an estimate for the necropsy. After the necropsy is complete, we will call back with our VISA information to reimburse your hospital.
- After the necropsy is complete, please send me the approximate weight of the following individual groups:
 - Fixed tissues in the jars
 - Frozen tissues

We will use this information to make prepaid shipping labels for you. You'll affix the prepaid shipping label to the box and call UPS for a pick-up on Monday-Wednesday.

I attached a copy of our network procedures. They explain how Vet-LIRN operates and how veterinarians help with our case investigations. An owner friendly version is also attached.

For more information, please also visit our open access article in JAVMA that explains the FDA Animal Food Concern Reporting process. It's free and located here: <https://avmajournals.avma.org/doi/pdf/10.2460/javma.253.5.550>

Thank you again,
Jen

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



From: [REDACTED] B6
Sent: Tuesday, [REDACTED] B6 12:33 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Necropsy authorization

Dear Dr. Jones,

I left a message on your number this morning but figured I would also follow up with an email. Dr. Josh Stern gave us your contact information – I reached out to both Renate and Sarah but both appear out of the office today. We have a nutrition mediated DCM case, diagnosed at UC Davis that will be euthanized [REDACTED] B6 [REDACTED] B6 is in CHF and isn't responding to treatment. She is a 3.5yroid, FS, Golden Retriever. The owner is willing to submit the body/tissues towards research on this condition. Please give me a call at your earliest convenience

to discuss next steps

B6

Sincerely,

B6

B6

B6

Tel:

B6

Fax:

B6

 Like us on
Facebook

Find us on Yelp 



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

Network Procedures for Owners

The purpose of this Network Procedure is to help you, the owner, understand how the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) Program Office conducts case investigations (follow up to consumer complaints).

The following items are explained below:

- General Introduction
- Billing
- Step by Step Process
- Types of Services and Tests

1. General Introduction:

1.1. What is the goal of the case investigation?

The goal of the case investigation is to determine if the product is causing your pet's illness. Our case investigation **MAY NOT** provide a definitive diagnosis for your pet's illness, although we may rule out several other potential reasons for your pet's illness.

1.2. What is the focus of a case investigation?

Most case investigations focus on diagnostic samples (such as blood, urine or tissue from the pet), although we occasionally request and test pet food samples.

1.3. What is my veterinarian's role during the case investigation?

Your veterinarian helps our investigation into FDA- regulated products by providing information about your pet's medical history and by obtaining any diagnostic samples like blood, urine or tissue.

1.4. What will Vet-LIRN ask of me during a case investigation?

We may ask that your veterinarian perform certain tests or services or provide diagnostic samples to FDA or a Vet-LIRN cooperating laboratory.



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

1.5. Will Vet-LIRN pay for tests or services requested?

Yes, we will pay veterinarians or laboratories *for tests or services requested by Vet-LIRN* and approved through our government purchasing system. We cannot, however, reimburse owners for tests already performed or not specifically requested by Vet-LIRN. We recommend that you discuss with your veterinarian which tests and services will be billed to you and which will be covered by Vet-LIRN. For instance, Vet-LIRN may request that your veterinarian perform a urinalysis on your pet while he or she is hospitalized. Vet-LIRN will pay for the collection and testing of the sample, but would not cover the cost of your pet's stay in the hospital.

1.6. Is the information received in the consumer complaint confidential?

Generally, the information received in the consumer complaint is not kept confidential. In most cases, only protected personal information (such as names and addresses) is withheld in an effort to prevent the complaint from being traced back to the individual who submitted it.

2. Billing:

2.1. Will Vet-LIRN pay for bills related to the case investigation?

Vet-LIRN will cover the cost of services and testing that we specifically request. You should understand that Vet-LIRN *CANNOT* reimburse owners for any veterinary bills. Services *MUST* be pre-authorized and paid directly to the veterinarian.

2.2. Will Vet-LIRN pay for testing that was not requested by Vet-LIRN?

No, we will only pay for testing that we request and authorize.

2.3. Will Vet-LIRN pay for treatments or private cremation?

No, we cannot pay for treatment or cremation.



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

2.4. If I allow my veterinarian to submit my pet's body for testing, will I be able to have back his or her remains?

Each Vet-LIRN member laboratory has its own procedures for handling remains. Some Vet-LIRN member laboratories offer private cremation services for a fee payable directly to the laboratory. We advise you to discuss directly with the member laboratory the possibilities and costs for obtaining your pet's remains after examination are complete.

3. Step by Step Process:

Vet-LIRN will do the following during a case investigation:

- 3.1. Assign a case number which **MUST** be included in all correspondences
- 3.2. Discuss the case with you and your veterinarian
- 3.3. Request medical records from your veterinarian
- 3.4. Coordinate with your veterinarian and you to obtain and submit samples for testing
- 3.5. Provide results to your veterinarian who will discuss the results with you.

Vet-LIRN requests that:

- 3.6. Any follow-up veterinary visits related to the investigation are reported to Vet-LIRN
- 3.7. Additional laboratory reports are reported to Vet-LIRN by your veterinarian.

4. Types of Services and Tests:

4.1. What may a veterinary examination include once the case investigation is started?

A veterinary examination may include:

- an office visit and physical examination to assess your animals current health
- collection of clinical samples from your animal (blood, urine, feces).

4.2. Will your animal be tested more than once?



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

It is possible that Vet-LIRN may request additional tests or examinations depending on results from initial testing.

4.3. Will Vet-LIRN need to conduct a necropsy in the event of an animal death?

Yes, if you are willing, we may request that your veterinarian or another Vet-LIRN cooperating laboratory to conduct a necropsy to collect samples for testing. The samples collected may be tested right away or may be held for future testing or archiving. If the veterinarian completes the necropsy then the remains will be handled according to the veterinarian's normal procedures. If a Vet-LIRN cooperative laboratory completes the necropsy the remains are usually disposed of by that laboratory. Vet-LIRN cannot pay for private cremation. You are welcome to discuss normal procedures with the laboratory.

4.4. Will Vet-LIRN ask for a food sample?

Our main focus is on testing diagnostic tissue or fluid samples from the animal, but we may need to test the food. Please hold all food samples once the consumer complaint is submitted. If needed, we will make arrangements to collect the food.

4.5. What are some general tests that Vet-LIRN may request?

General tests that we may request include, but are not limited to:

- Hematology
- Microbial cultures
- Urinalysis
- Fecal examination
- Necropsy/Histology/Toxicology

4.6. Will I get results from Vet-LIRN requested tests?

Results of testing on your animal's diagnostic tissue or fluid samples will be forwarded to your veterinarian who will be asked to share the results with you.

From: Nemser, Sarah </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5FC1EB8D2F5944ECAA02F40E225C2054-SNEMSER>
To: Jones, Jennifer L
Sent: [REDACTED] 11:44:34 PM
Subject: FW: Necropsy authorization

Forwarding this one on - DCM

Sarah Nemser M.S.

Vet-LIRN Network Coordinator

tel: 240-402-0892

fax: 301-210-4685

sarah.nemser@fda.hhs.gov

From: [REDACTED] B6
Sent: [REDACTED] B6 12:01 PM
To: Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: Necropsy authorization

Hi Sarah,

I left a message on your number this morning but figured I would also follow up with an email. Dr. Josh Stern gave us your contact information. We have a nutrition mediated DCM case, diagnosed at UC Davis that will be euthanized this afternoon. [REDACTED] B6 is in CHF and isn't responding to treatment. She is a 3.5yold, FS, Golden Retriever. The owner is willing to submit the body/tissues towards research on this condition. [REDACTED] B6 is out of the office today. Please give me a call at your earliest convenience to discuss next steps [REDACTED] B6

Sincerely,

[REDACTED] B6

B6

B6



Client:

Address:

B6

All Medical Records

Patient:

B6

Breed:

English Bulldog

DOB:

B6

Species: Canine

Sex: Female
(Spayed)

Home Phone:
Work Phone:
Cell Phone:

B6

Referring Information

B6

Client:

Patient:

B6

Initial Complaint:

Emergency

SOAP Text:

B6

9:31PM -

B6

Subjective

NEW VISIT (ER)

Doctor:

B6

Student: ---

Presenting complaint: Tachypnea

Referral visit? Yes

Diagnostics completed prior to visit-- radiographs, 2 view thorax, in ER email

HISTORY:

Signalment: 8 yo SF English Bulldog

Current history:

Earlier this afternoon, found her laying and trembling with shallow and rapid breathing. Owner also noticed that she had a hacking non productive cough. Has not appreciated it before today. Went to rDVM where radiographs were performed. No history of heart or pulmonary disease. No recent vomiting or diarrhea. Has recently been doing well at home with no concerns.

Prior medical history: anxiety, otherwise healthy

Current medications: B6 2mL once daily in PM, had tonight

Diet: Core Wellness, mix of wet and dry, grain free diet

Client: **B6**
Patient:

Vaccination status/flea & tick preventative use: UTD
Travel history: unknown

EXAM: performed with flow by O2

B6

ASSESSMENT: **B6**

PLAN:
Diagnostics:

B6

Treatments: **B6**

Diagnostics completed: **B6**

Diagnostics pending:
CBC

Client:
Patient:

B6

Chemistry
BNP

Client communication:

B6

Deposit & estimate status: **B6**

Resuscitation code (if admitting to ICU): **B6**

SOAP approved (DVM to sign): **B6** DVM

SOAP Text **B6** :38AM **B6**

SIGNALMENT: 8yo FS English Bulldog

PRESENTING COMPLAINT: dyspnea

HISTORY:

Presented on **B6** after O found her laying and trembling with shallow and rapid breathing. Owner also noticed that she had a hacking non productive cough. Has not appreciated it before today. Went to rDVM where radiographs were performed. No history of heart or pulmonary disease. No recent vomiting or diarrhea. Has recently been doing well at home with no concerns.

Prior medical history: **B6**

Current medications: **B6**

Diet: Core Wellness, mix of wet and dry, grain free diet

On presentation, P was dyspneic and tachycardic. rDVM rads unable to be assessed as CHF vs. pneumonia, so placed in O2 on Unasyn overnight with bloodwork pulled for CBC/Chem and nt-proBNP. Minimal improvement overnight with persistent tachycardia, but excellent appetite and good spirits.

SUBJECTIVE:

B6

OBJECTIVE:

B6

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

RECTAL: NP

ASSESSMENT:

A1: **B6**

PLAN:

P1: **B6**
P2: **B6**
P3: **B6**
P4: **B6**
P5: **B6**
P6: **B6**
P7: **B6**

Diagnostics completed:

B6

B6

Cardio Consult: DCM, suspect early CHF - add **B6** q8

Diagnostics pending:

BNP
Troponin
Taurine

Deposit & estimate status: **B6**

Resuscitation code (if admitting to ICU): **B6**

B6, DVM (ECC Resident)

SOAP Text **B6** 7:43AM - Clinician, Unassigned FHSA

HISTORY:

B6 is an **B6** yo FS English Bulldog that presented on **B6** for sudden onset dyspnea. O found her laying and trembling with shallow and rapid breathing. Owner also noticed that she had a hacking non productive cough. Has not appreciated it before. Went to rDVM where radiographs were performed. No history of heart or pulmonary disease. No recent vomiting or diarrhea, has been doing well at home with no concerns. Was on Core Wellness dry and wet grain

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

free diet.

On presentation to ER, P was dyspneic and tachycardic. rDVM rads unable to be assessed as CHF vs. pneumonia, so placed in **B6** on **B6** overnight with bloodwork pulled for CBC/Chem and nt-proBNP. Minimal improvement overnight on **B6** with persistent tachycardia, but excellent appetite and good spirits. Cardio consult was difficult to assess due to dyspnea and conformation, but showed DCM and suspect CHF.

Overnight, P had normal vitals, with RR 24-36 with no to mild effort in O2 cage. Walked well outside of O2 cage, but at 3:45am after a walk was trembling and anxious in the cage, was given **B6** and calmed after. Excellent appetite this morning. Has received **B6** so far since **B6**

Subjective

B6

Objective

B6

H/L: No murmur ausculted although very difficult auscultation due to the constant panting. No obvious arrhythmia either. Jugular pulse bottom 1/3 of the neck. Femoral pulses strong and synchronized with heart beat. Normal BVS bilateral

B6

Diagnostics completed:

B6

B6

- Mild cardiomegaly and left atrial enlargement without evidence of decompensation. Echocardiography can be considered (to evaluate mitral valve and to evaluate for pulmonary hypertension).

B6

Cardio Consult: DCM, suspect early CHF - ad **B6** 3

Diagnostics pending:

BNP

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

Troponin
Taurine

Assessment (A)

B6

Plan (P)

B6

SOAP completed by: **B6**
SOAP reviewed by: **B6** DVM

Addendum:

B6

SOAP Text **B6** 7:28AM **B6**

HISTORY:

B6 is an **B6** FS English Bulldog that presented on **B6** for sudden onset **B6**. O found her laying and trembling with shallow and rapid breathing. Owner also noticed that she had a hacking non productive cough. Has not appreciated it before. Went to rDVM where radiographs were performed. No history of heart or pulmonary disease. No recent vomiting or diarrhea, has been doing well at home with no concerns. Was on Core Wellness dry and wet grain free diet.

On presentation to ER, P was dyspneic and tachycardic. rDVM rads unable to be assessed as CHF vs. pneumonia, so placed in O2 on **B6** overnight with bloodwork pulled for CBC/Chem and nt-proBNP. Minimal improvement overnight on **B6** with persistent tachycardia, but excellent appetite and good spirits. Cardio consult was difficult to assess due to dyspnea and conformation, but showed DCM and suspect CHF.

Since yesterday P has been out of oxygen, increased **B6** to TID, and restarted **B6**. Overnight, P had normal vitals, with RR 28-32 with no effort, but panting earlier in the night. Walks well outside, and still has excellent appetite.

Subjective

B6

Objective

B6

Client: **B6**
Patient:

B6

H/L: No murmur ausculted although very difficult auscultation due to the constant panting. No obvious arrhythmia either. Jugular pulse bottom 1/3 of the neck. Femoral pulses strong and synchronized with heart beat. Normal BVS bilateral

B6

Diagnostics completed:

B6

- Mild cardiomegaly and left atrial enlargement without evidence of decompensation. Echocardiography can be considered (to evaluate mitral valve and to evaluate for pulmonary hypertension).

B6

Cardio Consult: DCM, suspect early CHF - add pimobendan and Lasix q8

B6

Diagnostics pending:

Troponin
Taurine

Assessment (A)

A1: DCM and suspect early CHF vs less likely pneumonia

Plan (P)

B6

Client:
Patient:

B6

SOAP completed by:

B6

SOAP reviewed by:

B6 DVM

Addendum:

B6

Disposition/Recommendations

Client:
Patient:

B6

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

Cummings
Veterinary Medical Center
 AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

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

Client: **B6**
 Veterinarian:
 Patient ID: 437321
 Visit ID:

Patient:	B6
Species:	Canine
Breed:	English Bulldog
Sex:	Female (Spayed)
Age:	B6 Years Old

Lab Results Report

CBC, Comprehensive, Sm Animal **B6** 11:21:12 PM **Accession ID: B6**

Test	Results	Reference Range	Units
WBC (ADVIA)	B6	4.4 - 15.1	K/uL
RBC(ADVIA)		5.8 - 8.5	M/uL
HGB(ADVIA)		13.3 - 20.5	g/dL
HCT(ADVIA)		39 - 55	%
MCV(ADVIA)		64.5 - 77.5	fL
MCH(ADVIA)		21.3 - 25.9	pg
MCHC(ADVIA)		31.9 - 34.3	g/dL
RDW (ADVIA)		11.9 - 15.2	
PLT(ADVIA)		173 - 486	K/uL
MPV (ADVIA)		8.29 - 13.2	fL
PLTCRT		0.129 - 0.403	%
RETIC(ADVIA)		0.2 - 1.6	%
RETICS (ABS) ADVIA		14.7 - 113.7	K/uL

CBC, Comprehensive, Sm Animal 19 11:21:26 PM **Accession ID: B6**

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L



10/47

B6

Printed Monday, February 25, 2019

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

T. PROTEIN	B6	5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
iCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
ALK PHOS		12 - 127	U/L
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE	409 - 1250	U/L	
OSMOLALITY (CALCULATED)	291 - 315	mmol/L	
COMMENTS (CHEMISTRY)	0 - 0		

CBC, Comprehensive, Sm Animal **B6** 11:21:08 PM Accession ID: **B6**

Test	Results	Reference Range	Units
SEGS%	B6	43 - 86	%
LYMPHS%		7 - 47	%
MONOS%		1 - 15	%
SEGS (AB)ADVIA		2.8 - 11.5	K/uL
LYMPHS (ABS)ADVIA		1 - 4.8	K/uL
MONOS (ABS)ADVIA		0.1 - 1.5	K/uL
WBC MORPHOLOGY		0 - 0	
Occasional reactive lymphocytes			
RBC MORPHOLOGY		0 - 0	
POIKILOCYTOSIS		0 - 0	

CBC, Comprehensive, Sm Animal **B6** 11:22:25 PM Accession ID: **B6**

Test	Results	Reference Range	Units
SO2%	B6	94 - 100	%
HCT (POC)		38 - 48	%
HB (POC)		12.6 - 16	g/dL
NA (POC)		140 - 154	mmol/L
K (POC)		3.6 - 4.8	mmol/L

Client: **B6**
 Patient:

CL(POC)		109 - 120	mmol/L
CA (ionized)		1.17 - 1.38	mmol/L
MG (POC)		0.1 - 0.4	mmol/L
GLUCOSE (POC)		80 - 120	mg/dL
LACTATE		0 - 2	mmol/L
BUN (POC)		12 - 28	mg/dL
CREAT (POC)		0.2 - 2.1	mg/dL
TCO2 (POC)		0 - 0	mmol/L
nCA		0 - 0	mmol/L
nMG		0 - 0	mmol/L
GAP		0 - 0	mmol/L
CA/MG		0 - 0	mol/mol
BEecf		0 - 0	mmol/L
BEb		0 - 0	mmol/L
A		0 - 0	mmHg
NOVA SAMPLE		0 - 0	
FiO2		0 - 0	%
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
PH		7.337 - 7.467	
PCO2		36 - 44	mmHg
PO2		80 - 100	mmHg
HCO3		18 - 24	mmol/L

B6

CBC, Comprehensive, Sm Animal		B6	11:28:40 PM	Accession ID:	B6
Test	Results	Reference Range	Units		
TS (FHSA)		0 - 0	g/dl		
PCV **	B6	0 - 0	%		
TS (FHSA)		0 - 0	g/dl		

CBC, Comprehensive, Sm Animal		B6	1:43:18 PM	Accession ID:	B6
Test	Results	Reference Range	Units		
GLUCOSE		67 - 135	mg/dL		
UREA		8 - 30	mg/dL		
CREATININE		0.6 - 2	mg/dL		
PHOSPHORUS		2.6 - 7.2	mg/dL		
CALCIUM2		9.4 - 11.3	mg/dL		
T. PROTEIN		5.5 - 7.8	g/dL		
ALBUMIN		2.8 - 4	g/dL		
GLOBULINS		2.3 - 4.2	g/dL		
A/G RATIO		0.7 - 1.6			
SODIUM		140 - 150	mEq/L		

B6



Client: **B6**
Patient:

CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
ALK PHOS	B6	12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)		291 - 315	mmol/L

CBC, Comprehensive, Sm Animal **B6** 3:44:46 PM Accession ID: **B6**

Test	Results	Reference Range	Units
TS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%
TS (FHSA)		0 - 0	g/dl

CBC, Comprehensive, Sm Animal **B6** 9:46:19 AM Accession ID: **B6**

Test	Results	Reference Range	Units
GLUCOSE		67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
ALK PHOS		12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)		291 - 315	mmol/L
COMMENTS (CHEMISTRY)		0 - 0	

CBC, Comprehensive, Sm Animal **B6** 10:20:57 AM Accession ID: **B6**

Test	Results	Reference Range	Units
TS (FHSA)		0 - 0	g/dl
PCV **	B6	0 - 0	%

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

TS (FHSA) **B6** 0 - 0 g/dl

stringsolt

14/47

B6

Printed Monday, February 25, 2019

Vitals Results

6:41:14 PM	Heart Rate (/min)
6:41:15 PM	Respiratory Rate
6:41:16 PM	Temperature (F)
6:41:17 PM	Weight (kg)
11:17:43 PM	Heart Rate (/min)
11:17:51 PM	Respiratory Rate
11:22:41 PM	Notes
11:26:08 PM	FiO2 (%)
1:03:01 AM	Respiratory Rate
2:54:19 AM	Catheter Assessment
2:56:22 AM	Heart Rate (/min)
2:56:33 AM	FiO2 (%)
2:57:15 AM	Respiratory Rate
5:07:52 AM	Respiratory Rate
7:34:37 AM	Eliminations
7:35:59 AM	FiO2 (%)
7:37:34 AM	Temperature (F)
7:37:44 AM	Amount eaten
7:46:29 AM	Respiratory Rate
7:46:58 AM	Heart Rate (/min)
7:47:06 AM	Catheter Assessment
9:13:53 AM	Weight (kg)
9:14:50 AM	Respiratory Rate
11:03:18 AM	FiO2 (%)
11:03:33 AM	Catheter Assessment
11:03:43 AM	Heart Rate (/min)
11:03:52 AM	Respiratory Rate
12:50:07 PM	Lasix treatment note
1:10:13 PM	Respiratory Rate
1:10:22 PM	Eliminations
3:18:03 PM	Catheter Assessment
3:18:20 PM	FiO2 (%)
3:18:55 PM	Respiratory Rate

B6

B6

Vitals Results

3:20:08 PM	Heart Rate (/min)
4:46:44 PM	Amount eaten
5:41:52 PM	Respiratory Rate
7:04:34 PM	FiO2 (%)
7:04:58 PM	Catheter Assessment
7:06:54 PM	Heart Rate (/min)
7:07:03 PM	Temperature (F)
7:34:10 PM	Weight (kg)
7:34:17 PM	Eliminations
7:45:53 PM	Lasix treatment note
7:46:17 PM	Respiratory Rate
8:55:18 PM	Nursing note
8:55:56 PM	Eliminations
9:53:33 PM	Respiratory Rate
11:31:43 PM	Catheter Assessment
11:32:37 PM	Catheter Assessment
11:34:10 PM	Heart Rate (/min)
11:34:31 PM	Amount eaten
11:49:45 PM	FiO2 (%)
11:49:58 PM	Respiratory Rate
1:55:25 AM	Respiratory Rate
3:35:30 AM	Lasix treatment note
3:37:10 AM	Catheter Assessment
3:45:10 AM	Heart Rate (/min)
3:45:19 AM	Eliminations
3:53:42 AM	FiO2 (%)
3:53:53 AM	Respiratory Rate
4:55:04 AM	Nursing note
5:55:31 AM	Respiratory Rate
6:11:40 AM	Nursing note
7:19:26 AM	Respiratory Rate
7:19:52 AM	FiO2 (%)
7:20:14 AM	Temperature (F)
7:20:30 AM	Heart Rate (/min)
7:20:46 AM	Amount eaten
7:33:19 AM	Weight (kg)
7:33:27 AM	Eliminations
8:01:36 AM	Catheter Assessment
9:32:45 AM	Respiratory Rate

B6

B6

Client:
Patient:

