CASE SUMMARY

DIAGNOSIS:
1. Dilated cardiomyopathy (DCM): rule out diet induced vs hypothyroidism vs primary (idiopathic)

HISTORY:
B6 is an approximately 4 year old female spayed mixed breed dog who was presented to B6 Cardiology on B6 for evaluation of a new heart murmur and suspected dilated cardiomyopathy.

B6 was presented to B6 on 10/2/18 for a wellness exam and annual bloodwork, and a new II/VI