B6

Vitals Results

11:16:45 AM	FiO2 (%)
12:41:34 PM	Catheter Assessment
12:41:43 PM	Respiratory Rate
12:42:33 PM	Heart Rate (/min)
12:42:50 PM	Lasix treatment note
1:52:56 PM	Heart Rate (/min)
3:03:09 PM	FiO2 (%)
3:03:22 PM	Respiratory Rate
3:40:13 PM	Respiratory Rate
3:55:45 PM	Eliminations
5:04:09 PM	Respiratory Rate
5:40:13 PM	Amount eaten
5:52:28 PM	Eliminations
5:54:07 PM	Respiratory Rate
5:54:57 PM	Heart Rate (/min)
5:55:05 PM	Catheter Assessment
6:52:18 PM	Respiratory Rate
7:17:27 PM	Eliminations
7:45:11 PM	Respiratory Rate
8:01:23 PM	Lasix treatment note
8:17:14 PM	Eliminations
8:54:56 PM	Respiratory Rate
9:32:19 PM	Heart Rate (/min)
9:32:26 PM	Catheter Assessment
9:32:35 PM	Eliminations
9:43:25 PM	Respiratory Rate
10:41:18 PM	Respiratory Rate
11:18:27 PM	Eliminations
11:18:49 PM	Weight (kg)
11:42:42 PM	Eliminations
11:53:16 PM	Respiratory Rate
12:52:00 AM	Respiratory Rate
1:22:40 AM	Heart Rate (/min)
1:22:46 AM	Catheter Assessment
1:45:25 AM	Respiratory Rate
2:53:51 AM	Respiratory Rate
3:34:16 AM	Lasix treatment note
3:34:45 AM	Respiratory Rate
3:43:47 AM	Eliminations
4:50:44 AM	Respiratory Rate
4:52:32 AM	Nursing note

B6

B6

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

Vitals Results

B6	5:25:32 AM	Catheter Assessment	B6
	5:27:43 AM	Heart Rate (/min)	
	5:27:50 AM	Respiratory Rate	
	5:28:01 AM	Amount eaten	
	6:42:00 AM	Respiratory Rate	
	7:25:45 AM	Respiratory Rate	
	7:26:00 AM	Weight (kg)	
	7:26:12 AM	Eliminations	
	8:56:03 AM	Respiratory Rate	
	9:47:19 AM	Respiratory Rate	
	9:50:04 AM	Catheter Assessment	
	9:50:22 AM	Heart Rate (/min)	
	11:05:09 AM	Respiratory Rate	
	12:00:28 PM	Respiratory Rate	
	12:00:44 PM	Eliminations	
	12:05:36 PM	Lasix treatment note	
	12:55:52 PM	Respiratory Rate	
	1:55:49 PM	Respiratory Rate	
	3:12:43 PM	Respiratory Rate	
	3:17:41 PM	Eliminations	
4:02:34 PM	Respiratory Rate		

Patient History

B6	06:41 PM	Vitals	B6
	06:41 PM	Vitals	
	06:41 PM	Vitals	
	06:41 PM	Vitals	
	07:50 PM	UserForm	
	09:52 PM	UserForm	
	11:17 PM	Treatment	
	11:17 PM	Vitals	
	11:17 PM	Treatment	
	11:17 PM	Vitals	
	11:19 PM	Treatment	
	11:21 PM	Purchase	
	11:21 PM	Purchase	
	11:21 PM	Purchase	
	11:21 PM	Purchase	
	11:21 PM	Purchase	
	11:21 PM	Purchase	
	11:22 PM	Purchase	
	11:22 PM	Purchase	
	11:22 PM	Vitals	

Client:
Patient:

B6

Patient History

11:22 PM	Purchase
11:22 PM	Purchase
11:25 PM	Treatment
11:26 PM	Treatment
11:26 PM	Vitals
11:26 PM	Treatment
11:28 PM	Labwork
12:50 AM	Treatment
12:53 AM	Treatment
01:03 AM	Treatment
01:03 AM	Vitals
02:54 AM	Treatment
02:54 AM	Treatment
02:54 AM	Vitals
02:56 AM	Treatment
02:56 AM	Vitals
02:56 AM	Treatment
02:56 AM	Vitals
02:57 AM	Treatment
02:57 AM	Vitals
05:07 AM	Treatment
05:07 AM	Vitals
07:34 AM	Treatment
07:34 AM	Treatment
07:34 AM	Vitals
07:35 AM	Treatment
07:35 AM	Vitals
07:37 AM	Treatment
07:37 AM	Vitals
07:37 AM	Treatment
07:37 AM	Vitals
07:46 AM	Treatment
07:46 AM	Vitals
07:46 AM	Treatment
07:46 AM	Vitals
07:47 AM	Treatment
07:47 AM	Vitals
08:13 AM	UserForm
08:19 AM	Purchase
08:32 AM	UserForm
08:39 AM	Treatment

B6

B6

Client:
Patient:

B6

Patient History

08:45 AM	Prescription
08:48 AM	Prescription
09:13 AM	Treatment
09:13 AM	Vitals
09:14 AM	Treatment
09:14 AM	Vitals
09:34 AM	Purchase
09:35 AM	Treatment
11:03 AM	Treatment
11:03 AM	Vitals
11:03 AM	Treatment
11:03 AM	Treatment
11:03 AM	Vitals
11:03 AM	Treatment
11:03 AM	Vitals
11:03 AM	Treatment
11:03 AM	Vitals
11:03 AM	Treatment
11:03 AM	Vitals
11:05 AM	Purchase
11:39 AM	Treatment
11:41 AM	Treatment
12:50 PM	Vitals
12:52 PM	Treatment
12:54 PM	Prescription
01:01 PM	Deleted Reason
01:10 PM	Treatment
01:10 PM	Vitals
01:10 PM	Treatment
01:10 PM	Vitals
01:10 PM	Treatment
03:14 PM	Treatment
03:17 PM	Treatment
03:18 PM	Treatment
03:18 PM	Vitals
03:18 PM	Treatment
03:18 PM	Vitals
03:18 PM	Treatment
03:18 PM	Vitals
03:20 PM	Treatment
03:20 PM	Vitals
04:14 PM	UserForm
04:46 PM	Treatment

B6

B6

Client:
Patient:

B6

Patient History

04:46 PM	Vitals
05:14 PM	Deleted Reason
05:14 PM	Deleted Reason
05:15 PM	Purchase
05:15 PM	Purchase
05:41 PM	Treatment
05:41 PM	Vitals
07:04 PM	Treatment
07:04 PM	Vitals
07:04 PM	Treatment
07:04 PM	Treatment
07:04 PM	Vitals
07:06 PM	Treatment
07:06 PM	Vitals
07:07 PM	Treatment
07:07 PM	Vitals
07:34 PM	Treatment
07:34 PM	Vitals
07:34 PM	Treatment
07:34 PM	Vitals
07:45 PM	Vitals
07:46 PM	Treatment
07:46 PM	Treatment
07:46 PM	Vitals
08:31 PM	Treatment
08:55 PM	Vitals
08:55 PM	Vitals
09:53 PM	Treatment
09:53 PM	Vitals
11:07 PM	Purchase
11:07 PM	Purchase
11:21 PM	Treatment
11:31 PM	Treatment
11:31 PM	Vitals
11:32 PM	Treatment
11:32 PM	Vitals
11:34 PM	Treatment
11:34 PM	Treatment
11:34 PM	Vitals
11:34 PM	Treatment
11:34 PM	Vitals
11:49 PM	Treatment
11:49 PM	Treatment

B6

B6

Client:
Patient:

B6

Patient History

11:49 PM	Vitals
11:49 PM	Treatment
11:49 PM	Vitals
01:55 AM	Treatment
01:55 AM	Vitals
03:05 AM	Treatment
03:35 AM	Vitals
03:37 AM	Treatment
03:37 AM	Treatment
03:37 AM	Vitals
03:45 AM	Treatment
03:45 AM	Vitals
03:45 AM	Treatment
03:45 AM	Vitals
03:45 AM	Vitals
03:45 AM	Vitals
03:53 AM	Treatment
03:53 AM	Vitals
03:53 AM	Treatment
03:53 AM	Vitals
04:50 AM	Treatment
04:55 AM	Treatment
04:55 AM	Vitals
05:55 AM	Treatment
05:55 AM	Vitals
06:03 AM	Treatment
06:11 AM	Vitals
07:19 AM	Treatment
07:19 AM	Vitals
07:19 AM	Treatment
07:19 AM	Vitals
07:20 AM	Treatment
07:20 AM	Treatment
07:20 AM	Vitals
07:20 AM	Treatment
07:20 AM	Vitals
07:20 AM	Treatment
07:20 AM	Vitals
07:33 AM	Treatment
07:33 AM	Vitals
07:33 AM	Treatment
07:33 AM	Vitals
08:01 AM	Treatment
08:01 AM	Vitals
08:01 AM	Treatment

B6

B6

Client: **B6**
Patient:

Patient History

08:46 AM	Purchase
09:32 AM	Treatment
09:32 AM	Vitals
09:46 AM	Purchase
10:50 AM	Purchase
10:51 AM	Treatment
11:05 AM	Purchase
11:16 AM	Treatment
11:16 AM	Vitals
12:41 PM	Treatment
12:41 PM	Vitals
12:41 PM	Treatment
12:41 PM	Vitals
12:42 PM	Treatment
12:42 PM	Vitals
12:42 PM	Vitals
12:43 PM	Treatment
12:46 PM	Treatment
01:43 PM	Purchase
01:52 PM	Treatment
01:52 PM	Vitals
03:03 PM	Treatment
03:03 PM	Vitals
03:03 PM	Treatment
03:03 PM	Vitals
03:40 PM	Vitals
03:46 PM	Labwork
03:50 PM	Treatment
03:53 PM	Prescription
03:55 PM	Treatment
03:55 PM	Vitals
05:04 PM	Treatment
05:04 PM	Vitals
05:09 PM	Treatment
05:09 PM	Treatment
05:40 PM	Treatment
05:40 PM	Vitals
05:52 PM	Vitals
05:54 PM	Treatment
05:54 PM	Vitals
05:54 PM	Treatment
05:54 PM	Vitals
05:55 PM	Treatment
05:55 PM	Vitals
06:48 PM	Prescription

B6

B6

Client: **B6**
Patient:

Patient History

B6	06:52 PM	Treatment	B6
	06:52 PM	Vitals	
	06:52 PM	Treatment	
	07:17 PM	Vitals	
	07:27 PM	Treatment	
	07:45 PM	Treatment	
	07:45 PM	Vitals	
	08:01 PM	Vitals	
	08:01 PM	Treatment	
	08:17 PM	Vitals	
	08:27 PM	Treatment	
	08:54 PM	Treatment	
	08:54 PM	Vitals	
	09:13 PM	Treatment	
	09:32 PM	Treatment	
	09:32 PM	Vitals	
	09:32 PM	Treatment	
	09:32 PM	Vitals	
	09:32 PM	Vitals	
	09:43 PM	Treatment	
	09:43 PM	Vitals	
	10:41 PM	Treatment	
	10:41 PM	Vitals	
	11:07 PM	Purchase	
	11:07 PM	Purchase	
	11:18 PM	Treatment	
	11:18 PM	Vitals	
	11:18 PM	Vitals	
	11:42 PM	Vitals	
	11:53 PM	Treatment	
	11:53 PM	Vitals	
	12:52 AM	Treatment	
	12:52 AM	Vitals	
	01:21 AM	Treatment	
	01:22 AM	Treatment	
	01:22 AM	Vitals	
	01:22 AM	Treatment	
	01:22 AM	Vitals	
	01:45 AM	Treatment	
	01:45 AM	Vitals	
02:53 AM	Treatment		
02:53 AM	Vitals		
03:34 AM	Vitals		
03:34 AM	Treatment		
03:34 AM	Treatment		
03:34 AM	Vitals		
03:34 AM	Treatment		

Client:
Patient:

B6

Patient History

03:35 AM	Treatment
03:43 AM	Treatment
03:43 AM	Vitals
04:50 AM	Treatment
04:50 AM	Vitals
04:52 AM	Vitals
05:25 AM	Treatment
05:25 AM	Vitals
05:25 AM	Treatment
05:27 AM	Treatment
05:27 AM	Vitals
05:27 AM	Treatment
05:27 AM	Vitals
05:28 AM	Treatment
05:28 AM	Vitals
06:41 AM	Treatment
06:42 AM	Vitals
07:25 AM	Treatment
07:25 AM	Vitals
07:26 AM	Treatment
07:26 AM	Vitals
07:26 AM	Treatment
07:26 AM	Vitals
07:26 AM	Vitals
08:56 AM	Treatment
08:56 AM	Vitals
09:31 AM	UserForm
09:39 AM	Purchase
09:47 AM	Treatment
09:47 AM	Vitals
09:50 AM	Treatment
09:50 AM	Vitals
09:50 AM	Treatment
09:50 AM	Vitals
09:50 AM	Treatment
10:21 AM	Labwork
11:05 AM	Purchase
11:05 AM	Treatment
11:05 AM	Vitals
11:25 AM	Treatment
11:25 AM	Treatment
11:48 AM	Purchase
11:48 AM	Treatment
12:00 PM	Treatment
12:00 PM	Vitals

B6

B6

Client:
Patient:

B6

Patient History

B6

12:00 PM	Treatment
12:00 PM	Vitals
12:05 PM	Vitals
12:05 PM	Treatment
12:55 PM	Treatment
12:55 PM	Vitals
01:01 PM	Treatment
01:55 PM	Treatment
01:55 PM	Vitals
03:12 PM	Treatment
03:12 PM	Vitals
03:17 PM	Treatment
03:17 PM	Treatment
03:17 PM	Vitals
03:55 PM	Prescription
03:56 PM	Prescription
04:02 PM	Treatment
04:02 PM	Vitals
04:02 PM	Prescription
04:03 PM	Prescription
04:20 PM	Purchase
12:52 PM	Appointment

B6

B6

B6

Female (Spayed)

Canine English Bulldog Brown/White

Patient ID:437321

STANDARD CONSENT FORM

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

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

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

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

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

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

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

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

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

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

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

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

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

Owner's name:

Date:

Owner's address:

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

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

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

Treatment Plan

Estimated Charges

B6

B6

This estimate is based upon our preliminary examination. This is an estimate and is not the final bill. Every effort will be made to keep you informed of the current status of your bill throughout your animal's hospitalization. The final fee may vary considerably from this estimated cost.

Patient	Description	Low Qty	Low Extended	High Qty	High Extended
B6		B6			

B6

Doctor of Record: **B6**

I understand that no guarantee of successful treatment is made. I certify that I have read and fully understand the authorization for medical and/or surgical treatment, the reason for why such medical and/or surgical treatment is considered necessary, as well as its advantages and possible complications, if any. I also assume financial responsibility for all charges incurred to this patient(s). I agree to pay 75% of the estimated cost at the time of admission. Additional deposits will be required if additional care or procedures are required. I further agree to pay the balance of the charges when this patient(s) is released.

Procedural billing is inclusive up to and including the estimated duration of hospitalization. There will be additional expenses if hospitalization extends beyond the specified duration.

I have read, understand, and agree to accept the conditions of this treatment plan.

Thank you for entrusting us with your pet's care.

High Total	B6
Low Total	
75% Deposit	

Radiology Request & Report

Patient

Name: B6
Species: Canine
Brown/White Female (Spayed)
English Bulldog
Birthdate: B6

Owner

Name: B6
Address: B6
01373

Patient ID: 437321
Date of request: B6

Attending Clinician: B6 DVM (Emergency & Critical Care Resident)

Student:

Date of exam: B6

Patient Location: Ward/Cage: ICU 02

Weight (kg) 19.80

- Inpatient
- Outpatient Time:
- Waiting
- Emergency

Sedation

- BAG
- OBAG
- 1/2 dose OBAG
- Butorphanol
- Anesthesia to sedate/anesthetize

Examination Desired: 3-view thorax (prioritize VD/DV and L lat)

Presenting Complaint and Clinical Questions you wish to answer:
Emergency

Pertinent History:

B6

Findings:

THORAX, THREE VIEWS:

B6

Conclusions:

- Diffuse bronchial and interstitial pulmonary pattern may indicate concurrent chronic lower airway disease (allergic, infectious, or parasitic) and interstitial lung disease. Airway sampling can be considered.
- Mild cardiomegaly and left atrial enlargement without evidence of decompensation. Echocardiography can be considered (to evaluate mitral valve and to evaluate for pulmonary hypertension).
- Multifocal intervertebral disk disease and breed-associated vertebral anomalies.
- Moderate bilateral elbow and right stifle degenerative joint disease.

Radiologists

Primary: DVM

Reviewing:

Dates

Reported:

Finalized:

Discharge Instructions

Patient

Name: B6
Species: Canine
Brown/White Female (Spayed) English
Bulldog
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: 437321

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student:

B6

Admit Date: B6 7:49:24 PM

Discharge Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with congestive heart failure

Diagnostic test results and findings:

- o
 - o
 - o
 - o
- B6

Case summary:

Thank you for bringing B6 to Tufts for evaluation of her heart disease. B6 originally presented to the Tufts ER of B6 for sudden onset of respiratory distress and a cough. B6 was stabilized with supplemental oxygen in the ICU and was given antibiotics and mild sedatives to keep her comfortable. X-rays of B6 chest showed a diffuse increased opacity in her lungs that was suspected to be fluid secondary to heart disease, but pneumonia could not be ruled out. A cardiology workup showed that B6 had enlargement of her heart chambers, and a blood test showed that one of the indicators of heart stretch was elevated, thus supporting the presence of 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. 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 her breathing easier.

B6 has been breathing well outside of the oxygen cage, and her recheck examinations, echocardiograms, and chest x-rays have been stable. At this time we are happy with her condition, and are comfortable to send her home.

Monitoring at home:

- o 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.
- o 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.
- o An increase in breathing rate or effort will usually mean that you should give an extra **B6** if difficulty breathing is not improved by within 30-60 minutes after giving extra **B6**; then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- o There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- o We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- o If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

B6

Diet suggestions:

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 her to continue to eat her normal diet for the first 7 to 14 days so we can make sure she 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.

The FDA is currently investigating an apparent association between diet and DCM. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.

We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.

The FDA issued a statement regarding this issue

(<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm>) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>).

Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:

Royal Canin Early Cardiac (veterinary diet)
Royal Canin Bower
Purina Pro Plan Adult Weight Management
Purina Pro Plan Bright Mind Adult Small Breed Formula

Canned Food Options:

Hill's Science Diet Adult Beef and Barley Entree
Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 8+

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

Exercise Recommendations:

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, 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 B6 care, she is such a spirited girl! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Sincerely,

Dr.

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/cvms/clinicaltrials

Case:

Owner:

Discharge Instructions

Radiology Request & Report

Patient

Name: B6
Species: Canine
Brown/White Female (Spayed)
English Bulldog
Birthdate: B6

Owner

Name: B6
Address: B6
01373

Patient ID: 437321
Date of request: B6

Attending Clinician: B6 OVM (Resident, Cardiology) Student: B6

Date of exam: B6

Patient Location: Ward/Cage: Cardio, ICU Weight (kg) 19.60

Sedation

- Inpatient
- Outpatient Time:
- Waiting
- Emergency
- BAG
- OBAG
- 1/2 dose OBAG
- DexDomitor/Butorphanol
- Anesthesia to sedate/anesthetize

Examination Desired: 2 view CXR- DV and R lateral
TECHS TO HANDLE ONLY- be careful due to dyspnea, do not stress further if dyspneic

Presenting Complaint and Clinical Questions you wish to answer:
Recheck rads for CHF before discharge

Pertinent History:
DCM, suspected CHF on rads B6

Findings:

B6

B6

Conclusions:

- Improving interstitial pulmonary pattern is consistent with response to medical management.
- Unchanged mild cardiomegaly and similar to mildly improved left atrial enlargement.
- Unchanged multifocal intervertebral disk disease and breed-associated vertebral anomalies.
- Unchanged moderate bilateral elbow degenerative joint disease.

Referrals:

Primary: VMD

Reviewing:

Dates

Reported:

Finalized:

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: 437321

B6

Canine

B6 Years Old Female (Spayed) English
Bulldog

Brown/White BW: Weight (kg) 19.80

Cardiology Inpatient ENROLLED IN DCM STUDY

Date: B6

Weight: Weight (kg) 19.80

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?

- Yes - in SS
- Yes - in PACS
- No

Patient location:

ICU O2 5/6

Presenting complaint and important concurrent diseases:

Presenting for new onset dyspnea, radiographs unintelligible between pneumonia and CHF. Persistent sinus tachycardia overnight

Current medications and doses:

B6

At-home diet: (name, form, amount, frequency)

Core Wellness grain-free wet + dry

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.)

dyspnea, contiguous B-lines

Questions to be answered:

fluid vs. lasix

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: Very hard to listen due to the marked dyspnea and referred upper airway.

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

Murmur location/description:

Jugular vein:

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

Arterial pulses: n/a

- 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: n/a

- Normal
- Hepatomegaly

- Abdominal distension
- Mild ascites

Echocardiogram Findings:

B6

Addendum exam:

B6

Mitral inflow:

- Summated
- Normal
- Delayed relaxation

- Pseudonormal
- Restrictive

Radiographic findings:

B6

Assessment and recommendations:

Despite the poor quality of the echocardiogram pictures obtained today, we suspect the patient to have DCM with moderate to marked LA enlargement. The radiographs are very hard to interpret, typical for bulldog radiographs, but we suspect CHF to be one of the main differential despite the atypical pattern visualized. Treatment for HF should be initiated and improvement of the clinical condition would be a vote in favor for CHF. Antibiotic treatment should be continued since pneumonia cannot be completely rule out. B6 was given during the echocardiogram and B6

B6 The patient was enrolled in Dr. Freeman's study due to its current grain free diet and blood was pulled today for the study. The patient, once more stable, B6 An NT-proBNP was pulled and will be very interesting in order to better assess the cardiovascular status of the patient since there is still some suspicions that the changes seen on radiographs are not all secondary to CHF. B6

B6

B6

An improvement of the interstitial pattern would confirm the suspected diagnosis of CHF versus no changes of the interstitial pattern would be more in favor of another disease process. A recheck echocardiogram should be repeated as well tomorrow once the patient is more stable in order to confirm today's findings. Bloodwork should be repeated tomorrow as well as 10-14 days after the start of the cardiac medications. Full recheck echocardiogram is recommended in 3 months or sooner if the patient develops clinical signs consistent with worsening heart disease.

Addendum:

B6

Final Diagnosis:

- Suspected DCM with moderate to marked LA enlargement and suspected CHF

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM CHF Classification:

- A
- B1
- B2
- C
- D

M-Mode

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

EDV(Teich)

ESV(Teich)

EF(Teich)

%FS

SV(Teich)

M-Mode Normalized

IVSdN

LVIDdN

LVPWdN

IVSsN

LVIDsN

LVPWsN

2D

SA LA

B6

cm
cm
cm
cm
cm
cm
ml
ml
%
%
ml

{0.290 - 0.520}
{1.350 - 1.730}!
{0.330 - 0.530}
{0.430 - 0.710}
{0.790 - 1.140}!
{0.530 - 0.780}

cm

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

B6

cm
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cm

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
Telephone: (508) 839-5395
Fax: (508) 839-7951
<http://vetmed.tufts.edu/>
Referring Vet Direct Line: 508-887-4988

Notice of Patient Admit

Date: B6 7:49:24 PM

Case #: 437321

Referring Doctor: B6

Client Name: B6

Patient Name: 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: Dyspnea (pneumonia > CHF)

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

Thank you for your referral to our Emergency Service.

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

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

B6

B6 Female (Spayed)
Canine English Bulldog
Brown/White
437321

Daily Update From the Cardiology Service

Today's date: **B6**

Dear Drs at **B6**

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
- discharged from the hospital today

Today's treatments include:

- bloodwork planned/pending
- echocardiography - DCM and L-CHF
- 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) 887-4096 before 5pm or email us at ~~card@tufts.edu~~ if you have any questions.
Thank you!

Attending Clinician: **B6** DVM (Resident, Cardiology)

Faculty Clinician: John Rush DVM, DACVIM, DACVECC

Senior student:

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

B6

B6

Female (Spayed)

Canine: English Bulldog

Brown/White

437321

1/21/2019

Dear Dr. **B6**

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

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

Thank you,

Dr. **B6** VM (Resident, Cardiology)

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 3/1/2019 9:50:52 PM
Subject: FW: taurine results for [REDACTED]
Attachments: Stern Lab Taurine Recommendations.pdf; T_27754.pdf; UCD Diet and DCM Handout.pdf

FYI

[REDACTED] 3 bulldogs from same household and on same diet
[REDACTED] DCM and CHF had [REDACTED] plasma and [REDACTED] WB
[REDACTED] – with ARVC and arrhythmias had [REDACTED] and [REDACTED]
[REDACTED] this most recent one (likely ARVC) was [REDACTED] and [REDACTED]

Lisa

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Board Certified Veterinary Nutritionist™
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Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

CARDIOLOGY SERVICE UPDATES: DOG FOOD & DILATED CARDIOMYOPATHY

The Cardiology Service has developed this document in response to the alerts from the FDA. These alerts identify an associated risk for some grain-free diets containing certain ingredients (legumes like peas, pea components, lentils; white potatoes, sweet potatoes) and a diagnosis of dilated cardiomyopathy (DCM). The links provided throughout this document can be copied and pasted to obtain additional information.

FDA Alerts found here:

<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm>

<https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm616279.htm>

What is Dilated Cardiomyopathy (DCM)?

DCM is a heart muscle disorder that results in a weak pump function and heart chamber enlargement. In the early stages of this disease pets may appear totally healthy with no apparent clinical signs. Later in the course of this disease, dogs may have a heart murmur, an arrhythmia (irregular heart beat), collapse episodes, weakness or tiredness with exercise, and even trouble breathing from congestive heart failure. While there are some breeds of dogs (like Dobermans) that have a genetic predisposition to development of DCM, there are also nutritional factors that may result in this disease.

What should I do?

If you are feeding a diet of concern based upon the FDA alert we recommend that you consult with your veterinarian or veterinary cardiologist. We provide 4 general points for guidance below:

1. An initial step is to **consider whether you are willing or interested in performing additional testing** to assess whether your pet is affected with DCM. If you believe your dog is at risk, showing any of the aforementioned clinical signs or would prefer to simply rule out any heart disease, we recommend that you first have your pet's taurine levels tested (both whole blood and plasma levels) as well as seek an echocardiogram by a board-certified veterinary cardiologist. Low taurine levels are associated with development of DCM in dogs and are sometimes a component of this current issue.

Information on taurine testing can be found here: <https://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory>

2. At this time, **diet change is recommended when possible** and should be considered regardless of the results obtained from any testing. You can consult with your veterinarian in selecting a new diet that avoids the ingredients of concern listed by the FDA. When selecting this diet, we recommend that you choose a diet that is manufactured with rigorous quality control measures and research behind the formulation. A way to ensure that your diet meets these recommendations is to follow the following guidelines that were generated by a large number of the world's leading experts in veterinary nutrition.

Food selection guidelines found here:

<https://www.wsava.org/WSAVA/media/Arpita-and-Emma-editorial/Selecting-the-Best-Food-for-your-Pet.pdf>

3. If your pet is identified through testing to have a low blood taurine level or evidence of DCM by echocardiogram, we urge you to **report this information to the FDA**.

FDA reporting guidelines found here: <https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

4. **Work with your veterinarian(s)** to determine the best course of action and medical treatments if indicated. In the case of a DCM diagnosis, diet change alone may not be sufficient and additional medications may be prescribed.

Please continue to monitor the FDA website and the UC Davis School of Veterinary Medicine Newsfeeds for updates and recommendations regarding this issue.

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: [REDACTED] 3:29:55 PM
Subject: [REDACTED] - time sensitive
Importance: High

Hi Jen
I also left you a voice message but I just heard that [REDACTED] died suddenly [REDACTED]. This is one of at least 3 dogs in the household affected by DCM eating the same diet. We're actually scheduled to see the 3 dogs tomorrow and to evaluate a 4th dog in the household that has an elevated BNP. So, this is a particularly interesting household.

The referring vet contacted me and said the owner is bringing [REDACTED] in for cremation. He will ask if he can get samples for you but we'd need to know what tissues to get, how to store them, etc.

Please let me know next steps
Thanks
Lisa

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Tufts University
www.petfoodology.org
508-887-4523

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Tuesday, March 26, 2019 1:50 PM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Subject: RE: Cobalt

Hi Lisa,
We based this on the 25 mg/kg diet for chicks, rats, and sheep per Mineral Tolerances of Animals 2nd Ed, 2005 (NRC). The cobalt in the products we tested was below 1 ppm.
Hope you're well,
Jen

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Saturday, March 23, 2019 11:43 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Cobalt

Hi Jen,
In the Feb, 2019 Vet-LIRN report, it states that cobalt was tested in the diets and was within normal nutrient

ranges recommended by AAFCO. Since Co is not an essential nutrient listed in the AAFCO profiles, are you using the max of 10 ppm that is for all species from AAFCO (ie, the level that "will not impair animal performance and should not produce unsafe residues in human food derived from that animal"?)

Thanks,
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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L
CC: Peloquin, Sarah
Sent: [REDACTED] **B6** 6:51:07 PM
Subject: RE: [REDACTED] **B6** - time sensitive

Jen,

I guess from my point of view, having an additional case would be helpful as I think some of the cases that I looked at will fall out of the counting.

I agree it's a predisposed breed, so perhaps it may make a good comparison (though I suspect we won't see a huge difference).

I will go the way of the consensus (three on the email 😊)

Dave

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



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

From: Jones, Jennifer L
Sent: [REDACTED] **B6** 2:43 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: FW: [REDACTED] **B6** - time sensitive
Importance: High

Dave,
I know we're chatting Thursday about the results and next steps. [REDACTED] **B5** I'm leaning

[REDACTED] **B5**
You're looking at the histo, though, what do you think?

Jen

Jennifer Jones, DVM
Veterinary Medical Officer

Tel: 240-402-5421



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: [REDACTED] 2:30 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: [REDACTED] - time sensitive
Importance: High

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From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Freeman, Lisa
CC: Peloquin, Sarah
Sent: [REDACTED] 11:05:51 AM
Subject: RE: [REDACTED] time sensitive (cc-297)

Thank you, Lisa. I see Jake sent you the necropsy procedures. Yes, we can work on a prioritized list for veterinarians collecting limited tissue sets. We can also have veterinarians freeze the bodies until we send them supplies (esp. if large intact hearts).

Please have [REDACTED] veterinarian contact me directly to coordinate the sample collection and reimbursement. I'll be at my desk until 3 pm.

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: [REDACTED] 2:30 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: [REDACTED] - time sensitive
Importance: High

Hi Jen
I also left you a voice message but I just heard that [REDACTED] died suddenly. [REDACTED] This is one of at least 3 dogs in the household affected by DCM eating the same diet. We're actually scheduled to see the 3 dogs tomorrow and to evaluate a 4th dog in the household that has an elevated BNP. So, this is a particularly interesting household.

The referring vet contacted me and said the owner is bringing [REDACTED] in for cremation. He will ask if he can get samples for you but we'd need to know what tissues to get, how to store them, etc.

Please let me know next steps
Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
Professor
Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org
508-887-4523

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Tuesday, March 26, 2019 1:50 PM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>

Subject: RE: Cobalt

Hi Lisa,

We based this on the 25 mg/kg diet for chicks, rats, and sheep per Mineral Tolerances of Animals 2nd Ed, 2005 (NRC). The cobalt in the products we tested was below 1 ppm.

Hope you're well,

Jen

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Saturday, March 23, 2019 11:43 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Cobalt

Hi Jen,

In the Feb, 2019 Vet-LIRN report, it states that cobalt was tested in the diets and was within normal nutrient ranges recommended by AAFCO. Since Co is not an essential nutrient listed in the AAFCO profiles, are you using the max of 10 ppm that is for all species from AAFCO (ie, the level that "will not impair animal performance and should not produce unsafe residues in human food derived from that animal"?)

Thanks,
Lisa

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Tufts University
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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Peloquin, Sarah
Sent: [REDACTED] 6:32:46 PM
Subject: FW: [REDACTED] - time sensitive
Importance: High

Hi Sarah

Got a message that Jen is out today so wanted to see how we can get samples assuming owner gives permission

Thanks

Lisa

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Tufts Clinical and Translational Science Institute
Tufts University
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From: Freeman, Lisa
Sent: [REDACTED] 2:30 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: [REDACTED] - time sensitive
Importance: High

Hi Jen

I also left you a voice message but I just heard that [REDACTED] died suddenly [REDACTED]. This is one of at least 3 dogs in the household affected by DCM eating the same diet. We're actually scheduled to see the 3 dogs tomorrow and to evaluate a 4th dog in the household that has an elevated BNP. So, this is a particularly interesting household.

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Thanks

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To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Subject: RE: Cobalt

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

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www.petfoodology.org

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
CC: Peloquin, Sarah
Sent: [REDACTED] 11:13:21 AM
Subject: RE: [REDACTED] - time sensitive (cc-297)

Thanks, Jen

I think that would be helpful. These obviously happen with no warning so that would be great to have ready to tell vets. Including the option of freezing on that same sheet would be great. These owners wanted to get the body back for cremation so this seemed like the best option.

I heard last night that the owners gave permission for sample collection and [REDACTED] was going to take the heart and some liver

If you could send him a box for shipping, that would be great

B6

B6

We'll be seeing the other 3 dogs in the household today
Thanks
Lisa

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Tufts Clinical and Translational Science Institute
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From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: [REDACTED] 7:06 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: [REDACTED] - time sensitive (cc-297)

Thank you, Lisa. I see Jake sent you the necropsy procedures. Yes, we can work on a prioritized list for veterinarians collecting limited tissue sets. We can also have veterinarians freeze the bodies until we send them supplies (esp. if large intact hearts).

Please have [REDACTED] veterinarian contact me directly to coordinate the sample collection and reimbursement.

I'll be at my desk until 3 pm.

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: [REDACTED] 2:30 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: [REDACTED] - time sensitive
Importance: High

Hi Jen

I also left you a voice message but I just heard that [REDACTED] died suddenly, [REDACTED]. This is one of at least 3 dogs in the household affected by DCM eating the same diet. We're actually scheduled to see the 3 dogs tomorrow and to evaluate a 4th dog in the household that has an elevated BNP. So, this is a particularly interesting household.

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Jen

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



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Report Details - EON-372828

ICSR: 2059621
 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 17:59:30 EST

Reported Problem:
Problem Description: Eating BEG diet (Earthborn) Echo had subjectively reduced contractility, elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months
Date Problem Started: 11/20/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Earthborn Meadow Feast dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** See diet history in records for more details
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Boxer (German Boxer)
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Not pregnant
Lactation Status: Not lactating
Weight: 30.3 Kilogram
Age: 3 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 5
Number of Animals Reacted: 4
Owner Information: Owner Yes
Contact Information provided:
Contact: Name: B6
 Phone: B6
 Email: B6
Address: B6
 United States
Healthcare Professional Information: **Practice Name:** Tufts Cummings School of Veterinary Medicine
Contact: Name: Lisa Freeman

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

Report Details - EON-372834			
ICSR:	2059624		
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 18:12:06 EST		
Reported Problem:	Problem Description: Littermate diagnosed with reduced cardiac contractility Eating BEG diet (Earthborn) so screened all housemates Subjectively reduced contractility on echo and elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months		
	Date Problem Started: 11/20/2018		
	Concurrent Medical Problem: No		
	Outcome to Date: Stable		
Product Information:	Product Name: Earthborn Meadow Feast dry		
	Product Type: Pet Food		
	Lot Number:		
	Package Type: BAG		
	Product Use Information: Description: See diet history in medical record for more info		
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name: B6		
	Type Of Species: Dog		
	Type Of Breed: Boxer (German Boxer)		
	Gender: Male		
	Reproductive Status: Neutered		
	Weight: 30.3 Kilogram		
	Age: 3 Years		
	Assessment of Prior Health: Excellent		
	Number of Animals Given the Product: 5		
	Number of Animals Reacted: 4		
	Owner Information:	Owner Information provided: Yes	
		Contact:	Name: B6
			Phone: B6
			Email: B6
		Address: B6 United States	
Healthcare Professional Information:	Practice Name: Tufts Cummings School of Veterinary Medicine		
	Contact:	Name: Lisa Freeman	
		Phone: (508) 887-4523	
		Email: lisa.freeman@tufts.edu	

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

Client:

B6

Address:

All Medical Records

Patient:

B6

Breed:

Boxer

DOB:

B6

Species: Canine

Sex: Male

(Neutered)

Home Phone:

B6

Work Phone: () -

Cell Phone:

B6

Referring Information

B6

Client:

B6

Patient:

Initial Complaint:

Scanned Record

SOAP Text Nov 20 2018 12:22PM -

B6

Initial Complaint:

DCM Study

SOAP Text Nov 20 2018 1:10PM -

B6

Disposition/Recommendations

Client:
Patient:

B6

Client:
Patient: **B6**

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

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

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

Patient:	B6
Species:	Canine
Breed:	Boxer
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

11/20/2018 5:45:23 PM Accession ID: **B6**

Test	Results	Reference Range	Units
Troponin I Research - FHSA	B6	0 - 0.08	mg/dl



3/13

B6

B6

Printed Tuesday, December 04, 2018

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

IDEXX BNP - 11/20/2018

IDEXX Reference Laboratories

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

Client: **B6**
Patient: **B6**
Species: CANINE
Breed: BOXER
Gender: MALE NEUTERED
Age: 3Y

Date: 11/20/2018
Requisition #: 433148
Accession #: **B6**
Ordered by: NOT SPECIFIED

IDEXX VetConnect 1-888-433-9967
TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536
508-839-5395
Account #88933

CARDIOPET proBNP- CANINE

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

B6

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

Client: **B6**
Patient:

CARDIAC TROPONIN/TEXGI SST 11/20/18



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



Website User ID: clinpath@tufts.edu

GI Lab Assigned Clinic ID: 11405

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

Phone: 508 887 4669
Fax: 9 508 839 7936
Animal Name:
Owner Name: **B6**
Species: Canine
Date Received: Nov 27, 2018

Tufts University-Clinical Pathology Lab
Tracking Number: 1811200093

GI Lab Accession: **B6**

Test	Result	Reference Interval	Assay Date
Ultra-Sensitive Troponin I Fasting	B6 ng/ml	≤0.06	11/27/18

B6

Comments:

B6

Canine
11/20/2018 1:18 PM
CARDIAC TROPONIN/TEXGI
SST

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

GI Lab Contact Information

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

Client: **B6**
Patient:

CARDIAC TROPONIN/TEXGI SST 11/20/18



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



Important Notices:

Ongoing studies

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

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

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

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

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

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

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

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

GI Lab Contact Information

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

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

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

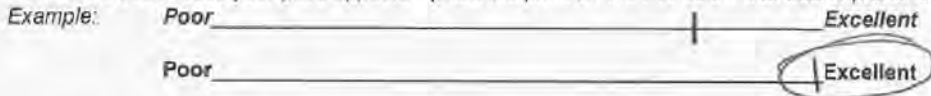
Diet hx

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** Today's date: 20 NOV 2018

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



2. Have you noticed a change in your pet's appetite over the last 1-2 weeks? (check all that apply)
 Eats about the same amount as usual Eats less than usual Eats more than usual
 Seems to prefer different foods than usual Other _____

3. Over the last few weeks, has your pet (check one)
 Lost weight Gained weight Stayed about the same weight Don't know

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

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

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 1/2 cup	2x/day	Jan 2018
85% lean hamburger	microwaved	3 oz	1x/week	Jan 2015
Pupperoni original beef flavor	treat	1/2	1x/day	Aug 2015
Rawhide	treat	6 inch twist	1x/week	Dec 2015
EARTHBOEN - MEADOWFEAST	dry	~ 1 1/2c +	2x DAY	FEB 2016

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

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

	Brand/Concentration	Amount per day
Taurine	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Carnitine	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Antioxidants	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Multivitamin	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Fish oil	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Coenzyme Q10	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Other (please list): Example: Vitamin C	_____	_____
SUPPLEMENT	Nature's Bounty NUPRO - DOG SUPPLEMENT	500 mg tablets - 1 per day 1 SCOOP (~ 1 TSP) 1-2x DAY

6. How do you administer pills to your pet?
 I do not give any medications
 I put them directly in my pet's mouth without food
 I put them in my pet's dog/cat food
 I put them in a Pill Pocket or similar product
 I put them in foods (list foods): BALOGNA or CHEESE

Client:
Patient:

B6

Client:
Patient:

B6

ECG from Cardio

B6

11/20/2018 3:27:51 PM

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

11/20/2018 3:28:15 PM

Page 1 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

Client: **B6**
Patient:

ECG from Cardio

B6

11/20/2018 3:28:15 PM

Page 2 of 2

Tufts University
Tufts Cummings School of Vet Med
Cardiology

B6

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

Patient History

11/20/2018 11:45 AM	Appointment
11/20/2018 12:23 PM	UserForm
11/20/2018 01:11 PM	UserForm
11/20/2018 04:04 PM	Purchase
11/20/2018 04:04 PM	Purchase
11/20/2018 04:04 PM	Purchase
11/20/2018 04:55 PM	Treatment
11/20/2018 05:45 PM	Labwork
11/20/2018 05:46 PM	Purchase
11/21/2018 11:25 AM	UserForm
11/26/2018 11:33 AM	Email

B6

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

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

B6

B6 Male (Neutered)
Canine Boxer Fawn
433149

11/22/2018

Dear **B6**

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

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

Thank you,

B6 DVM, DACVIM (Cardiology)

Report Details - EON-372834		
ICSR:	2059624	
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 18:12:06 EST	
Reported Problem:	Problem Description: Littermate diagnosed with reduced cardiac contractility Eating BEG diet (Earthborn) so screened all housemates Subjectively reduced contractility on echo and elevated NT-proBNP and cardiac troponin I Taurine pending Owner changing diet and will recheck in 3 months	
	Date Problem Started: 11/20/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: Earthborn Meadow Feast dry	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Product Use Information: Description: See diet history in medical record for more info	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Boxer (German Boxer)	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 30.3 Kilogram	
	Age: 3 Years	
	Assessment of Prior Health: Excellent	
	Number of Animals Given the Product: 5	
	Number of Animals Reacted: 4	
	Owner Information:	Owner Information provided: Yes
		Contact: Name: B6
		Phone: B6
		Email: B6
Address: B6 United States		
Healthcare Professional Information:	Practice Name: Tufts Cummings School of Veterinary Medicine	
	Contact: Name: Lisa Freeman	
	Phone: (508) 887-4523	
	Email: lisa.freeman@tufts.edu	

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

Report Details - EON-380707

ICSR: 2063114
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 16:31:40 EST

Reported Problem:
Problem Description: DCM and CHF diagnosed Aug 2018 We saw 1/11/19 - CHF still not well controlled Eating Purina Lamb and Rice - unlikely to be associated with DCM but reporting just in case Owner is now changing to different diet and will recheck in 3 months 2 other dogs eating same diet - we have not screened them yet. BNP = [B6] troponin [B6] but taurine normal ([B6] plasma [B6] whole blood)
Date Problem Started: 08/01/2018
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Purina One Smart Blend Lamb and Rice dry
Product Type: Pet Food
Lot Number:
Product Use Information: **Description:** 1/2 cup twice daily since a puppy See diet history for additional details
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: 29.9 Kilogram
Age: [B6] Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 3
Number of Animals Reacted: 1
Owner Information:
Owner Information provided: Yes
Contact: **Name:** [B6]
Phone: [B6]
Email: [B6]
Address: [B6]
United States
Healthcare Professional Information:
Practice Name: Tufts Cummings School of Veterinary Medicine
Contact: **Name:** Lisa Freeman
Phone: (508) 887-4523
Email: lisa.freeman@tufts.edu

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

Report Details - EON-380709

ICSR: 2063117
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2019-02-24 17:31:22 EST

Reported Problem:
Problem Description: Murmur and arrhythmia ausculted by RDVM. Echoed by another cardiologist who referred to us for study. Eating Fromm Lg Breed Adult (not grain free) so unclear if diet related. Screened other 2 standard poodles in household eating same diet and their hearts were fine. Owners have changed diet for all 3 dogs to Iams MiniChunks and we will recheck in 3 months
Date Problem Started: 01/29/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:
Product Name: Fromm Large Breed Adult dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** Please see diet history for additional details
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Poodle - Standard
Gender: Male
Reproductive Status: Neutered
Weight: 24 Kilogram
Age: 16 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 3
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** Yes
Contact: **Name:** B6
Phone:
Email:
Address: B6
United States
Healthcare Professional Information: **Practice Name:** Tufts Cummings School of Veterinary Medicine
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
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Pre Existing Conditions: B6

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Product Information:

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Product Type: Pet Food

Lot Number:

Package Type: BAG

Product Use Information: **Description:** Please see diet history for additional details

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Poodle - Standard

Gender: Male

Reproductive Status: Neutered

Weight: 24 Kilogram

Age: 16 Years

Assessment of Prior Health: Good

Number of Animals Given the Product: 3

Number of Animals Reacted: 1

Owner Information:

Owner Information provided: Yes

Contact: Name: B6
 Phone:
 Email:

Address: B6
 United States

Healthcare Professional Information:

Practice Name: Tufts Cummings School of Veterinary Medicine

Contact: Name: Lisa Freeman

		Phone: (508) 887-4523
		Email: lisa.freeman@tufts.edu
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	Preferred Method Of Contact:	Email
Additional Documents:	Attachment:	rpt_medical_record_preview.pdf
	Description:	Medical records
	Type:	Medical Records

Client:

B6

Address:

All Medical Records

Patient:

B6

Breed: Poodle

DOB:

B6

Species: Canine

Sex: Male

(Neutered)

Home Phone:

B6

Work Phone:

Cell Phone: () -

Referring Information

B6

Client:

B6

Patient:

Initial Complaint:

Scanned Record

Initial Complaint:

Cardiology New - per Dr. Freeman

SOAP Text Feb 1 2019 9:52AM - Rush, John

Initial Complaint:

B6

Blood draw and ECG for DCM study

Client:
Patient:

B6

Disposition/Recommendations

Client: **B6**
Patient:

Client: **B6**
Patient:

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Foster Hospital for Small Animals

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

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

Patient:	B6
Species:	Canine
Breed:	Poodle
Sex:	Male (Neutered)
Age:	B6 Years Old

Lab Results Report

Accession ID:

Test	Results	Reference Range	Units
------	---------	-----------------	-------



4/24

B6

Printed Sunday, February 24, 2019

Vitals Results

2/1/2019 1:49:26 PM	Weight (kg)	24.0000
---------------------	-------------	---------

Patient History

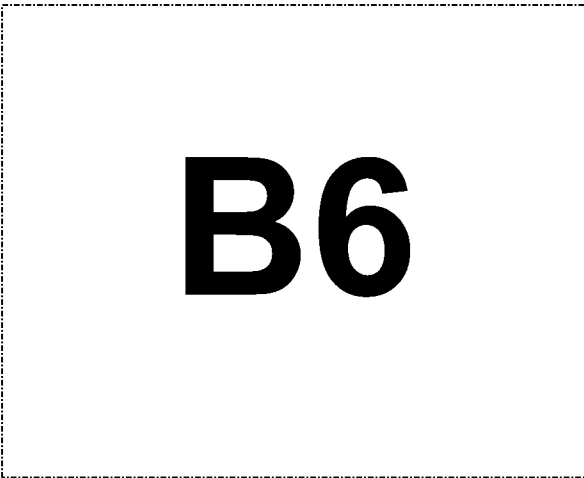
01/30/2019 12:06 PM	Appointment
02/01/2019 08:30 AM	UserForm
02/01/2019 08:30 AM	UserForm
02/01/2019 08:38 AM	UserForm
02/01/2019 09:06 AM	Purchase
02/01/2019 01:49 PM	Vitals
02/01/2019 05:45 PM	UserForm
02/06/2019 04:01 PM	Appointment

B6

Client: **B6**
Patient:

Patient History

02/18/2019 11:34 AM	Appointment
02/20/2019 09:24 AM	Purchase
02/20/2019 09:25 AM	Purchase
02/20/2019 09:25 AM	Purchase
02/20/2019 10:31 AM	UserForm
02/20/2019 05:20 PM	Appointment
02/20/2019 05:47 PM	Email
02/21/2019 04:30 PM	Purchase



B6

B6

B6

Male (Neutered)

Canine Poodle Beige

Patient ID: 438325

STANDARD CONSENT FORM

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

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

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

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

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

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

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

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

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

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

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

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

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

Owner's name:

Date: 2/1/2019

B6

2/1/19
Date

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

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

Authorized Agent - Please Print

Agent's Signature

Street Address

Date

Town/City State Zip

Discharge Instructions

Patient

Name: B6

Species: Canine

Breed: Male (Neutered) Poodle

Birthdate: B6

Owner

Name: B6

Address: B6

Patient ID: 438325

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Also Veterinary Nutritionist Dr. Lisa Freeman

Student: B6

Admit Date: 1/30/2019 10:27:28 AM

Discharge Date: 2/1/2019

Diagnoses: Dilated cardiomyopathy (DCM) with congestive heart failure, ventricular arrhythmias (ventricular tachycardia, ventricular bigeminy), short runs of supraventricular arrhythmias

Case Summary:

Thank you for bringing B6 to Tufts Cardiology Service for evaluation of his 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. If you notice that B6 breathing rate is faster than normal at home we will want to have chest x-rays taken. B6 also have some arrhythmias that are likely secondary to his heart disease. We will be starting him on some medications to try to limit the arrhythmias that he is experiencing. We would like to adjust B6 diet and we provided some dietary recommendations below.

Diagnostic test results and findings:

- o **Echocardiogram findings:** The walls of the chambers of his heart are thinner than normal and he has reduced contractile function. The left ventricle and left atrium are dilated.
- o **ECG findings:** The ECG showed arrhythmias that are mostly ventricular in origin but there are also some from the upper heart chamber as well.
- o **Labwork findings:** We will call you when we have the results of his bloodwork. Most of it should come back

tomorrow, but some of it will take a week or so to return.

Monitoring at home:

- o 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.
- o 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.
- o 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 give another dose, and if after giving 2 doses of furosemide then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- o There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- o We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- o If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

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.). 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.

- o The FDA is currently investigating an apparent association between diet and a type of heart disease called dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- o We recommend switching B6 to a commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas.
- o The FDA issued a statement regarding this issue (<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm>) and a recent article published by Dr. Lisa Freeman on the Cummings School's Pet Foodology blog can further explain these findings (<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>).
- o Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:

Royal Canin Early Cardiac (veterinary diet)
Purina Pro Plan Adult Weight Management
Purina Pro Plan Bright Mind Adult Small Breed Formula
Iams Chunks

Canned Food Options:

Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 8+

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

Exercise Recommendations:

We recommend limited activity. Leash walking only is ideal, and short walks to start. 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:

Thank you for enrolling B6 in our clinical study. Ideally, B6 would get an ECG (or an Alivecor reading sent to us) in around two weeks once he has had some time on the anti-arrhythmic medication. It would also be great if you can obtain an Alivecor reading if B6 has an episode of collapse or abnormal behavior.

A recheck of liver values, kidney values, and electrolytes is recommended in 2-3 weeks and then about 1 month after that, so we can keep an eye on the liver values, kidney values, and potassium. This can be done at your primary care veterinarian.

B6 is supposed to have an appointment here at Tufts in about 3 months. We will perform an echo, ECG and bloodwork at this time.

Thank you for entrusting us with B6 care! It was a pleasure to meet you all today and he was a very good boy. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case:

B6

Owner:

B6

Discharge Instructions

B6

B6
B6 Male (Neutered)
Canine Poodle Beige
Patient ID: 438325

Outside Prescription Log

B6

- 3. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

- 4. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

- 5. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:
Origin of request:

- 6. Date:
Clinician:
Prescription:
Pharmacy sent to:
Completed by:

Origin of request:

7. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

8. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

9. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

10. Date:

Clinician:

Prescription:

Pharmacy sent to:

Completed by:

Origin of request:

B6

Patient ID: 438325

B6 Canine
Years Old Male (Neutered) Poodle
Beige

**Cardiology Appointment Report
Enrolled in DCM Study**

Date: 2/1/2019

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Presenting Complaint:

DCM diagnosed 1/29/19 by B6 (VPCs but asymptomatic). Eating BEG diet x 3 years

B6

Concurrent Diseases:

B6

General Medical History:

B6

Diet and Supplements: Fromm Large Breed Adult dry

Cardiovascular History:

Prior CHF diagnosis? no

Prior heart murmur? yes

Prior ATE? no

Prior arrhythmia? yes

Monitoring respiratory rate and effort at home? no

Cough? maybe

Shortness of breath or difficulty breathing? no

Syncope or collapse? no

Sudden onset lameness? chronic lameness and weakness back legs

Exercise intolerance? limited by above

Current Medications Pertinent to CV System:

Medication: B6

B6

Medication:

B6

Cardiac Physical Examination:

B6

Muscle condition:

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

Cardiovascular Physical Exam:

Murmur Grade:

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

Murmur location/description: left apical

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 to
- 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: minimal exam

- Normal
- Hepatomegaly
- Mild ascites
- Marked ascites

- Abdominal distension

Problems:

Prior DCM, arrhythmia, +/- cough/gag from laryngeal disease vs other

Diagnostic plan:

- Echocardiogram
- Chemistry profile
- ECG
- Renal profile
- Blood pressure
- Dialysis profile
- Thoracic radiographs
- NT-proBNP
- Troponin I
- Other tests: DCM study testing

B6

Assessment and recommendations:

DCM with VPCs and APCs and some runs of SVT and ventricular tachycardia. Suspect the cough/gag is related to more chronic laryngeal disease, but the dog is breathing with slightly more effort than normal at rest. DCM may be related to diet or may be unrelated. Recommend continuing B6 but maybe at B6 since maybe arrhythmias more frequent now than before B6? vs day-to-day variation?, give furosemide if dyspnea develops, ideally start low dos B6 if tolerated (potassium is a bit high on recent bloodwork so will have to watch this serially too). The dog has enough arrhythmia that I would likely start an antiarrhythmic today B6 might be the choice, but the dog has increased liver enzymes - if we start this then follow LFs closely. I am not sure if sotalol would be tolerated. B6 is TID and might not get supraventricular ectopy, but this might be an option if B6 is not well tolerated. Diet change +/- taurine is recommended. Recheck ECG and kidney values, potassium, and liver enzymes in about 2 weeks. Discussed Alivacor option with owners.

Final Diagnosis:

DCM with cardiac arrhythmias

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib close to II
- II
- IIIa
- IIIb

ACVIM Classification:

- A
- B1
- B2 close to C
- C
- D

M-Mode

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

EDV(Teich)

ESV(Teich)

EF(Teich)

%FS

SV(Teich)

Ao Diam

LA Diam

LA/Ao

Max LA

TAPSEI

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)

LV Major

LV Minor

Sphericity Index

LVLd LAX

B6

cm

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cm

cm

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ml

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%

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cm

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cm

cm

(0.290 - 0.520)

(1.350 - 1.730) !

(0.330 - 0.530)

(0.430 - 0.710)

(0.790 - 1.140) !

(0.530 - 0.780) !

(0.680 - 0.890)

(0.640 - 0.900) !

cm

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LVAd LAX
LVEDV A-L LAX
LVEDV MOD LAX
LVLS LAX
LVA_s 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
R-R
HR
CO A-L LAX
CO MOD LAX

Doppler

MR Vmax
MR maxPG
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
TR Vmax
TR maxPG

B6

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Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

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

Discharge Instructions

Cardiology Technician

Patient

Name: B6

Species: Canine

Breed: Beige Male (Neutered) Poodle

Birthdate: B6

Owner

Name: B6

Address: B6

Patient ID: 438325

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Date: 2/20/2019

We saw B6 today for an ECG and a chemistry panel. We are happy to hear he is doing well at home, although he has been a bit more clingy at night in the last week. Dr Rush saw a bit more arrhythmia today on his ECG than he would like to see. His bloodwork looked ok, although his liver values are still moderately elevated. He would like to add in a low dose of a beta blocker called Carvadilol.

Medications:

B6

B6

Recheck Visits: A recheck visit is scheduled for

May 30th at 10:00am

Thank you for bringing **B6** to see us today, he is such a sweet boy!

Kind Regards,

B6

Thank you for entrusting us with **B6** care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case: **B6**

Owner: **B6**

Discharge Instructions

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

B6

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

B6
B6 Male (Neutered)
Canine Poodle Beige
B6

2/12/2019

Dear B6

Thank you for referring B6 with their pet B6

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

Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Cummings
Veterinary Medical Center
AT TUFTS UNIVERSITY

Foster Hospital for Small Animals
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North Grafton, MA 01536
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B6 Male (Neutered)
Cane Corso Beige

B6

2/23/2019

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Male (Neutered)

Canine Poodle Beige

B6

2/23/2019

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Thank you,

John Rush DVM, DACVIM (Cardiology), DACVECC

Report Details - EON-380720

ICSR: 2063120
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 19:08:40 EST

Reported Problem:

Problem Description:	Annual RDVM visit identified murmur. Echo done by mobile ultrasonographer showed DCM. We evaluated as part of study 2/1/19 - has DCM Eating BEG diet Changed to Pro Plan Weight management dry and we will recheck in 3 months
Date Problem Started:	02/01/2019
Concurrent Medical Problem:	Yes
Pre Existing Conditions:	B6
Outcome to Date:	Stable

Product Information:

Product Name:	Earthborn Coastal Catch dry
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Product Use Information:	Description: Please see diet history for more info
Manufacturer /Distributor Information:	
Purchase Location Information:	

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Retriever - Golden
Gender:	Male
Reproductive Status:	Neutered
Weight:	36.3 Kilogram
Age:	B6 Years
Assessment of Prior Health:	Excellent
Number of Animals Given the Product:	1
Number of Animals Reacted:	1
Owner Information:	Owner Information provided: Yes
Contact:	Name: B6 Phone: B6 Email: B6
Address:	B6 United States
Healthcare Professional Information:	Practice Name: Tufts Cummings School of Veterinary Medicine Contact: Name: Lisa Freeman Phone: (508) 887-4523

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

Report Details - EON-380720

ICSR: 2063120
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
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Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

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Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** Please see diet history for more info
Manufacturer /Distributor Information:
Purchase Location Information:

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Type Of Breed: Retriever - Golden
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Reproductive Status: Neutered
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Age: B6 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
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Owner Information: **Owner Information provided:** Yes
Contact: **Name:** B6
Phone: B6
Email: B6
Address: B6
 United States
Healthcare Professional Information: **Practice Name:** Tufts Cummings School of Veterinary Medicine
Contact: **Name:** Lisa Freeman
Phone: (508) 887-4523

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

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'cvca [B6] @cvcavets.com'
Sent: 3/28/2018 6:40:32 PM
Subject: FDA Case investigation for [B6] (EON-350158)
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; 03-Vet-LIRN-NetworkProceduresOwners-12.22.2015.pdf

Good afternoon [B6]

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 email (preferred) or fax (301-210-4685) a copy of [B6] entire medical history (not just this event).
 - Do you have records from her referring veterinarian?
- **Potentially Test Remaining OPEN product**
 - Do you have any remaining product left?
 - Is there a lot number or best by date for the leftover food?
- **Hold any remaining UNOPENED product** for potential collection.

I attached a copy of our Vet-LIRN network procedures. The procedures describe how Vet-LIRN operates and how veterinarians 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
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: CVCA - Cardiac Care for Pets [B6]
To: Jones, Jennifer L
Sent: 3/28/2018 10:08:41 PM
Subject: Re: FDA Case investigation for [B6] (EON-350158)

Dear Dr. Jones,

Thank you for following up on our patient, [B6]. We will be sending you our complete records for [B6] including the primary veterinarian history that we have and the history from her previous emergency room visit. Unfortunately, the diagnosis was made in October and the client has disposed of the diet. We will certainly keep this in mind for future patients with dilated cardiomyopathy which could potentially be diet-related and have those owners keep a sample and record the lot number for future testing/tracking. Thank you again for looking into this issue for our patients.

Sincerely,

[B6] VMD, DACVIM - Cardiology

On Wed, Mar 28, 2018 at 2:40 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon [B6]

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Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine

Office of Research
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new tel: 240-402-5421

fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov

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



--

CVCA - Cardiac Care for Pets

B6

Phone: **B6**

Fax: **B6**

Email: **B6** cvcavets.com

Visit our website at: www.cvcavets.com

"Like" us on Facebook at: www.facebook.com/CVCAVETS

"Follow" us on Instagram at: www.instagram.com/CVCAVETS

We want to hear from you! Access our online survey by clicking [here](#).

If there is anything that we can do to improve our service for you, please do not hesitate to contact us directly. We would greatly appreciate your feedback and invite you to fill out a survey based on your experience with CVCA.

Share your photos with us!

If you have a photo that you would like to share, we would love to post it on our Facebook page. Like us on [Facebook](#) and post to our wall or you can email the image with a fun fact to cvcainfo@cvcavets.com and we will forward it to our Facebook administrator.

Please note -- Images are usually posted within 1 month of submission.

From: CVCA - Cardiac Care for Pets [B6]
To: Jones, Jennifer L
Sent: 3/28/2018 10:27:10 PM
Subject: Re: FDA Case investigation for [B6] (EON-350158)
Attachments: [B6] BW.pdf; [B6] BW1.pdf; [B6] echo adata.pdf; [B6] hx.pdf; [B6] consult.pdf; [B6] echo 2.pdf; [B6] echo data.pdf; [B6] echo report 1.pdf; [B6] er.pdf; [B6] fecal.pdf; [B6] hx2.pdf; [B6] hx44.pdf; [B6] labs3.pdf; [B6] labs38.pdf; [B6] taurine.pdf

Attached is entire medical records for [B6]. Please let us know if you need anything else-
Thank-

On Wed, Mar 28, 2018 at 6:08 PM, CVCA - Cardiac Care for Pets [B6] wrote:

Dear Dr. Jones,

Thank you for following up on our patient, [B6]. We will be sending you our complete records for [B6] including the primary veterinarian history that we have and the history from her previous emergency room visit. Unfortunately, the diagnosis was made in October and the client has disposed of the diet. We will certainly keep this in mind for future patients with dilated cardiomyopathy which could potentially be diet-related and have those owners keep a sample and record the lot number for future testing/tracking. Thank you again for looking into this issue for our patients.

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



--

CVCA - Cardiac Care for Pets

B6

Phone: **B6**

Fax: **B6**

Email: **B6** [@cvcavets.com](mailto:B6@cvcavets.com)

Visit our website at: www.cvcavets.com

"Like" us on Facebook at: www.facebook.com/CVCAVETS

"Follow" us on Instagram at: www.instagram.com/CVCAVETS

We want to hear from you! Access our online survey by clicking [here](#).

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--

CVCA - Cardiac Care for Pets

B6

Phone: **B6**

Fax: **B6**

Email: **B6**@cvcavets.com

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"Like" us on Facebook at: www.facebook.com/CVCAVETS

"Follow" us on Instagram at: www.instagram.com/CVCAVETS

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Please note -- Images are usually posted within 1 month of submission.

Client: B6 (8546)

Patient Name: B6

Species: Canine

Breed: Labrador Retriever

Gender: Female/Spayed

Weight: 67.60 lbs

Age: 11 Years

Doctor: B6

B6

B6

B6

Test	Results	Reference Interval	LOW	NORMAL	HIGH
------	---------	--------------------	-----	--------	------

Catalyst Dx (November 14, 2017 4:20 PM)

10/27/17
10:05 AM

GLU		70 - 143	LOW
CREA		0.5 - 1.8	
BUN		7 - 27	
BUN/CREA			
PHOS		2.5 - 6.8	
CA		7.9 - 12.0	
TP		5.2 - 8.2	
ALB		2.2 - 3.9	
GLOB		2.5 - 4.5	HIGH
ALB/GLOB			
ALT	B6	10 - 125	
ALKP		23 - 212	HIGH
GGT		0 - 11	HIGH
TBIL		0.0 - 0.9	
CHOL		110 - 320	
AMYL		500 - 1500	
LIPA		200 - 1800	
Na		144 - 160	
K		3.5 - 5.8	
Na/K			
Cl		109 - 122	
Osm Calc			

B6

Client: **B6** (8546)
Patient Name: **B6**
Species: Canine
Breed: Labrador Retriever

Gender: Female/Spayed
Weight: 67.60 lbs
Age: 11 Years
Doctor: **B6**

B6
B6
B6

Test Results Reference Interval LOW NORMAL HIGH

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10/27/17

GLU		70 - 143	LOW
CREA		0.5 - 1.8	
BUN		7 - 27	
BUN/CREA			
PHOS		2.5 - 6.8	
CA		7.9 - 12.0	
TP		5.2 - 8.2	
ALB		2.2 - 3.9	
GLOB		2.5 - 4.5	HIGH
ALB/GLOB	B6		
ALT		10 - 125	
ALKP		23 - 212	HIGH
GGT		0 - 11	HIGH
TBIL		0.0 - 0.9	
CHOL		110 - 320	
AMYL		500 - 1500	
LIPA		200 - 1800	
Na		144 - 160	
K		3.5 - 5.8	
Na/K			
Cl		109 - 122	
Osm Calc			

B6



Patient Demographics

B6	Study Date: 11/01/2017					
Patient ID: 121217B	Accession #:	Alt ID:				
DOB:	Age:	Gender:	Ht:	Wt: 67lb 4oz	BSA:	
Institution: CVCA	B6					
Referring Physician:				Performed By:		
Physician of Record:						
Comments:						

Adult Echo: Measurements and Calculations

2D

LVIDd (2D) LVPWd (2D) EDV (2D-Teich) EDV (2D-Cubed) A4Cd LV Vol LV Length LV Area B6	LVAd (A4C) LVAs (A4C) EDV (A4C) ESV (A4C) LV Mass (Cubed)	B6	IVSd (2D) RVIDd/LVIDd RVIDd (2D) LA Area LA Dimen (2D)	B6
A4Cs LV Vol LV Length LV Area LVLd (A4C) LVLs (A4C)	IVS/LVPW (2D)	B6	LA/Ao (2D)	B6
	SV (A4C) EF (A4C)	B6	AoR Diam (2D)	B6

MMode

IVSd (MM) LVIDd (MM) LVPWd (MM)	SV (MM-Teich)	B6	LVPW % (MM)	
IVSs (MM) LVIDs (MM) LVPWs (MM)	FS (MM-Teich) EF (MM-Teich)	B6	RVIDd (MM) LA Dimen (MM) AoR Diam (MM) LA/Ao (MM)	B6
IVS/LVPW (MM)	EDV (MM-Cubed) ESV (MM-Cubed) SV (MM-Cubed) EF (MM-Cubed)	B6	MV D-E Exc Dist MV D-E Slope	

EDV (MM-Teich)	B6	FS (MM-Cubed)	B6	MV E-F Slope	B6
ESV (MM-Teich)		IVS % (MM)		MV EPSS	

Doppler

LVOT Vmax Max PG Vmax	B6	MV Peak A Vel Vel PG	B6	Lat A` Vel	B6
RVOT Vmax Max PG Vmax		MV E/A		E`/A` Lateral	B6
MR Vmax Max PG Vmax		Lat E` Vel		TR Vmax Max PG Vmax	B6
MV Peak E Vel Vel PG		E/Lat E`			

Other Measurements

Dimensions: 2D LAX

LA lax (2D)

Dimensions: Diameters

LVID/Ao (2D)

EF & Volume: Simpson's

Sphericity Id

Dimensions: Diameters

LVEDDN

LVID/Ao (2D)

B6

Images

B6

B6

B6

Signature

Signature:
Name(Print):

Date:

Patient Chart for B6

Client: B6

B6

B6

B6

B6

DISCHARGE INSTRUCTIONS AND REFERRAL CORRESPONDENCE

Primary Veterinarian: **B6**
Phone number: **B6**

Owner's name: **B6**
Phone number: **B6**

Patient Name: **B6**
Species: Canine
Sex: Spayed Female

Weight: 28.6 Kgs
Breed: Retriever, Golden
Age: **B6**

Admission Date: **B6**
Discharge Date: **B6**

History: Presented for Screening Echocardiogram for DCM. **B6** is currently in a Grain free diet and a low Taurine level was noted on her blood work. No signs of cardiac disease noted by the owner.

B6

Diagnostic Tests Performed

Echocardiogram: Evidence of occult dilated cardiomyopathy (DCM) based systolic dysfunction and left ventricular dilation noted on the echocardiogram today. Treatment with [B6] has been shown to significantly delay the onset of congestive heart failure (CHF) in these dogs. Since [B6] is an atypical breed to develop DCM, and the fact that she was being fed a grain free diet, with a low blood taurine level, we suspect that the cause is dietary taurine deficiency in golden retriever.

Clinical Diagnosis: Occult Dilated Cardiomyopathy - suspect dietary deficiency. Taurine is an amino acid that is found in high concentrations in heart and muscle. Among its many functions, it aids in normal contractile function. Evidence shows that taurine helps mediate calcium channel transports and modulates calcium sensitivity of the myofibrils. Taurine deficiency as a cause of dilated cardiomyopathy (DCM) is not a new issue. Taurine deficiency in cats was characterized by Pion et al in the late 1980s. Taurine deficiency has since been characterized as a cause of acquired DCM in dogs as well.

Treatment and Recommendations: Ongoing monitoring is recommended for signs of lethargy, decreased appetite, coughing, weakness/collapse, increased respiratory effort or rate (>40 breaths per minute AT REST) as these may be signs of progression of cardiac disease. If any of these signs are noted, please contact a veterinarian.

Medications:

[B6]

Diet: We recommend switching diet to a regular dog balanced diet and supplement Taurine and Omega 3 as follow. Taurine dose in dogs is 500 mg/ dog PO q 12h. Omega-3 fatty acids may improve appetite and reduce cachexia (EPA 30-40 mg/kg PO q 24h, DHA 20-25 mg/kg PO q 24h). Consider L-carnitine (110 mg/kg PO q 12h) in dogs not responding to taurine.

Results Pending: None.

Progress Exam: We recommend a recheck Echocardiogram in 1 month, or sooner should you notice clinical signs listed above.

Questions or Problems: If any problems or questions arise associated with the procedures and treatment performed at [B6] please do not hesitate to call us at [B6]

[B6] If any problems or questions arise concerning [B6] general health, please contact Dr.

[B6] If you have an emergency outside of our business hours, please contact the

[B6] with locations in [B6]

[B6]

[B6]

[B6]
Approved By:

[B6]
Owner/Agent's Signature of
[B6]

Doctor

B4

DISCHARGE INSTRUCTIONS AND REFERRAL CORRESPONDENCE

Primary Veterinarian: [Redacted] **B4, B6**

Phone number: [Redacted] **B4, B6**

Owner's name: [Redacted] **B6**
Phone number: [Redacted]

Patient Name: [Redacted] **B6**
Species: Canine
Sex: Spayed Female

Weight: 28.6 Kgs
Breed: Retriever, Golden
Age: 1 Yrs. 10 Mos.

Admission Date: 10/19/2018
Discharge Date: 10/19/2018

History: Presented for Screening Echocardiogram for DCM. [Redacted] **B6** is currently in a Grain free diet and a low Taurine level was noted on her blood work. No signs of cardiac disease noted by the owner.

B6

Diagnostic Tests Performed:

Echocardiogram: Evidence of occult dilated cardiomyopathy (DCM) based systolic dysfunction and left ventricular dilation noted on the echocardiogram today. Treatment with [B6] has been shown to significantly delay the onset of congestive heart failure (CHF) in these dogs. Since [B6] is an atypical breed to develop DCM, and the fact that she was being fed a grain free diet, with a low blood taurine level, we suspect that the cause is dietary taurine deficiency in golden retriever.

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[B6]

[B6]

[B6]

Board Certified Specialist - Cardiology

[B6]
Approved By:

Owner/Agent's Signature of
[B6]

Doctor

Report Details - EON-364577

ICSR: 2054750
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 17:16:09 EDT

Reported Problem:
Problem Description: Not true DCM but reduced contractility **B6** taurine (whole blood)
Date Problem Started: 09/05/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Ziwi Peak (recently started)
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Honest Kitchen Whole Grain Turkey, Beef, or CHicken
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: Retriever - Golden
Gender: Male
Reproductive Status: Neutered
Weight: 31.5 Kilogram
Age: **B6** Years
Assessment of Prior Health: Excellent
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** Yes
Contact: **Name:** **B6**
Phone: **B6**
Address: **B6**
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B6

Patient ID: 426744

B6 Canine

B6 Years Old Male (Neutered) Golden Retriever
Gold

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 Stern recommended getting an echo. Tested positive for (B6) 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 (B6 bpm).

Owner sent out whole blood taurine test after reading about low taurine on line.

Concurrent Diseases:

B6

B6

General Medical History:

Is on (B6) prevention every 6 weeks to 2 months. (B6)

Diet and Supplements:

ZiwePeak grain free, air dried; home cooked. Switched to honest kitchen about 3 years ago. Bravo canned rotates food, got treats with 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

Syncope 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:

Medication: B6

Formulation/Tab Size: B6

Administration Frequency:

Need refills?

Medication: B6

Formulation/Tab Size: B6

Administration Frequency: Give 1 Tablet Twice a day

Need refills?

Medication: B6

Formulation/Tab Size: B6

Administration Frequency:

Need refills?

Cardiac Physical Examination:

B6

Muscle condition:

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

Cardiovascular Physical Exam:

Murmur Grade:

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

Jugular vein:

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

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- Yes
- No
- Intermittent

- Pronounced
- Other:

Pulmonary assessments:

- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

- Pulmonary crackles
- Wheezes
- Upper airway stridor

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension

- Mild ascites
- Marked ascites

Problems:

Low whole blood taurine, on grain free diet

Diagnostic plan:

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

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

Echocardiogram Findings:

B6

Mitral inflow:

- Summated
- Normal
- Delayed relaxation

- Pseudonormal
- Restrictive

ECG findings:

B6

Assessment and recommendations:

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 **B6** and **B6** has not been checked recently, so **B6** was also submitted today (6 hours post pill) **B6**

B6

Final Diagnosis:

Mildly reduced LV contractile function

M-Mode

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

%FS

Ao Diam

LA Diam

LA/Ao

Max LA

B6

cm

cm

cm

cm

cm

cm

%

cm

cm

cm

M-Mode Normalized

IVSdN

LVIDdN

LVPWdN

IVSsN

LVIDsN

LVPWsN

Ao Diam N

LA Diam N

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)

2D

SA LA

Ao Diam

SA LA / Ao Diam

IVSd

LVIDd

B6

cm

cm

cm

cm

LVPWd
EDV(Teich)
IVSs
LVIDs
LVPWs
ESV(Teich)
EF(Teich)
%FS
SV(Teich)
LVID A2C
LVEDV MOD A2C
LVIs A2C
LVESV MOD A2C
LVEF MOD A2C
SV MOD A2C
LVID LAX
LVAd LAX
LVEDV A-L LAX
LVEDV MOD LAX
LVIs 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
MV E Vel
MV DecT
MV A Vel
MV E/A Ratio
E'
A'
E/E'
PV Vmax
PV maxPG
AV Vmax
AV maxPG
TR Vmax
TR maxPG

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Report Details - EON-367347

ICSR: 2055560
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: 2018-10-01 16:59:24 EDT

Reported Problem:
Problem Description: Housemate diagnosed with reduced contractile function on echo (B6) (B6) Asymptomatic NT-proBNP tested at RDVM. Will send results
Date Problem Started: 09/27/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Honest Kitchen whole grain turkey, beef, or chicken + Ziwi Peak (just started again) - see diet history for (B6) attached
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** See attached diet history
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: 29.1 Kilogram
Age: (B6) Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
Number of Animals Reacted: 1

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

Healthcare Professional Information:
Practice Name: Tufts Cummings School of Veterinary Medicine
Contact: **Name:** Lisa Freeman
Phone: (508) 887-4523
Email: lisa.freeman@tufts.edu

Address: 200 Westboro Rd
North Grafton
Massachusetts
01536
United States

Sender Information:

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

Additional Documents:

Attachment:	B6 18100117080.pdf
Description:	Diet history (for B6 - housemates)
Type:	Medical Records
Attachment:	echo 9-27-18.pdf
Description:	Echo
Type:	Echocardiogram
Attachment:	discharge 9-27-18.pdf
Description:	Discharge
Type:	Medical Records
Attachment:	taurine.pdf
Description:	Taurine
Type:	Laboratory Report

Report Details - EON-364577

ICSR: 2054750
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 17:16:09 EDT

Reported Problem:
Problem Description: Not true DCM but reduced contractility. **B6** taurine (whole blood)
Date Problem Started: 09/05/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Ziwi Peak (recently started)
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Honest Kitchen Whole Grain Turkey, Beef, or CHicken
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: Retriever - Golden
Gender: Male
Reproductive Status: Neutered
Weight: 31.5 Kilogram
Age: **B6** Years
Assessment of Prior Health: Excellent
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: **B6**
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Address: **B6**
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Discharge Instructions

Patient

Name: B6
Species: Canine
Gold Male (Neutered) Golden Retriever
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: 426744

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Date: 9/5/2018

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 B6 heart health. We also submitted a total T4 to assess B6 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:

B6

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

(508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case: B6

Owner: B6

Discharge Instructions

B6

Patient ID: 426744

B6 Canine

B6 Years Old Male (Neutered) Golden Retriever
Gold

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 Stern recommended getting an echo. Tested B6 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 B6

Owner sent out whole blood taurine test after reading about low taurine on line.

Concurrent Diseases:

B6

B6

Happy and healthy

otherwise.

General Medical History:

Is on heartworm prevention every 6 weeks to 2 months.

B6

Diet and Supplements:

ZiwePeak grain free, air dried; home cooked. Switched to honest kitchen about 3 years ago. Bravo canned rotates food, got treats with 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

Syncope 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:

Medication: B6

Formulation/Tab Size: B6 twice a day

Administration Frequency:

Need refills?

Medication: B6

Formulation/Tab Size: B6

Administration Frequency: Give 1 Tablet Twice a day

Need refills?

Medication: omega 3 fatty acids

Formulation/Tab Size: nordic naturals once a day 2 teaspoons

Administration Frequency:

Need refills?

Cardiac Physical Examination:

B6

Muscle condition:

- | | |
|--|--|
| <input type="checkbox"/> Normal | <input type="checkbox"/> Moderate cachexia |
| <input checked="" type="checkbox"/> Mild muscle loss | <input type="checkbox"/> Marked cachexia |

Cardiovascular Physical Exam:

Murmur Grade:

- | | |
|--|--------------------------------|
| <input checked="" type="checkbox"/> None | <input type="checkbox"/> IV/VI |
| <input type="checkbox"/> I/VI | <input type="checkbox"/> V/VI |
| <input type="checkbox"/> II/VI | <input type="checkbox"/> VI/VI |
| <input type="checkbox"/> III/VI | |

Jugular vein:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Bottom 1/3 of the neck | <input type="checkbox"/> 1/2 way up the neck |
| <input type="checkbox"/> Middle 1/3 of the neck | <input type="checkbox"/> Top 2/3 of the neck |

Arterial pulses:

- | | |
|--|---|
| <input type="checkbox"/> Weak | <input type="checkbox"/> Bounding |
| <input type="checkbox"/> Fair | <input type="checkbox"/> Pulse deficits |
| <input checked="" type="checkbox"/> Good | <input type="checkbox"/> Pulsus paradoxus |
| <input type="checkbox"/> Strong | <input type="checkbox"/> Other: |

Arrhythmia:

- | | |
|---|--------------------------------------|
| <input checked="" type="checkbox"/> None | <input type="checkbox"/> Bradycardia |
| <input type="checkbox"/> Sinus arrhythmia | <input type="checkbox"/> Tachycardia |
| <input type="checkbox"/> Premature beats | |

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:

Low whole blood taurine, on grain free diet

Diagnostic plan:

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

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

Echocardiogram Findings:

B6

Mitral inflow:

- Summated
- Normal
- Delayed relaxation

- Pseudonormal
- Restrictive

ECG findings:

B6

Assessment and recommendations:

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

B6

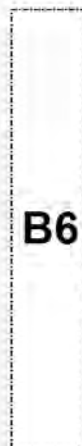
B6

Final Diagnosis:

Mildly reduced LV contractile function

M-Mode

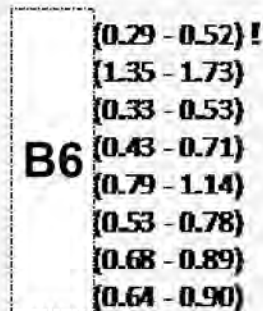
- IVSd
- LVIDd
- LVPWd
- IVSs
- LVIDs
- LVPWs
- %FS
- Ao Diam
- LA Diam
- LA/Ao
- Max LA



- cm
- cm
- cm
- cm
- cm
- cm
- %
- cm
- cm
- cm

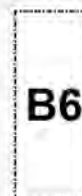
M-Mode Normalized

- IVSdN
- LVIDdN
- LVPWdN
- IVSsN
- LVIDsN
- LVPWsN
- Ao Diam N
- LA Diam N



2D

- SA LA
- Ao Diam
- SA LA / Ao Diam
- IVSd
- LVIDd



- cm
- cm
- cm
- cm

LVPWd
EDV(Teich)
IVSs
LVIDs
LVPWs
ESV(Teich)
EF(Teich)
%FS
SV(Teich)
LVID A2C
LVEDV MOD A2C
LVIs A2C
LVESV MOD A2C
LVEF MOD A2C
SV MOD A2C
LVID LAX
LVAd LAX
LVEDV A-L LAX
LVEDV MOD LAX
LVIs 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
MV E Vel
MV DecT
MV A Vel
MV E/A Ratio
E'
A'
E/E'
PV Vmax
PV maxPG
AV Vmax
AV maxPG
TR Vmax
TR maxPG

B6

B6

cm
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BPM
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%
ml
ml
l/min
l/min

m/s
ms
m/s

m/s
m/s

m/s
mmHg
m/s
mmHg
m/s
mmHg

B6

Patient ID: 426794

B6 Canine
B6 Years Old Female (Spayed) Golden Retriever
Gold

Cardiology Appointment Report

Date: 9/27/2018

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V19

Presenting Complaint: Check for DCM (has been on grain free diet)

Concurrent Diseases: none

General Medical History: B6 had been on a grain free diet at home, and another golden retriever of owner's was low in taurine (B6 taurine level was normal)- owner wants to make sure B6 does not have DCM. No concerns at home.

Diet and Supplements:

Honest Kitchen (grain free), primal once a month, home cooked here and there (Old diet)
Now on Canine Natural, Bag of royal canin Golden retriever, zee wee peak

Omega 3 fatty acid oil
Eye drops- diclofenac for pigmentary uveitis
On heartworm preventative

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? 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: None

Cardiac Physical Examination:

B6

Muscle condition:

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

Cardiovascular Physical Exam:

Murmur Grade:

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

Jugular vein:

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

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:

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

Abdominal exam:

- Normal
- Hepatomegaly
- Mild ascites
- Marked ascites

Abdominal distension

Problems: Hx of grain free diet; apparently healthy dog

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, HR 90 bpm

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 diet, but other mild cardiomyopathy, age related change, or variation of normal for this patient cannot be ruled out. An NTproBNP level was submitted for additional information. Given the possibility of a dietary association **B6** ing

B6

Final Diagnosis:

Mildly reduced LV contractile function (r/o cardiomyopathy v variation of normal)

M-Mode

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

B6

- cm
- cm
- cm
- cm
- cm
- cm
- %
- cm
- cm
- cm

EPSS
Max LA

B6

cm
cm

M-Mode Normalized

IVSdN
LVIDdN
LVPWdN
IVSsN
LVIDsN
LVPWsN
Ao Diam N
LA Diam N

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}

2D

Ao Diam
IVSd
LVIDd
LVPWd
EDV(Teich)
IVSs
LVIDs
LVPWs
ESV(Teich)
EF(Teich)
EF(Cube)
%FS
SV(Teich)
LVld LAX
LVAd LAX
LVEDV A-L LAX
LVEDV MOD LAX
LVls LAX
LVAs LAX
LVESV A-L LAX
LVESV MOD LAX
HR
EFA-L LAX
LVEF MOD LAX
SV A-L LAX
SV MOD LAX
CO A-L LAX
CO MOD LAX
SA LA

B6

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BPM
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ml
ml
l/min
l/min
cm

Doppler

MV E Vel
MV DecT
MV Dec Slope
MV A Vel

m/s
ms
m/s
m/s

MV E/A Ratio
E'
E/E'
PV Vmax
PV maxPG
AV Vmax
AV maxPG

B6

m/s
m/s
mmHg
m/s
mmHg

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Reimschuessel, Renate
CC: Jones, Jennifer L
Sent: 7/20/2018 12:06:11 PM
Subject: RE: 800.267-FDA Case Investigation for [B6] (EON-358523)

Dear Renata and Jennifer

That seems reasonable. I was never contacted about the other cases that I submitted. There was some confusion about the way I submitted them so I want to be sure you actually got them [B6]

[B6] I'm sure you're all getting slammed with reports (and there will probably be even more coming now) but just wanted to check to be sure they got recorded.

Thanks
Lisa

From: Reimschuessel, Renate [mailto:Renate.Reimschuessel@fda.hhs.gov]
Sent: Friday, July 20, 2018 7:55 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267-FDA Case Investigation for [B6] (EON-358523)

Dear Lisa

Thanks for gathering the information.

I think, since we are getting so many reports since our CVM update, we should pass on the [B6] case as it is not clear-cut.

I think Jen is more familiar with the [B6] case, so I'll let her respond regarding that one. Thank you again for all your work on this investigation.

rr

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

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Thursday, July 19, 2018 5:59 PM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.267-FDA Case Investigation for [B6] (EON-358523)

Dear Renate

In looking back through this case, I'm not sure this is a completely clear-cut one. The dog has degenerative mitral valve disease and CHF but also has reduced cardiac contractility so might be a combination. Do you still want me to collect the info below?

Also, I have an update on [B6] who died at home last week. I do have food from the owner if you want that.

Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor

Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Sent: Tuesday, July 17, 2018 11:48 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: 800.267-FDA Case Investigation for [B6] (EON-358523)

Dear Dr. Freeman,

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 email (preferred) or fax (301-210-4685) a copy of [B6] **entire** medical history (not just this event), including any referral diagnostics.

- **Phone interview** about [B6] diet and environmental exposures

- Please confirm permission to contact the owner.
 - The interview generally lasts 30 minutes.

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

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

Thank you kindly, especially for submitting multiple cases,
Dr. Reimschuessel

Renate Reimschuessel V.M.D. Ph.D.

Director: Vet-LIRN

(Veterinary Laboratory Investigation and Response Network)

Center For Veterinary Medicine, FDA,

8401 Muirkirk Road, Laurel, MD 20708

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

EMAIL : renate.reimschuessel@fda.hhs.gov

Vet-LIRN

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

Phish-Pharm

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ToolsResources/Phish-Pharm/default.htm>

Aquaculture

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm>

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Freeman, Lisa'
Sent: 8/31/2018 1:03:03 PM
Subject: [REDACTED] **B6**

Thank you, Lisa! Enjoy your weekend,
Jen

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Wednesday, August 29, 2018 6:45 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: [REDACTED] **B6**

Dear Jen,
I just spoke to [REDACTED] **B6** owner. I already submitted his case and sent in his food earlier this week (he is deceased).
They gave permission to be contacted directly for more info. Their phone is [REDACTED] **B6**
Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
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Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Freeman, Lisa
Sent: Thursday, July 19, 2018 5:59 PM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.267-FDA Case Investigation for [REDACTED] **B6** (EON-358523)

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Do you still want me to collect the info below?

Also, I have an update on [REDACTED] **B6** who died at home last week. I do have food from the owner if you want that.
Thanks
Lisa

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Professor

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From: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Sent: Tuesday, July 17, 2018 11:48 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: 800.267-FDA Case Investigation for [REDACTED] (EON-358523)

Dear Dr. Freeman,

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

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

- **Full Medical Records**

- Please email (preferred) or fax (301-210-4685) a copy of [REDACTED] **entire** medical history (not just this event), including any referral diagnostics.

- **Phone interview** about [REDACTED] diet and environmental exposures

- Please confirm permission to contact the owner.
- The interview generally lasts 30 minutes.

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Aquaculture

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm>

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 8/1/2018 10:33:10 PM
Subject: RE: 800.267-FDA Case Investigation for [B6] (EON-358523)
Attachments: [B6] dcm taurine deficiency 7 7 17.pdf; [B6] august 2017 echo.pnrx; [B6] [B6] medical records.pnrx; [B6] nutrition request.pnrx; [B6] diet history.pnrx

Hi Jen
I'll ask [B6] to send their records. I'm attaching what I have from [B6] and the primary care vet plus some Tufts records including diet history.
I don't know if owner still has the original food but will check
Thanks
Lisa

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Friedman School of Nutrition Science and Policy
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Tufts University
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From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Wednesday, August 01, 2018 2:53 PM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.267-FDA Case Investigation for [B6] (EON-358523)

Thank you, Lisa.
Yes, please send [B6] medical records. We can send you a box to collect the foods. Where would be the best address? It will have a prepaid shipping label, and you can reuse the box to ship the samples by UPS.

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



From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Wednesday, August 01, 2018 2:45 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.267-FDA Case Investigation for [B6] (EON-358523)

Hi Jen
I'm still working on getting permission from [B6] owners. They may be on vacation – tough to get people at this time of year.

I also just heard that [B6] (Boxer with low taurine eating Petcurean) has improved even further on echo after diet change and taurine supplementation. I submitted that but wanted to be sure that got entered into the system correctly. His cardiologist and I are happy to provide records.
Thanks

Lisa

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From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Friday, July 20, 2018 8:47 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.267-FDA Case Investigation for [REDACTED] (EON-358523)

Good morning Lisa,

Yes, we got the reports you previously submitted and recorded the information for our database. Will you please forward any medical records for:

- [REDACTED] are you able to send any updates on the Taurine testing or echocardiogram (if done?)
- [REDACTED] Also was an autopsy done?

Thank you in advance and for your time to report all the cases!

Jen

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



From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Friday, July 20, 2018 8:06 AM
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Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
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Dear Renata and Jennifer

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[REDACTED] I'm sure you're all getting slammed with reports (and there will probably be even more coming now) but just wanted to check to be sure they got recorded.

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Lisa

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To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
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Subject: RE: 800.267-FDA Case Investigation for [REDACTED] (EON-358523)

Dear Lisa

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not clear-cut.

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

From: Freeman, Lisa [<mailto:Lisa.Freeman@tufts.edu>]
Sent: Thursday, July 19, 2018 5:59 PM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
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Sent: Tuesday, July 17, 2018 11:48 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
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 - Please confirm permission to contact the owner.
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Director: **Vet-LIRN**

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<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ToolsResources/Phish-Pharm/default.htm>

Aquaculture

<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm>

Report Details - EON-367344

ICSR: 2055558
 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: 2018-10-01 16:39:24 EDT

Reported Problem:
Problem Description: Eating grain-free diet so owner wanted baseline echo. No clinical signs. Echo showed no overt DCM but reduced contractility. Taurine low (plasma WB=**B6**). Recommended diet change and taurine supplementation
Date Problem Started: 09/19/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Honest Kitchen Grain Free beef (love), fish (zeal), chicken (force), or turkey (keen). Also, Instinct raw beef patties
Product Type: Pet Food
Lot Number:
Product Use Information: **Description:** See diet history
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: 25.9 Kilogram
Age: **B6** Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information:
Owner Information provided: Yes
Contact: **Name:** **B6**
Phone:
Email:
Address: **B6**
 United States
Healthcare Professional Information:
Practice Name: Tufts Cummings School of Veterinary Medicine
Contact: **Name:** Lisa Freeman
Phone: (508) 887-4523
Email: lisa.freeman@tufts.edu
Address:

200 Westboro Rd
North Grafton
Massachusetts
01536
United States

Sender Information:

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

Additional Documents:

Attachment:	rdvm records.pdf
Description:	RDVM records
Type:	Medical Records
Attachment:	B6 diet history 9-19-18.pdf
Description:	Diet history
Type:	Medical Records
Attachment:	cardio discharge.pdf
Description:	Cardio discharge
Type:	Medical Records
Attachment:	echo 9-19-18.pdf
Description:	Echo
Type:	Echocardiogram
Attachment:	taurine: B6 .jpg
Description:	Taurine results
Type:	Laboratory Report

Discharge Instructions

Patient

Name: B6
Species: Canine
Blonde Female (Spayed) Golden
Retriever
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Date: 9/19/2018

Diagnoses:

Thank you for bringing B6 to see us for her cardiology evaluation since she has been eating grain free dog food. We did an echocardiogram and found that B6 does not have any major changes to her heart, but she does have mildly reduced contractile function. There is some normal variation in dogs, so it is hard to say if this is clearly something that could be related to diet or if it could just be her normal.

We submitted Taurine levels today, and should have those results within 2 weeks. We will plan to call you with the results, but if you have not heard from us in 25 weeks then feel free to give us a call.

Monitoring at Home:

We don't expect any concerns related to B6 heart at this time, but please call if you notice any trouble breathing, coughing, or collapse.

Diet Suggestions:

We recommend feeding a main-stream brand, non-grain-free diet. Dry options that our nutritionist recommends are Royal Canin Early Cardiac, Royal Canin Boxer, or Purina ProPlan Adult Weight Management. B6 heart changes are very mild, so she would not be restricted to one of these diets as long as it is from a large company such as Purina, Royal Canin, or Hills.

If you are struggling to find a diet that B6 does well on then you can schedule a nutrition consult with Dr Lisa Freeman or one of the other Tufts Nutritionists.

Exercise Recommendations:

B6 can continue to have normal exercise and activity.

Recommended Medications:

You could consider supplementing with taurine. [B6] dose would be 500mg by mouth twice daily. We recommend Swanson, NOW, or GNC brands, and you can get this over the counter from a vitamin store.

Recheck Visits: A recheck visit is recommended in 6-12 months. At this visit we would recheck the contractile function of [B6] heart, and decide if continued cardiology rechecks are necessary.

Thank you for entrusting us with [B6] care. She is such a sweet girl! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case: [B6]

Owner: [B6]

Discharge Instructions

B6

Patient ID: B6
B6 Canine
B6 Years Old Female (Spayed) Golden Retriever
Blonde

Cardiology Appointment Report

Date: 9/19/2018

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: None

Presenting Complaint: Would like a base-line echo because she has been on a grain free diet. Has been on raw (Instinct) as well. Is on heartworm prev.

Concurrent Diseases: Front legs will shake sometimes when she is standing or lying down. No clear cause or associations. Passes on own.

General Medical History:

Diet and Supplements: Honest Kitchen - fish, beef, turkey, chicken gives her itchy feet. Previously Instinct Raw. When puppy Taste of the Wild.

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? 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:

None

Cardiac Physical Examination:

B6

Muscle condition:

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

Cardiovascular Physical Exam:

Murmur Grade:

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

Jugular vein:

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

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:

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

Abdominal exam:

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

Problems:

Grain free diet

Diagnostic plan:

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

Echocardiogram Findings:

B6

Mitral inflow:

- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

ECG findings:

B6

Assessment and recommendations:

Echocardiogram reveals mildly reduced contractile function, but no overt evidence of DCM such as wall thinning or LV or LA dilation. Taurine whole blood and plasma submitted today.

B6

B6

Final Diagnosis:

Grain free diet

Mildly reduced contractile function (r/o nutritional induced early cardiomyopathy v variation of normal)

M-Mode

- IVSd
- LVIDd
- LVPWd
- IVSs
- LVIDs
- LVPWs
- %FS
- Max LA
- TAPSE
- EPSS

B6

- cm
- cm
- cm
- cm
- cm
- cm
- %
- cm
- cm
- cm

M-Mode Normalized

IVSdN
LVIDdN
LVPWdN
IVSsN
LVIDsN
LVPWsN

(0.29 - 0.52)
(1.35 - 1.73)
B6 (0.33 - 0.53)
(0.43 - 0.71) !
(0.79 - 1.14)
(0.53 - 0.78)

2D

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

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l/min
l/min

Doppler

MV E Vel
MV DecT
MV A Vel
MV E/A Ratio
E'
A'
E/E'
PV Vmax

m/s
ms
m/s
B6
m/s
m/s
m/s

PV maxPG
AV Vmax
AV maxPG

B6

mmHg
m/s
mmHg

Report Details - EON-390092

ICSR:	2068038
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-06-10 16:15:32 EDT
Initial Report Date:	05/28/2019
Parent ICSR:	2067510
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Patient presented to rDVM for evaluation of abdominal distension x 5 weeks and increase in respiratory rate and effort. FAST scan revealed moderate ascites. Patient was referred to Tufts for further evaluation. Findings consistent with advanced DMVD with suspect L-CHF and poor contractile function. Considering LA enlargement and severity of MR and AI, we would expect a better systolic function. B6 is recommended. Mild respiratory effort and occasional b-lines vote in favor to L-CHF. There is enough cardiac changes to justify L and R CHF. Since patient is on a BEG diet, it is unclear whether diet is playing a role on decreased contractile function. Recommend transition to a grain-based, low sodium diet and consider Taurine supplementation. Abdominocentesis was performed (5 liters of serous sanguineous fluid) and analysis is recommended. Recommend hospitalization, patient on telemetry monitoring and respiratory watch. Fluid check in the morning and kidney values daily while in the hospital. Since patient is on a BEG diet, recommend transition to a grain-based, low sodium diet.
	Date Problem Started:	04/16/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
Outcome to Date:		Better/Improved/Recovering

Product Information:	Product Name:	Fromm Game Bird Recipe Dog Four-Star Dry Grain-Free formula
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	

Animal Information:	Name:	
	Type Of Species:	Dog
	Type Of Breed:	Hound (unspecified)
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	38.9 Kilogram
	Age:	B6 Years
	Assessment of Prior Health:	Good
Number of Animals	1	

	Given the Product:																					
	Number of Animals Reacted:	1																				
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Owner Information provided:	Yes	Contact: Name:	B6	Phone:		Address:	B6		United States										
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	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>Tufts Cummings School of Veterinary Medicine</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> <tr> <td>Address:</td> <td>200 Westboro Road North Grafton Massachusetts 01536 United States</td> </tr> <tr> <td>Practice Name:</td> <td>Tufts University Cummings School of Veterinary Medicine</td> </tr> <tr> <td>Contact: Name:</td> <td>Lisa Freeman</td> </tr> <tr> <td>Phone:</td> <td>(508) 887-4696</td> </tr> <tr> <td>Address:</td> <td>200 Westboro Road North Grafton Massachusetts 01536 United States</td> </tr> <tr> <td>Permission to Release Records to FDA:</td> <td>Yes</td> </tr> </table>	Practice Name:	Tufts Cummings School of Veterinary Medicine	Contact: Name:	B6	Phone:		Email:		Address:	200 Westboro Road North Grafton Massachusetts 01536 United States	Practice Name:	Tufts University Cummings School of Veterinary Medicine	Contact: Name:	Lisa Freeman	Phone:	(508) 887-4696	Address:	200 Westboro Road North Grafton Massachusetts 01536 United States	Permission to Release Records to FDA:	Yes
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	Contact: Phone:																					
	Email:	B6																				
	Permission To Contact Sender:	Yes																				
	Preferred Method Of Contact:	Email																				
	Reported to Other Parties:	None																				
Additional Documents:	Attachment:	Complete amino acid analysis 5-29-2019.pdf																				
	Description:	Lab work																				
	Type:	Laboratory Report																				
	Attachment:	troponin 5-30-2019.pdf																				
	Description:	Lab work																				
	Type:	Laboratory Report																				

Attachment: Follow-up medical records.pdf

Description: Medical Records

Type: Medical Records

Discharge Instructions

Patient

Name: B6
Species: Canine
Blonde Female (Spayed) Golden
Retriever
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Date: 9/19/2018

Diagnoses:

Thank you for bringing B6 to see us for her cardiology evaluation since she has been eating grain free dog food. We did an echocardiogram and found that B6 does not have any major changes to her heart, but she does have mildly reduced contractile function. There is some normal variation in dogs, so it is hard to say if this is clearly something that could be related to diet or if it could just be her normal.

We submitted Taurine levels today, and should have those results within 2 weeks. We will plan to call you with the results, but if you have not heard from us in 25 weeks then feel free to give us a call.

Monitoring at Home:

We don't expect any concerns related to B6 heart at this time, but please call if you notice any trouble breathing, coughing, or collapse.

Diet Suggestions:

We recommend feeding a main-stream brand, non-grain-free diet. Dry options that our nutritionist recommends are Royal Canin Early Cardiac, Royal Canin Boxer, or Purina ProPlan Adult Weight Management. B6 heart changes are very mild, so she would not be restricted to one of these diets as long as it is from a large company such as Purina, Royal Canin, or Hills.

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Recheck Visits: A recheck visit is recommended in 6-12 months. At this visit we would recheck the contractile function of [B6] heart, and decide if continued cardiology rechecks are necessary.

Thank you for entrusting us with [B6] care. She is such a sweet girl! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

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

Clinical Trials:

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

Case: [B6]

Owner: [B6]

Discharge Instructions

**DOCUMENT
PRODUCED IN NATIVE**

**DOCUMENT
PRODUCED IN NATIVE**

**DOCUMENT
PRODUCED IN NATIVE**

B6

Patient Information

Patient: **B6** Age: 6 years Referring Veterinarian: **B6**
Patient Number: **B6** Weight:(kg) 25.10 Cardiologist: **B6**
Breed: lab mix Sex: F Client Number: 147921
Exam Date: 01/10/2018 08:21 BSA: 0.87

History: **B6** was presented for evaluation of cough, labored breathing, multiple episodes of collapse, cardiomegaly, and suspected congestive heart failure. **B6** was initially seen by her rDVM on December 30th for cough. She was initially treated with a humidifier, **B6** and a decrease in length of walks and did not improve. On January 4th she had a collapse episode during which she circled, fell over, and flopped for about a minute. She has a second less severe episode on January 5th. Labwork at this date showed mild elevation of ALT and AST with mild increase in CK. T4 was low normal. She has continued to be short of breath and tires easily. She chased a squirrel a couple of days ago and stood with a wide based stance afterward. She is on year-round heartworm, flea and tick preventative and was last tested negative for heartworm 9/9/17. She eats California Natural Kangaroo and Red Lentil dry food with vegetables and 2 tbsn. of canned pumpkin. She is on **B6** **B6** twice daily and **B6**. The **B6** was discontinued yesterday.

Physical Examination: T 102.7 P 208 R 150. Grade 3/6 left apical systolic murmur and gallop. Regular tachycardia. Quiet heart sounds. Localized fine crackles left cranial hilar region, dry cough. Poor femoral pulses. Unremarkable abdominal palpation. mm pale pink, normal refill. Hydration OK. Normal PLNs.

Diagnostic Tests:

1/10/18:

B6

Echo - see below. Sinus tachycardia on ECG.

Taurine level (whole blood): pending, will call with results.

B6

B6

Thoracic radiographs: Mild decrease in severity of cardiomegaly (as compared to rDVM films from 1/9/18). Resolving cardiogenic edema.

Hospitalization:

An IV catheter was placed and **B6** was hospitalized in ICU with continuous ECG monitoring. She was started on **B6** and **B6** in AM and 10 mg in PM). She did well overnight with an improvement in respiratory rate/effort. **B6** had occasional short paroxysms of "slow" ventricular tachycardia (160-270 bpm) that were noted to persist beyond ~7 pm.

B6 was started on **B6** the following morning. She continued to do well with a normal appetite and improved respiratory rate.

Echocardiographic Report

2D ECHO

LA Systolic Diameter LX

DOPPLER

AV Peak Velocity
 AV Peak Gradient
 MR Peak Velocity
 PV Peak Velocity

PV Peak Gradient
 TR Peak Velocity
 TR Peak Gradient

M-MODE

LV Diastolic Diameter MM
 LV Systolic Diameter MM
 LV Fractional Shortening MM
 LV Diastolic Volume Cube
 LV Systolic Volume Cube
 LV Ejection Fraction Cube
 IVS Diastolic Thickness MM
 IVS Systolic Thickness MM
 IVS Percent Thickening MM

B6

LVPW Diastolic Thickness MM
 LVPW Systolic Thickness MM
 LVPW Percent Thickening MM
 IVS to PW Ratio MM
 LV Mass MM
 LV Mass Normalized MM
 RV Diastolic Diameter MM
 LA Systolic Diameter MM
 Aortic Root Diameter MM

B6

Left Ventricle: Severe dilation (normalized LVIDd 2.85) with severe myocardial dysfunction (normalized LVIDs 2.34). Increased sphericity.

Left Atrium: Severe dilation.

Right Ventricle: Mild dilation with subjective decrease in contractility.

Right Atrium: Mild dilation.

Mitral Valve: Normal valve morphology. 4+ central mitral regurgitation.

Aortic Valve: Normal.

Tricuspid Valve: Mildly thickened valve leaflets. 1+ tricuspid regurgitation. Normal regurgitant velocities.

Pulmonic Valve: Mildly thickened valve leaflets. Mild pulmonic insufficiency.

Aorta: Normal

Pericardium: Normal

Diagnosis

Dilated cardiomyopathy - This is a disease characterized by weakening of the heart muscle and dilation of the heart chambers. As the disease progresses, it can lead to congestive heart failure (fluid in the lungs causing shortness of breath and cough). Abnormal heart rhythms are common and can result in sudden death. Most commonly this is an inherited disease, though it can occur secondary to a deficiency in an amino acid called taurine.

Left sided congestive heart failure

Recommendations

Give all medications as directed:

B6

One thing that can be very helpful for home monitoring is checking sleeping or resting respiratory rates. A recent study showed that even pets with severe heart disease rarely have resting respiratory rates greater than 30 breaths per minute unless they are starting to decompensate for that disease. Elevated respiratory rates at home may be even more sensitive than chest radiographs at picking up early decompensation. Count your pet's respiratory rate when he/she is at rest or sleeping (not within 20 minutes of being active). If his/her respiratory rate is greater than 30 breaths per minute, recheck again in a couple of hours. If persistently elevated above this level, call.

With advanced heart disease, our biggest dietary concerns are adequate calorie content and low sodium content. We aim for less than 80mg sodium per 100 kilocalories (kcal) in patients that have developed congestive heart failure. We do not advise protein restriction unless there is concurrent kidney disease (i.e. kidney diets are not advised unless there is concurrent kidney disease). Please refer to our diet handouts with a list of currently adequate diets and treats, though this list is not exclusive. If you wish to feed a diet that is not on these lists, you will need to call the manufacturer of the diet to obtain a sodium content.

As we discussed, we have had three other cases of severe DCM where the dogs have been eating a kangaroo and lentil diet. There is no data that has shown an association with this diet and DCM but we are concerned there may be a connection there and are looking into it at this time. For this reason, we would consider changing **B6** diet.

We sent **B6** home with a few cans of Hill's Science Diet Canine Maintenance canned food. This food has an appropriate level of sodium for dogs in congestive heart failure and is available at most pet stores. Lamb should be avoided as a protein source but any other protein is appropriate (with the exception of kangaroo).

The very best diet for dogs with DCM/heart failure is probably Hill's Science Diet Prescription j/d. This food has a good source of taurine, carnitine and fatty acids. However, this diet is rather costly.

We have submitted a taurine level and will call you with the results when they are available.

Exercise is also a concern in advanced heart disease. While cage rest is ideal with active heart failure, some exercise is permissible in asymptomatic disease. However, vigorous or extended exercise should be avoided.

***As long as **B6** does well at home we would like to re-evaluate her in 7-10 days. At this time we will recheck her kidney values/electrolytes and blood pressure as well as repeat chest x-rays.

B6

B6 DVM, DACVIM (Cardiology)

(Electronically Signed)

Final Date:

Like us on Facebook!

www.facebook.com/B6

Notes to our clients

- Please bring all medications to your pet's scheduled appointments.
- We require a 48 hour notice for all refills. When you call to request a refill, please leave the pharmacy phone number or clearly indicate if you plan on picking up the medication at our facility. **PRESCRIPTION REFILLS ARE NOT AVAILABLE AFTER B6 REGULAR BUSINESS HOURS (Evenings, Fridays, holidays and weekends).**
- Check out B6 and enter your local zip code to search for the best prices on your medications at your local pharmacies.
- If an emergency arises with your pet, B6 is a 24 hour facility.

**DOCUMENT
PRODUCED IN NATIVE**

**DOCUMENT
PRODUCED IN NATIVE**

**DOCUMENT
PRODUCED IN NATIVE**

Withheld in Full as B5

Withheld in Full as B5

Report Details - EON-351031

ICSR: 2045676
 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 13:26:01 EDT

Reported Problem:
Problem Description: Feb.23, 2018. Patient presented to the cardiology service at **B6** **B6** for tachypnea. He was diagnosed with dilated cardiomyopathy and left side congestive heart failure. Whole blood taurine level was **B6** (ref 200-350, critical level <150). At the time, patient consuming Zignature Kangaroo Formula and was advised to change.
Date Problem Started: 02/22/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: **B6**
Outcome to Date: Stable

Product Information:
Product Name: Zignature Kangaroo Formula
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
Description: Owner feeding for 2-3 years prior to diagnosis.
Last Exposure Date: 03/01/2018
Time Interval between Product Use and Adverse Event: 3 Years
Product Use Stopped After the Onset of the Adverse Event: Yes
Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:
Purchase Location Information: Name: Chewy.com

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Male
Reproductive Status: Neutered
Weight: 40 Kilogram

	Age:	6 Years														
	Assessment of Prior Health:	Good														
	Number of Animals Given the Product:	1														
	Number of Animals Reacted:	1														
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Owner Information provided:	Yes	Contact: Name:	B6	Phone:		Address:	B6		United States				
Owner Information provided:	Yes															
Contact: Name:	B6															
Phone:																
Address:	B6															
	United States															
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> <tr> <td>Type of Veterinarian:</td> <td>Referred veterinarian</td> </tr> <tr> <td>Date First Seen:</td> <td>02/23/2018</td> </tr> </table>	Practice Name:	B6	Contact: Name:	B6	Phone:		Address:	B6		United States	Type of Veterinarian:	Referred veterinarian	Date First Seen:	02/23/2018
Practice Name:	B6															
Contact: Name:	B6															
Phone:																
Address:	B6															
	United States															
Type of Veterinarian:	Referred veterinarian															
Date First Seen:	02/23/2018															
Sender Information:	Name:	B6														
	Address:	B6														
		United States														
	Contact: Phone:	B6														
	Email:															
	Reporter Wants to Remain Anonymous:	No														
	Permission To Contact Sender:	Yes														
	Preferred Method Of Contact:	Email														
	Reported to Other Parties:	None														
Additional Documents:																

Report Details - EON-367845

ICSR: 2055793
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-08 14:34:26 EDT

Reported Problem:
Problem Description: DCM and atrial fibrillation diagnosed 10/5/18
Date Problem Started: 10/04/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:
Product Name: Rawz meal free dry food limited recipe wild salmon 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: Male
Reproductive Status: Neutered
Weight: 33.2 Kilogram
Age: 10 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: B6
 Phone: B6
 Email: B6
Address: B6
 United States
Healthcare Professional Information:
Practice Name: Tufts Cummings School of Veterinary Medicine
Contact: Name: Lisa Freeman
 Phone: (508) 887-4523
 Email: lisa.freeman@tufts.edu
Address: 200 Westboro Rd

North Grafton
Massachusetts
01536
United States

Sender Information:

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

Additional Documents:

Attachment:	B6 compiled records small.pdf
Description:	Compiled records
Type:	Medical Records

Discharge Instructions

Patient

Name: B6
Species: Canine
Yellow Male (Neutered) Labrador
Retriever
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V19

Date: B6

Diagnoses: DCM (Dilated Cardiomyopathy), history of congestive heart failure

Clinical Findings:

Thank you for bringing B6 to the Tufts Cardiology service for a recheck of his DCM. You report that B6 has been doing very well at home, as he is not coughing, has a normal resting respiratory rate, and does not seem to have any exercise intolerance. B6 has been taking his medications well, and has not needed any additional doses.

Today we did a recheck echocardiogram (ultrasound of the heart) and ECG. Our findings were consistent with the last echocardiogram, all chambers of the heart are enlarged with a leak at the mitral valve, but the measurements have not worsened. We are very happy that B6 is stable and doing well at home!

We are also running a blood test to check B6 renal values, and we will call you with the results.

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 furosemide, you can try giving him a second extra dose. If his breathing is still not improved within an hour after the second extra dose, 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 have any concerns, please call or have B6 evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Diet Suggestions: You may continue B6 normal diet, but we recommend avoiding the lamb flavor, as foods with lamb may be associated with heart disease. Please avoid high sodium foods. A fish oil supplement may be considered as well.

Exercise Recommendations:

Intense activity is not advisable for dogs with heart disease. However, we understand that B6 is an active dog and it is a balancing act between moderating his activity and letting him live his life as a happy dog. B6 can continue being active within reason, but 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 disease.

Recommended Medications:

B6

Recheck Visits: We would like to see B6 again in about 4-6 months for a recheck echocardiogram, or sooner if he is not feeling well at home. Please call or email to schedule this appointment.

Thank you for entrusting us with B6 care, he is always a pleasure! Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case: B6

Owner: B6

Discharge Instructions

B6

Patient Information

Patient: **B6** Age: 6 years Referring Veterinarian: **B6**
Patient Number: **B6** Weight:(kg) 25.10 Cardiologist: **B6**
Breed: lab mix Sex: F Client Number: 147921
Exam Date: 01/10/2018 08:21 BSA: 0.87

History: **B6** was presented for evaluation of cough, labored breathing, multiple episodes of collapse, cardiomegaly, and suspected congestive heart failure. **B6** was initially seen by her rDVM on December 30th for cough. She was initially treated with a humidifier, **B6** and a decrease in length of walks and did not improve. On January 4th she had a collapse episode during which she circled, fell over, and flopped for about a minute. She has a second less severe episode on January 5th. Labwork at this date showed mild elevation of ALT and AST with mild increase in CK. T4 was low normal. She has continued to be short of breath and tires easily. She chased a squirrel a couple of days ago and stood with a wide based stance afterward. She is on year-round heartworm, flea and tick preventative and was last tested negative for heartworm 9/9/17. She eats California Natural Kangaroo and Red Lentil dry food with vegetables and 2 tbsn. of canned pumpkin. She is on **B6** **B6** twice daily and **B6**. The **B6** was discontinued yesterday.

Physical Examination: T 102.7 P 208 R 150. Grade 3/6 left apical systolic murmur and gallop. Regular tachycardia. Quiet heart sounds. Localized fine crackles left cranial hilar region, dry cough. Poor femoral pulses. Unremarkable abdominal palpation. mm pale pink, normal refill. Hydration OK. Normal PLNs.

Diagnostic Tests:

1/10/18:

B6

Echo - see below. Sinus tachycardia on ECG.

Taurine level (whole blood): pending, will call with results.

B6

B6

Thoracic radiographs: Mild decrease in severity of cardiomegaly (as compared to rDVM films from 1/9/18). Resolving cardiogenic edema.

Hospitalization:

An IV catheter was placed and **B6** was hospitalized in ICU with continuous ECG monitoring. She was started on **B6** and **B6** in AM and 10 mg in PM). She did well overnight with an improvement in respiratory rate/effort. **B6** had occasional short paroxysms of "slow" ventricular tachycardia (160-270 bpm) that were noted to persist beyond ~7 pm.

B6 was started on **B6** the following morning. She continued to do well with a normal appetite and improved respiratory rate.

Echocardiographic Report

2D ECHO

LA Systolic Diameter LX

DOPPLER

AV Peak Velocity
AV Peak Gradient
MR Peak Velocity
PV Peak Velocity

PV Peak Gradient
TR Peak Velocity
TR Peak Gradient

M-MODE

LV Diastolic Diameter MM
LV Systolic Diameter MM
LV Fractional Shortening MM
LV Diastolic Volume Cube
LV Systolic Volume Cube
LV Ejection Fraction Cube
IVS Diastolic Thickness MM
IVS Systolic Thickness MM
IVS Percent Thickening MM

B6

LVPW Diastolic Thickness MM
LVPW Systolic Thickness MM
LVPW Percent Thickening MM
IVS to PW Ratio MM
LV Mass MM
LV Mass Normalized MM
RV Diastolic Diameter MM
LA Systolic Diameter MM
Aortic Root Diameter MM

B6

- Left Ventricle:** Severe dilation (normalized LVIDd 2.85) with severe myocardial dysfunction (normalized LVIDs 2.34). Increased sphericity.
- Left Atrium:** Severe dilation.
- Right Ventricle:** Mild dilation with subjective decrease in contractility.
- Right Atrium:** Mild dilation.
- Mitral Valve:** Normal valve morphology. 4+ central mitral regurgitation.
- Aortic Valve:** Normal.
- Tricuspid Valve:** Mildly thickened valve leaflets. 1+ tricuspid regurgitation. Normal regurgitant velocities.
- Pulmonic Valve:** Mildly thickened valve leaflets. Mild pulmonic insufficiency.
- Aorta:** Normal
- Pericardium:** Normal

Diagnosis

Dilated cardiomyopathy - This is a disease characterized by weakening of the heart muscle and dilation of the heart chambers. As the disease progresses, it can lead to congestive heart failure (fluid in the lungs causing shortness of breath and cough). Abnormal heart rhythms are common and can result in sudden death. Most commonly this is an inherited disease, though it can occur secondary to a deficiency in an amino acid called taurine.

Left sided congestive heart failure

Recommendations

Give all medications as directed:

B6

One thing that can be very helpful for home monitoring is checking sleeping or resting respiratory rates. A recent study showed that even pets with severe heart disease rarely have resting respiratory rates greater than 30 breaths per minute unless they are starting to decompensate for that disease. Elevated respiratory rates at home may be even more sensitive than chest radiographs at picking up early decompensation. Count your pet's respiratory rate when he/she is at rest or sleeping (not within 20 minutes of being active). If his/her respiratory rate is greater than 30 breaths per minute, recheck again in a couple of hours. If persistently elevated above this level, call.

With advanced heart disease, our biggest dietary concerns are adequate calorie content and low sodium content. We aim for less than 80mg sodium per 100 kilocalories (kcal) in patients that have developed congestive heart failure. We do not advise protein restriction unless there is concurrent kidney disease (i.e. kidney diets are not advised unless there is concurrent kidney disease). Please refer to our diet handouts with a list of currently adequate diets and treats, though this list is not exclusive. If you wish to feed a diet that is not on these lists, you will need to call the manufacturer of the diet to obtain a sodium content.

As we discussed, we have had three other cases of severe DCM where the dogs have been eating a kangaroo and lentil diet. There is no data that has shown an association with this diet and DCM but we are concerned there may be a connection there and are looking into it at this time. For this reason, we would consider changing **B6** diet.

We sent **B6** home with a few cans of Hill's Science Diet Canine Maintenance canned food. This food has an appropriate level of sodium for dogs in congestive heart failure and is available at most pet stores. Lamb should be avoided as a protein source but any other protein is appropriate (with the exception of kangaroo).

The very best diet for dogs with DCM/heart failure is probably Hill's Science Diet Prescription j/d. This food has a good source of taurine, carnitine and fatty acids. However, this diet is rather costly.

We have submitted a taurine level and will call you with the results when they are available.

Exercise is also a concern in advanced heart disease. While cage rest is ideal with active heart failure, some exercise is permissible in asymptomatic disease. However, vigorous or extended exercise should be avoided.

***As long as **B6** does well at home we would like to re-evaluate her in 7-10 days. At this time we will recheck her kidney values/electrolytes and blood pressure as well as repeat chest x-rays.

B6

B6 DVM, DACVIM (Cardiology)

(Electronically Signed)

Final Date:

Like us on Facebook!

www.facebook.com/B6

Notes to our clients

-Please bring all medications to your pet's scheduled appointments.

-We require a 48 hour notice for all refills. When you call to request a refill, please leave the pharmacy phone number or clearly indicate if you plan on picking up the medication at our facility. PRESCRIPTION REFILLS ARE NOT AVAILABLE AFTER B6 REGULAR BUSINESS HOURS (Evenings, Fridays, holidays and weekends).

-Check out B6 and enter your local zip code to search for the best prices on your medications at your local pharmacies.

-If an emergency arises with your pet, B6 is a 24 hour facility.

Report Details - EON-367850

ICSR: 2055797
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-10-08 15:17:24 EDT

Reported Problem:
Problem Description: Presented to ER of **B6** for CHF and DCM (had rads at RDVM for cough). Full echo on 8/28/18. Unlikely to be associated with diet but reporting because he is sometimes fed the lamb formula Pro Plan. Taurine WNL
Date Problem Started: **B6**
Concurrent Medical Problem: Yes
Pre Existing Conditions: Atopy (on Atopica)
Outcome to Date: Stable

Product Information:
Product Name: Pro Plan Savory dry - chicken, beef, or lamb (1 cup TID)
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: Retriever - Labrador
Gender: Male
Reproductive Status: Neutered
Weight: 37.7 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:** Yes
Contact: **Name:** **B6**
Phone: **B6**
Email: **B6**
Address: **B6**
United States
Healthcare Professional Information: **Practice Name:** Tufts Cummings School of Veterinary Medicine
Contact: **Name:** Lisa Freeman
Phone: (508) 887-4523

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

Report Details - EON-375111

ICSR: 2060740
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-01-01 16:29:18 EST

Reported Problem:
Problem Description: Weight loss x 3-4 weeks Coughing and dyspnea developed - too to B6 B6 where they did T-FAST and suspected DCM. Started on B6 and B6 before we saw him Eating BEG diet. Taurine pending. Switched to new food. Will also try to evaluate other dog in their home eating the same diet (15 years old) Owners happy to provide additional info and have saved some of the food they've been feeding (4Health)
Date Problem Started: 12/20/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: 4Health grain-free beef and potato
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: Description: See diet history for additional info
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Male
Reproductive Status: Intact
Weight: 29.2 Kilogram
Age: B6 years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 2
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: B6
 Phone: B6
 Email: B6
Address: B6
 United States
Healthcare Professional Information: Practice Name: Tufts Cummings School of Veterinary Medicine
 Contact: Name: Lisa Freeman

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

Report Details - EON-375111

ICSR: 2060740
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-01-01 16:29:18 EST

Reported Problem:
Problem Description: Weight loss x 3-4 weeks Coughing and dyspnea developed - too to ER in B6 B6 where they did B6 and suspected DCM. Started on B6 and B6 before we saw him Eating BEG diet. Taurine pending. Switched to new food. Will also try to evaluate other dog in their home eating the same diet (15 years old) Owners happy to provide additional info and have saved some of the food they've been feeding (4Health)
Date Problem Started: 12/20/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: 4Health grain-free beef and potato
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Description: See diet history for additional info
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Male
Reproductive Status: Intact
Weight: 29.2 Kilogram
Age: B6 years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 2
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: B6
 Phone: B6
 Email: B6
Address: B6
 United States
Healthcare Professional Information: Practice Name: Tufts Cummings School of Veterinary Medicine
 Contact: Name: Lisa Freeman

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

From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: [REDACTED] 5:06:38 PM
Subject: RE: [REDACTED]

Hi Jen
It is [REDACTED] has been my contact and I let her know you'd be arranging for a box. She removed the heart last night and put it in formalin so that's ready to ship. We won't be able to get other tissues but hopefully this will be helpful.
If you need additional info, please let me know. I have a bunch of cases I need to report to you so I'll get those submitted asap.
Thanks
Lisa

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: [REDACTED] 8:53 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Subject: RE: [REDACTED]

Hi Lisa,
Ok, we can offer a full gross necropsy if the vet will perform that and collect the tissues on the list. Alternatively, if the vet will only get the heart, they can put the full heart intact into 10% NBF. Either way, we can send a box to collect.

Will you please confirm that it's [REDACTED] I'll need to make a purchase request.
Thank you again,
Jen

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: [REDACTED] 8:02 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: [REDACTED]

Hi Jen
Unfortunately, they can't bring the body to Tufts and the dog is scheduled to be picked up for cremation today. If we can't do whole body donation, do you have a preferred approach to getting heart and any other selected tissues? The referring vet is willing to help get some samples and I can probably drive to [REDACTED] tonight to pick up

Thanks
Lisa

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: [REDACTED] 7:58 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Cc: Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: [REDACTED]

Hi Lisa,

Thank you for the head's up. If the owner can bring the body to Tufts for the necropsy, we can authorize and pay for it. I attached the most recent version of the necropsy protocol. Your lab can perform the gross necropsy and histopathology of the non-heart tissues. We'll need a set of slide recuts sent to us for review. We'll need to collect the intact formalin-fixed heart, fresh frozen tissues, and slide recuts. When the time comes, I can send you a box for this with a prepaid shipping label.

If you're willing to do this, please send me an estimate for the necropsy and histopathology with recuts. I'll make the purchase request today.
Thank you for bringing this to our attention,
Jen

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: [REDACTED] 4:19 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: [REDACTED]
Importance: High

Hi Jen

I left a message on your machine but in case you're checking email, one of the cases I submitted [REDACTED] died [REDACTED]. The owner has given permission for a necropsy or getting heart samples so I am hoping to get in touch with you asap to see if we can work it out (I'm assuming you're back at work since I got this email from you)

thanks
Lisa

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

Friedman School of Nutrition Science and Policy
Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: [REDACTED] **B6** 10:02 AM
To: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Subject: RE: [REDACTED] **B6**

Thank you for the update, Lisa. I'm sorry to hear that he passed away. Can you please forward the records for his case?

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: [REDACTED] **B6** 3:13 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: [REDACTED] **B6**

Hi Jen
Wanted to let you know that [REDACTED] **B6** died unexpectedly due to choking yesterday while eating. Owner said he had been doing well and we were going to do a recheck in Feb.
So sad ☹️
Lisa

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

Report Details - EON-367903

ICSR: 2055827
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: 2018-10-09 10:05:22 EDT

Reported Problem:

Problem Description:	Serial echoes were being done for SAS. Cardiologist noted reduced contractile function over time and that dog was eating BEG diet so recommended change. Owner changed from Orijen to Royal Canin Early Cardiac Diet. Significant improvement in cardiac size and function (and NT-proBNP) after diet change. Had taurine level checked in 2014 - was normal then. Was not retested.
Date Problem Started:	01/18/2018
Concurrent Medical Problem:	Yes
Pre Existing Conditions:	B6
Outcome to Date:	Better/Improved/Recovering

Product Information:

Product Name:	Orijen 6 fish 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:	33.7 Kilogram												
Age:	B6 Years												
Assessment of Prior Health:	Good												
Number of Animals Given the Product:	1												
Number of Animals Reacted:	1												
Owner Information:	<table border="1"><tr><td>Owner Information provided:</td><td>Yes</td></tr><tr><td>Contact:</td><td><table border="1"><tr><td>Name:</td><td>B6</td></tr><tr><td>Phone:</td><td></td></tr><tr><td>Email:</td><td></td></tr></table></td></tr><tr><td>Address:</td><td>B6</td></tr></table>	Owner Information provided:	Yes	Contact:	<table border="1"><tr><td>Name:</td><td>B6</td></tr><tr><td>Phone:</td><td></td></tr><tr><td>Email:</td><td></td></tr></table>	Name:	B6	Phone:		Email:		Address:	B6
Owner Information provided:	Yes												
Contact:	<table border="1"><tr><td>Name:</td><td>B6</td></tr><tr><td>Phone:</td><td></td></tr><tr><td>Email:</td><td></td></tr></table>	Name:	B6	Phone:		Email:							
Name:	B6												
Phone:													
Email:													
Address:	B6												
Healthcare Professional Information:	<table border="1"><tr><td>Practice Name:</td><td>Tufts Cummings School of Veterinary Medicine</td></tr><tr><td>Contact:</td><td><table border="1"><tr><td>Name:</td><td>Lisa Freeman</td></tr></table></td></tr></table>	Practice Name:	Tufts Cummings School of Veterinary Medicine	Contact:	<table border="1"><tr><td>Name:</td><td>Lisa Freeman</td></tr></table>	Name:	Lisa Freeman						
Practice Name:	Tufts Cummings School of Veterinary Medicine												
Contact:	<table border="1"><tr><td>Name:</td><td>Lisa Freeman</td></tr></table>	Name:	Lisa Freeman										
Name:	Lisa Freeman												

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

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID: B6

B6

Canine

B6

Years Old Female (Spayed) Terrier Cross
Blue

Cardiology Appointment Report

Date: 1/17/2019

Attending Cardiologist

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student:

B6

Presenting Complaint:

Presenting for recheck of:

- Subvalvular aortic stenosis with small aortic root - mild to moderate disease
- Mitral valve disease - mild
- Left ventricular dilation with reduced contractile function - mild and somewhat improved

Following as part of grain free/DCM

Concurrent Diseases: none

General Medical History:

Exercise tolerance improved - goes out less bc cold

Overall doing very well at home

Off heart worm prev right now - stopped 1 month or 2 mo ago and test again in spring

Diet and Supplements:

Royal canin early cardiac - been on it since August

Cardiovascular History:

Prior CHF diagnosis? no

Prior heart murmur? yes

Prior ATE? no

Prior arrhythmia? no

Monitoring respiratory rate and effort at home? yes

Cough? no
Shortness of breath or difficulty breathing? no
Syncope or collapse? no
Sudden onset lameness? no
Exercise intolerance? mild

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination

B6

Muscle condition:

- Normal - very muscular
- 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: III/VI left mid cardiac systolic, II/VI right systolic

Jugular vein:

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

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- Yes
- No
- Intermittent
- Prominent
- 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:

Hx DCM/reduced myocardial function and aortic stenosis - clinically doing very well at home
aortic stenosis with small aortic root - mild to moderate disease
Mitral valve disease - mild
Left ventricular dilation with reduced contractile function - possibly diet related

Diagnostic plan:

B6

Echocardiogram Findings:

General/2-D findings:

B6

Doppler findings:

B6

Mitral inflow:

- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive

ECG findings:

Sinus rhythm and sinus arrhythmia during the echo

Assessment and recommendations:

There is impressive resolution of the findings seen in July, with now fairly normal LV and LA size and better LV contractile function - findings that might be considered typical for a dog with SAS. There is still mild aortic stenosis. It is suspected that most of the improvement is a result of the diet change. Recommend continue the diet, but maybe feed less, since the dog is a bit overweight now. When

B6

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM Classification:

- A
- B1
- B2
- C
- D

2D

SA LA

Ao Diam

SA LA / Ao Diam

IVSd

LVIDd

LVPWd

EDV(Teich)

IVSs

LVIDs

LVPWs

BSV(Teich)

EF(Teich)

%FS

SV(Teich)

LV Major

LV Minor

Sphericity Index

LVID LAX

LVA d LAX

LVEDV A-L LAX

B6

cm

cm

cm

cm

cm

ml

cm

cm

cm

ml

%

%

ml

cm

cm

cm

cm

cm

cm

ml

LVEDV MOD LAX
LVLs LAX
LVA_s LAX
LVBSV A-L LAX
LVBSV MOD LAX
HR
EF A-L LAX
LVEF MOD LAX
SV A-L LAX
SV MOD LAX
CO A-L LAX
CO MOD LAX
R-R
HR
CO A-L LAX
CO MOD LAX

M-Mode

IVSd
LVIDd
LVPWd
IVSs
LVIDs
LVPWs
Ao Diam
LA Diam
Max LA

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
cm
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ml
BPM
%
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ml
l/min
l/min
ms
BPM
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ms
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m/s

m/s

m/s
m/s
m/s
mmHg
m/s
mmHg

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4695

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01936
Telephone: (508) 839-5395
Fax: (508) 839-7951
<http://vetmed.tufts.edu/>

Discharge Instructions

Patient

Name: B6

Species:

Blue Female (Spayed) Terrier Cross

Birthdate: B6

Owner

Name: B6

Address:

B6

Patient ID: B6

Attending Cardiologist:

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

CRCB:

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6

Admit Date: 1/17/2019 9:35:33 AM

Discharge Date: 1/17/2019

Diagnoses:

- Subvalvular aortic stenosis with small aortic root - mild to moderate disease
- Mitral valve disease - mild - trivial leak today
- Left ventricular dilation with reduced contractile function - essentially normal today

Clinical Findings:

Thank you for bringing B6 in to see the Tufts Cardiology Service for a recheck of her aortic stenosis, mitral valve disease, and mildly reduced contractile function. B6 is reported to be doing very well at home and has adjusted well to her new diet over the last six months. It is hard to say exactly how her exercise tolerance levels are doing, due to the impact of winter on her activity levels.

On exam today, her heart murmur remained stable (III/VI) and her pulses were good. The echocardiogram (ultrasound of the heart) showed that she continues to have improvement of her contractile function, and the heart size is getting smaller, and is essentially back to what I would think is "typical" for a dog with aortic stenosis. Historically she has also had a small leak at her mitral valve, but today we saw only a trace leak at that valve, which is great. At this time, overall her heart looks to be that of a dog with only mild aortic stenosis. She had no arrhythmia today.

B6

Monitoring at home:

Please continue to monitor her at home as you have been doing.

Recommended Medications:

B6

Diet suggestions:

B6

Thank you for entrusting us with **B6** care. Please contact our Cardiology liaison at (508)-887-4096 or email us at cardio@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/twoc/clinical-studies

Case: **B6**

Owner: **B6**

Discharge Instructions

Report Details - EON-358519

ICSR: 2051555
 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 08:43:16 EDT

Reported Problem:
Problem Description: Diagnosed with LV cavity dilation and reduced contractile function
Date Problem Started: 06/20/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Unknown

Product Information:
Product Name: Earthborn Coastal Catch 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: Boxer (German Boxer)
Gender: Female
Reproductive Status: Neutered
Weight: 33.2 Kilogram
Age: 7.6 Years
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: B6
 Phone: B6
Address: B6
 United States
Healthcare Professional Information:
Practice Name: Tufts Cummings School of Veterinary Medicine
Contact: Name: Lisa Freeman
 Phone: (508) 887-4523
 Email: lisa.freeman@tufts.edu
Address: 200 Westboro Rd
 North Grafton
 Massachusetts
 01536
 United States

Sender Information: Name: Lisa Freeman

	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	Contact:	Phone:	5088874523	
		Email:	lisa.freeman@tufts.edu	
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Reported to Other Parties:	None			

Additional Documents:

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: 412374

Canine

B6 Years Old Male (Neutered) Labrador
Retriever

Black BW: Weight(lbs) 0.00

Cardiology Consultation

Date: 2/9/2018

Weight: Weight(lbs) 98

Patient location: ICU

Requesting Clinician: **B6** (Resident, Emergency & Critical Care)

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?

- Yes - in SS
 Yes - in PACS
 No

Presenting complaint and important concurrent diseases:

Difficulty breathing, increased heart rate and lethargy since last night after running in the afternoon.
Diagnosed with

Current medications and doses:

B6

Key indication for consultation: (murmur, arrhythmia, needs fluids, etc.):

In CHF - has arrhythmia, pulmonary edema, increased size of left ventricle and right atrium.
EKG: VPCs, Afib, tachycardia

Questions to be answered from the Consult:

Reasonable expectations for future and quality of life? Dog is very high energy and o has difficulty restraining.

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

- Yes (explain)
 No

Physical Examination

B6

Muscle condition:

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

Cardiovascular Physical Exam

Murmur Grade: difficult to auscult due to panting

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

Murmur location/description:

Jugular vein: difficult to assess due to panting

- 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:

General/2-D findings:

B6

Doppler findings:

1+ MR

ECG findings:

B6

Radiographic findings:

B6

Assessment and recommendations:

DCM with clinical signs consistent with CHF. We recommend continuing with B6 increasing B6 (if he is actually on a higher dose) given the concern of the renal values. We will recheck his arrhythmia on his 2 week recheck to decide at that time if an anti-arrhythmic medication is indicated when his heart failure is under control. We will also recheck his renal values at that time.

Final Diagnosis:

DCM with CHF and ventricular arrhythmia

Heart Failure Classification Score:

ISACHC Classification:

- Ia IIIa
- Ib IIIb
- II

ACVIM CHF Classification:

- A C
- B1 D
- B2

M-Mode

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

%FS

Ao Diam

LA Diam

LA/Ao

Max LA

B6

om
om
om
om
om
om
om
om
om
om

EPSS

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

{0.64 - 0.90} !

B6

2D

SA LA

cm

Ao Diam

cm

SA LA / Ao Diam

Doppler

AV Vmax

m/s

AV maxPG

mmHg

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4896

B6

Patient ID: 412374

B6

Canine

Years Old Male (Neutered) Labrador

Retriever

Black

Cardiology Appointment Report

Date: 2/21/2018

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student:

B6

V18

Presenting Complaint:

Recheck DCM with CHF

Concurrent Diseases:

None

General Medical History:

O thinks he is doing better. No more gagging like he was doing prior to ER visit. RR was 30-35 first few days after ER visit and now has been 20-25/min. More hesitant to go up stairs. No coughing or collapses. Appetite is good and normal eliminations. O thinks there is a secondary process happening in the neck. Has a mass on neck that has never been aspirated. Has a history of positional snorting/snoring. O interested in carnitine and CoQ-10. O interested in immuno-boosters.

Diet and Supplements:

Feeding kibbles (Canidae with duck or bison) with chicken breast and yams

B6

Cardiovascular History:

Prior CHF diagnosis? Yes

Prior ATE? No

Prior arrhythmia? Yes, episodes of VPCs, ventricular bigeminy

Cough? No

Shortness of breath or difficulty breathing? Increased RR/RE and gagging episodes

Syncope or collapse? No

Sudden onset lameness? No

Exercise intolerance? More hesitant to go upstairs

Prior heart murmur? Difficult to assess

Current Medications Pertinent to CV System:

B6

Need refills?

Cardiac Physical Examination:

B6

Muscle condition:

Normal

Mild muscle loss

Moderate cachexia

Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade: difficult to assess due to breathing and temperament

None

I/VI

II/VI

III/VI

IV/VI

V/VI

VI/VI

Murmur location/description:

Jugular vein: difficult to assess due to breathing and temperament

Bottom 1/3 of neck

Middle 1/3 of neck

Top 2/3rd of neck

Arterial pulses:

Weak

Fair

Bounding

Pulse deficits

- Good
- Strong

- Pulsus parvus
- Other:

Arrhythmias:

- None
- Sinus arrhythmia
- Premature beats

- Bradycardia
- Tachycardia

Gallop:

- Yes
- No
- Intermittent

- Pronounced
- Other:

Pulmonary assessments:

- Expansive
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

- Pulmonary crackles
- Wheezes
- Upper airway stridor

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension

- Mild ascites
- Marked ascites

Problems:

DCM with no active CHF

Upper airway noise: r/o nasal (neoplasia vs FB) vs laryngeal (lar par) vs tracheal mass

Diagnostic plan:

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

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

Echocardiogram Findings:

General/2-D findings:

not performed today

Assessment and recommendations:

Patient appears to be breathing comfortably. We will be rechecking his renal values today. The upper airway noise does not appear to be associated with the heart disease (RR remains in the 20s at home, and the video that the owner recorded showed him breathing comfortably and resting while making the snorting sound). This is likely an upper airway noise, which is also not related to the lipoma at the sternum. Continue with the current medication doses. Nutrition consultation is scheduled for tomorrow. Recheck echocardiogram, ECG, and renal values in 3-4 months.

Final Diagnosis:

DCM with history of LCHF

Heart Failure Classification Score:

ISACHC Classification:

- Ia

- IIIa

- Ib
- II

IIIb

ACVIM Classification:

- A
- B1
- B2

- C
- D

Discharge Instructions

Patient

Name: B6
Species: Canine
Black Male Doberman Pinscher
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: B6

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V19

Admit Date: B6 10:15 PM

Discharge Date: B6

Diagnoses:

Dilated Cardiomyopathy with Congestive Heart Failure

Case Summary:

Thank you for bringing B6 to the Tufts Cardiology Service for a recheck of his heart disease. We are happy to hear B6's appetite has recently improved at home, although he unfortunately does not enjoy his new diet.

Today we performed an electrocardiogram (ECG) to monitor his heart rate and rhythm. He has a normal rhythm and there was no evidence of an arrhythmia (abnormal rhythm). We also looked quickly at his chest and heart with the ultrasound and there was no evidence of free fluid in his chest, which is excellent!

As discussed, B6's taurine levels were normal, which means he does not require his taurine supplementation. If he is taking his supplementation readily, you may continue the supplementation if desired.

We also took a blood sample to monitor his kidney and liver values. We will call you with these results when they return, either later today or tomorrow, and recommend any needed changes to his medications. We hope that B6 continues to improve at home!

Monitoring at Home:

We would like you to monitor B6'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 within 30-60 minutes after giving extra 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/>).

Diet Suggestions:

We sent you home with Royal Canin Early Cardiac today. Please slowly mix this food in with his old food to transition his diet. We hope that he likes this food, but please contact us if you would like to try another diet (below are other possibilities).

Dry Food Options:

Royal Canin Early Cardiac (veterinary diet)

Royal Canin Boxer

Purina Pro Plan Adult Weight Management

Purina Pro Plan Bright Mind Adult Small Breed Formula

Canned Food Options:

Hill's Science Diet Adult Beef and Barley Entree

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

Royal Canin Mature 8+

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

Exercise Recommendations:

As B6 heart failure has improved, you may start taking him on longer leash walks. 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.

Continue Medications:

B6

Recheck Visits:

B6 will need a recheck in 3 months for an echocardiogram and bloodwork. We may also reassess his heart rhythm with an ECG at this appointment and a recheck echocardiogram.

Thank you for entrusting us with B6 care. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@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 (508-887-4629) 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/cvma/clinical-studies

Case: B6

Owner: B6

Discharge Instructions

B6

Patient ID: B6
B6 Canine
B6 Years Old Male Doberman Pinscher
Black

Cardiology Appointment Report

Date: B6

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6 V19

Presenting Complaint: Recheck DCM with CHF

Concurrent Diseases: Chronic skin issues

General Medical History:

Hospitalized from B6 for coughing and increased RR/RE - diagnosed with DCM and CHF. Doing well since last here. Owner tried to switch his food and adding in new food, but he won't eat the new food, spits out those pieces. Since getting home his appetite wasn't that great, but over the last 1-2 days his appetite has finally gotten back to normal. RR at rest is usually around 25 bpm. When sleeping and awake he is shaking more than he used to. His urine stream is much slower since he has been home. Urinating frequently (2-3 times overnight). Activity is normal, has always been "lazy" and hasn't changed.

Diet and Supplements:

New food - Purina Sensitive Skin and Stomach
Previous diet - Canidae

Cardiovascular History:

Prior CHF diagnosis? Y
Prior heart murmur? N
Prior ATE? N
Prior arrhythmia?

Monitoring respiratory rate and effort at home? Y

Cough? N

Shortness of breath or difficulty breathing? N

Syncope or collapse? N

Sudden onset lameness? N

Exercise intolerance? N

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination:

B6

Muscle condition:

Normal

Mild muscle loss

Moderate cachexia

Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

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

Murmur location/description: Right apical, systolic

Jugular vein:

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

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:

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

Abdominal exam:

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

Problems:

DCM with CHF
 History of Atrial fibrillation
 Grade III/VI Right sided systolic heart murmur

Differential diagnoses:

Murmur - r/o tricuspid regurgitation (secondary to DCM vs valvular disease) vs pulmonic stenosis

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: **Fluid check**

No evidence of pleural effusion.

ECG findings:

Normal sinus rhythm with no evidence of atrial fibrillation today.

Assessment and recommendations:

The patient has been doing well at home since the last appointment and the owner estimates that he is 85% back to his normal self. They tried switching him to the Purina sensitive skin and stomach but he didn't like the food and is back to his previous food. His RR and RE have been within normal limits and the owner do not have any issues giving the medications. Today, B6 looked very good! There was no pleural effusion and he remains in sinus rhythm. We submitted some bloodwork to reassess his kidney and liver values today and decide if we need to adjust any of his current cardiac medications. We also send him home with a bag of Royal Canin Early Cardiac diet. Recheck echocardiogram is recommended in 3 months or sooner if the patient develops clinical signs consistent with worsening heart disease.

Final Diagnosis:

- DCM with history of active CHF

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM Classification:

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

Discharge Instructions

Patient

Name: B6

Species: Canine

Blue Male (Neutered) Great Dane

Birthdate: B6

Owner

Name: B6

Address: B6

Patient ID: B6

Attending Cardiologist:

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

B6

Student: B6 V19

Cardiology Technician:

B6

Admit Date: B6

Discharge Date: B6

Diagnoses:

Dilated cardiomyopathy (DCM) with congestive heart failure

Clinical Findings:

Thank you for bringing B6 to Tufts Cardiology Service for recheck of his heart function. We're happy to hear that B6 is back to his baseline in terms of appetite and activity level. Keep up the good work! You report that B6 did have one episode of increased respiratory rate which led you to give an additional dose of furosemide.

We took the blood sample from B6 today and submitted it for kidney values as well as thyroid hormone level. We will call you (or leave a message as you may be on a vacation) and email you of the results once they get available. Until we get the result, please continue B6 on the current medication regimen.

We also did a quick electrocardiogram check of B6 heart, and we did not see previously noted VPC's. Which is good news!

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 Harley evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Diet Suggestions:

As discussed, we have talked to our nutritionist for low sodium diet that's appropriate for B6. They have recommended Purina ONE Smartblend Healthy Puppy Formula

(<https://www.chewy.com/purina-one-smartblend-large-breed/dp/37580>) for B6. We recommend giving 6 cups of this food per day total (so 3 cups in the morning and 3 cups in the dinner schedule works well). We understand this diet is indicated for puppies, but considering his need to gain weight, we think this diet is the best option while meeting the low sodium requirement of cardiac patients. Please monitor his weight regularly and increase the amount fed as needed.

You mentioned that you are using high calory syrup to coat medication for B6. We ask you to check the sodium content in that syrup and find a better alternative if the sodium level is too high. You can visit Tufts HeartSmart website for low sodium treat options.

You can start the supplements you've ordered for B6 anytime!

Exercise Recommendations:

You can take B6 for a longer walks. As discussed, dogs with heart disease are usually good at self-regulating the amount of exercise they get, so please do not push Harley if he seemed exhausted and tired.

Recommended Medications:

B6

Recheck Visits:

A recheck echocardiogram is recommended in 3-4 months. Please schedule this as soon as possible as our appointment slots tends to fill up very quickly and may need to be scheduled up to 4 months in advance. Please contact our Cardiology liaison, B6, at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Thank you for entrusting us with B6 care. He is such a good boy, and always a pleasure to work with!

Please visit our HeartSmart website for more information

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case: B6

Owner: B6

Discharge Instructions

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

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

Cardiology Inpatient

Date: 5/17/2018

Weight: Weight(lbs) 0.00

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?

B6

Presenting complaint and important concurrent diseases:

suspect CHF with enlarged heart, suspect DCM

Current medications and doses:

B6

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 Crackles
- Wheezes
- Upper airway stridor
- Other auscultatory findings:

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

Echocardiogram Findings:

B6

B6

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

B6

Once the patient is home and eating with a good appetite, then an

B6

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:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM CHF Classification:

- A
- B1
- B2
- C
- D

M-Mode

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

%FS

Ao Diam

LA Diam

LA/Ao

EPSS

B6

cm

cm

cm

cm

cm

cm

%

cm

cm

cm

cm

M-Mode Normalized

IVSdN
LVIDdN
LVPWdN
IVSsN
LVIDsN
LVPWsN
Ao Diam N
LA Diam N

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}!

2D

SA LA
Ao Diam
SA LA / Ao Diam
IVSd
LVIDd
LVPWd
EDV(Teich)
IVSs
LVIDs
LVPWs
ESV(Teich)
EF(Teich)
%FS
SV(Teich)
LVld A4C
LVEDV MOD A4C
LVls A4C
LVESV MOD A4C
LVEF MOD A4C
SV MOD A4C

B6

cm
cm

cm
cm
cm
ml
cm
cm
cm
ml
%
%
ml
cm
ml
ml
cm
ml
%
ml

Doppler

MR Vmax
MR maxPG
MV E Vel
MV DecT
MV A Vel
MV E/A Ratio
E'
A'
E/E'
PV Vmax
PV maxPG
TR Vmax
TR maxPG

m/s
mmHg
m/s
ms
m/s

m/s
m/s

m/s
mmHg
m/s
mmHg

Discharge Instructions

Patient

Name: B6

Species: Canine

Blue Male (Neutered) Great Dane

Birthdate: B6

Owner

Name:

Address:

B6

Patient ID: B6

Attending Cardiologist:

John E. Rush DVM, MS, DACVIM /Cardiology, DACVECC

B6

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 VPC's occurring side by side)

Labwork findings:

The kidney values are slightly elevated, but should be good enough to continue the current medication.

The results of the blood taurine 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 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 he 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:

- o 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.
- o 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.
- o An increase in breathing rate or effort will usually mean that you should give an extra dose of **B6** if difficulty breathing is not improved by within 30-60 minutes after giving extra **B6** then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- o There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- o We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- o If you have any concerns, please call or have Harley evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

Diet suggestions:

Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable - a sheet that has suggestions for low sodium treats can be found on the HeartSmart web site (<http://vet.tufts.edu/heartsmart/diet/>)

Because B6 had been fed a diet that is potentially deficient in taurine (amino acids 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 (50mg/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's care. Please contact our Cardiology liaison, B6 email us at cardiovet@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 (508-887-4629) 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/cvnc/clinical-studies

Case: B6

Owner: B6

Discharge Instructions

Radiology Request & Report

Patient

Name: B6

Species: Canine

Blue Male (Neutered) Great Dane

Birthdate: B6

Owner

Name:

Address:

B6

Patient #: B6

Date of request: 5/18/2018

Attending Clinician: B6

Student:

Date of exam: B6

Patient Location: B6

Weight (kg) 46.10

Sedation

- Inpatient
- Outpatient Time:
- Waiting
- Emergency

- BAG
- OBAG
- 1/2 dose OBAG
- DexDomitor/Butorphanol
- 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:

RIGHT LATERAL THORAX, TWO VIEWS. Compared to rDVM images in stringsoft.

The cardiac silhouette is mildly generally enlarged with the impression of being mildly smaller in size compared to the rDVM study. The cranial lobar vein remains mildly enlarged compared to the artery and the tertiary vessels within the caudodorsal lung field are more conspicuous than typically expected. The previously noted interstitial pattern has resolved. There are three ECG lead pads overlying the lateral thorax.

There are non-obstructive mineral opaque foci within the region of pylorus and intestines

cranioventrally. The visible osseous structures are normal.

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: 5/18/2018

Finalized:

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID: B6

B6

Canine

B6 years Old Male (Neutered) Caucasian

Shepherd Dog

Gray/Black

Cardiology Appointment Report

Date: 6/12/2018

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Intern:

B6

Cardiology Technician:

B6

Student:

B6

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:

B6

Muscle condition:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Normal | <input type="checkbox"/> Moderate cachexia |
| <input type="checkbox"/> Mild muscle loss | <input type="checkbox"/> Marked cachexia |

Cardiovascular Physical Exam:

Murmur Grade:

- | | |
|--|--------------------------------|
| <input checked="" type="checkbox"/> None | <input type="checkbox"/> IV/VI |
| <input type="checkbox"/> I/VI | <input type="checkbox"/> V/VI |
| <input type="checkbox"/> II/VI | <input type="checkbox"/> VI/VI |
| <input type="checkbox"/> III/VI | |

B6

Jugular vein:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Bottom 1/3 of neck | <input type="checkbox"/> Top 2/3 rd of neck |
| <input type="checkbox"/> Middle 1/3 of neck | |

Arterial pulses:

- Weak
- Fair
- Good
- Strong

- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other:

Arrhythmias:

- None
- Sinus arrhythmia
- Premature beats

- Bradycardia
- Tachycardia

Gallop:

- Yes
- No
- Intermittent

- Pronounced
- Other:

Pulmonary assessments:

- Eupneic - panting
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

- Pulmonary crackles
- 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:

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 at home monitoring of respiratory rate and effort. Recommend continuing on current B6. If not azotemic on bloodwork, increase B6 in the morning and B6 in the evening; monitor for signs of weakness or lethargy. Recheck echocardiogram recommended in 3-4 months or sooner if worsening clinical signs at home.

Final Diagnosis:

DCM with CHF (currently controlled on medications)

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM Classification:

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

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: **B6**

B6 Canine

B6 Years Old Male (Neutered)

Caucasian Shepherd Dog

Gray/Black BW: Weight (kg) 62.00

Cardiology Inpatient

Date: 5/29/2018

Weight: Weight (kg) 60.30

Requesting Clinician: **B6**

Attending Cardiologist:

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

B6

Presenting complaint and important concurrent diseases: Increased respiratory rate and effort for 1 day + recent history of cough (~2 wks). No exercise intolerance noted.

Current medications and doses:

B6

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

Physical Examination

B6

Muscle condition:

- Normal Moderate cachexia
 Mild muscle loss Marked cachexia

Cardiovascular Physical Exam

Murmur Grade:

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

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:

- 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

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:

B6

Final Diagnosis: DCM with CHF

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM CHF Classification:

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

M-Mode

IVSd	OM
LVIDd	OM
LVPWd	OM
IVSs	OM
LVIDs	OM
LVPWs	OM
%FS	%
Ao Diam	OM
LA Diam	OM
LA/Ao	
Max LA	OM
EPSS	OM

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	{0.64 - 0.90} !

2D

SA LA	OM
Ao Diam	OM

B6

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

B6

cm
cm
cm
ml
cm
cm
ml
ml
%
%
ml

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), DACVCP
B6

Cardiology Resident:

B6

Resident:

B6

Student:

Cardiology Technician:

B6

Admit Date: B6 6:55:16 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:

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

Recommended Medications:

B6

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 [B6] 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 [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. 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 [B6] 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 [B6] care. Please contact our Cardiology liaison [B6] or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case:

[B6]

Discharge Instructions:

Discharge Instructions

Patient

Name: B6

Species: Canine

Gray/Black Male (Neutered) Caucasian

Shepherd Dog

Birthdate: B6

OwnerName: B6
Address: B6

Patient ID: B6

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

B6

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. 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.

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

Diet Suggestions:

Continue to transition [B6] over to the 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 [B6] 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 [B6] 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 web site (<http://vet.tufts.edu/heartsmart/diet/>).

Exercise Recommendations:

As it appears that [B6] heart failure is better controlled, slightly longer walks on a leash 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.

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] dose.

2. We have scheduled a recheck visit for September 4, 2018 at 1:00pm 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 Pennsylvania 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 cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

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

Prescription Refill Disclaimer:

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

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Clinical Trials:

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

Case:

[B6]

Discharge Instructions

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6

B6

Canine

B6 Years Old Male (Neutered) Great Dane
Black BW: Weight (kg) 71.60

Cardiology Consultation

Date: B6

Weight: Weight (kg) 71.60

Requesting Clinician: Unassigned Clinician

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

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:

B6

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.)

Afib on EKG

Decreased contractility on TFAST

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 murmur

Jugular vein:

- Bottom 1/3 of the neck to
- 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

Echocardiogram Findings:

B6

ECG findings: Rapid irregularly irregular rhythm consistent with atrial fibrillation.

Assessment and recommendations: Findings consistent with advanced DCM with active CHF. Severe LV dilation with systolic dysfunction is observed. **B6** are recommended. Tachycardic irregularly irregular consistent with AFib worsens CHF as decrease overall cardiac output from loss of atrial contraction and fast ventricular rate. **B6**

B6

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:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM CHF Classification:

- A
- B1
- B2
- C
- D

M-Mode

IVSd	B6	cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
%FS		%
Ao Diam		cm
LA Diam		cm
LA/Ao		
EPSS		cm
Max LA		cm

2D

Ao Diam	B6	cm
IVSd		cm
LVIDd		cm
LVPWd		cm
IVSs		cm
LVIDs		cm
LVPWs		cm
EF(Cube)		%
%FS		%
SA LA		cm

Doppler

MR Vmax	B6	m/s
MR maxPG		mmHg
AV Vmax		m/s
AV maxPG		mmHg
TR Vmax		m/s
TR maxPG		mmHg

Report Details - EON-363365		
ICSR:	2054221	
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:	2018-08-24 18:09:51 EDT	
Reported Problem:	Problem Description:	Previously healthy dog. Eating Petcurean Go Limited ingredient dry primarily. Also, some Petcurean Now Fresh, Stella and Chewy Raw patties, lean treats, Wellness Core treats. Had been on Petcurean Now Fresh lg breed puppy initially. See nutrition consultation for full diet history. Dilated cardiomyopathy diagnosed with low taurine level. DCM reversed after diet change and taurine and carnitine supplementation. Note: maxed out on attachments - will send more by email. Also, I am submitting this report in collaboration with B6 ; I will submit a small sample of dog's food when I ship other food samples on 8/27/18
	Date Problem Started:	06/19/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering
Product Information:	Product Name:	Petcurean Now Fresh
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name:	Petcurean Limited Ingredient Salmon Dry
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Product Use Information:	Description: Fed daily
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Boxer (German Boxer)
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	31.5 Kilogram
	Age:	2 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	Owner Information Yes

		provided:																									
		<table border="1"> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td>B6</td> </tr> </table>	Contact: Name:	B6	Phone:		Email:	B6																			
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Description: Diet history

Type: Other

Client: **B6**
 Veterinarian: **B6**
 Patient ID: **B6**
 Visit ID: 2492791

Patient: **B6**
 Species: Canine
 Breed: Doberman
 Sex: Male (Neutered)
 Age: **B6** Years Old

Lab Results Report

Chemistry 21 (Cobas)		B6	1:29:21 PM	Accession ID: B6
Test	Results	Reference Range	Units	
GLUCOSE	B6	67 - 135	mg/dL	
UREA		8 - 30	mg/dL	
CREATININE		0.6 - 2	mg/dL	
PHOSPHORUS		2.6 - 7.2	mg/dL	
CALCIUM2		9.4 - 11.3	mg/dL	
T. PROTEIN		5.5 - 7.8	g/dL	
ALBUMIN		2.8 - 4	g/dL	
GLOBULINS		2.3 - 4.2	g/dL	
A/G RATIO		0.7 - 1.6		
SODIUM		140 - 150	mEq/L	
CHLORIDE		106 - 116	mEq/L	
POTASSIUM		3.7 - 5.4	mEq/L	
NA/K		29 - 40		
T BILIRUBIN		0.1 - 0.3	mg/dL	
D.BILIRUBIN		0 - 0.1	mg/dL	
I BILIRUBIN		0 - 0.2	mg/dL	
ALK PHOS		12 - 127	U/L	
ALT		14 - 86	U/L	
AST		9 - 54	U/L	
CHOLESTEROL		82 - 355	mg/dL	
OSMOLALITY (CALCULATED)	291 - 315	mmol/L		
COMMENTS (CHEMISTRY)	0 - 0			

Cummings

Veterinary Medical Center

AT TUFTS UNIVERSITY

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

Patient

Name:

B6

Signalment:

B6 Years Old Red/White Male
(Neutered) English Cocker
Spaniel

Owner

Name:

Address:

B6

Patient ID:

B6

Contact Clinician:

B6

Alternate Clinician:

Student:

B6

V19

RE-EXAMINATION FORM

Date: 1/22/2019

Problem: Ortho Recheck:

B6

History:

Thank you for bringing B6 to the Tufts Orthopedic Surgery Service for recheck radiographs (x-rays B6 B6 B6). B6 presented to the Tufts ER on B6 after he was hit by a car. Pelvic radiographs showed B6 fractures B6 underwent surgery of B6.

You report that he is doing well at home, and is standing up and walking well. B6 also has a history of B6 which is managed by our neurology service. He has an episode of B6 and had one seizure since then on 1/10/19.

Physical Examination:

B6

Diagnosis/conclusions: B6 was ambulatory on all four legs, and appeared much more stable when walking than on his last recheck.

Procedures Performed & Future Plans:

Today B6 had a consult with our Cardiology department to evaluate his heart murmur prior to being sedated for radiographs. Cardiology found that B6 has 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. This disease can be attributed to several factors; one potential cause of DCM is diet, especially diets that are grain-free or contain exotic ingredients. Based on B6 current diet and the findings of his cardiology evaluation, we recommend switching B6 diet; some recommendations are listed below. At this time B6 does not require any medications for his heart disease; however we recommend rechecking an echocardiogram (ultrasound of the heart) in 3 months. We also recommend starting B6 on a Taurine supplement, which may help the heart muscle. You have elected to enroll B6 in a study relating diet and dilated cardiomyopathy in dogs.

B6 was sedated and

B6

B6

surgery. We will contact you with the results of the radiographs when we receive them.

Today we also drew blood to check B6 level. His level today was B6 which is higher than his previous level, but is within the reference range.

Medications:

B6

Home Instructions:

1. Activity Restriction: Since B6 radiographs look good we can begin to loosen his exercise restrictions. Since B6 has had decreased activity for the past few weeks, we want to gradually build up his exercise tolerance. You can gradually increase the length of his walks by 5 minutes every two weeks, until his next recheck.

2. Diet: The FDA is currently investigating an apparent association between diet and dilated cardiomyopathy. The exact cause is still unclear, but it appears to be associated with boutique diets and those containing exotic ingredient or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets. We recommend switching B6 to commercial diet made by a well-established company that is not grain-free and does not contain any exotic ingredients, such as kangaroo, duck, lamb, venison, lentils, peas, beans, buffalo, tapioca, barley, and chickpeas. The FDA issued a statement regarding this issue (<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucom613305.htm>) and a recent article published by Dr. Lisa Freeman on the Cummings School's Petfoodology blog can further explain these findings (<http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/>).

Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease.

Dry Food Options:

- Royal Canin Early Cardiac (veterinary diet)
- Royal Canin Bxer
- Purina Pro Plan Adult Weight Management
- Purina Pro Plan Bright Mind Adult Small Breed Formula

Canned Food Options:

- Hill's Science Diet Adult Beef and Barley Entree
- Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
- Royal Canin Mature 8+

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

We would like to see B6 back for a surgery recheck in 6 weeks. Please contact the Surgery Liaison at (508) 887-4794 to arrange your next appointment. If you have any problems or questions, please contact B6 DVM, MS, DACVS IA, DACVS SA as soon as possible. If it is an emergency, contact the emergency service at (508) 887-4623.

We have scheduled a recheck for B6 with our Cardiology service on Tuesday, 4/23/19 at 11:30am. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiovet@tufts.edu if you need to reschedule this appointment, or if you have any non-emergent questions or concerns.

You can schedule an appointment with our Nutrition service by calling 508-887-4696.

Prescription Refill Disclaimer:

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

Ordering Food:

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

prescription/veterinary approval

Clinical Trials:

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

Case: B6

Owner: B6

Discharge Instructions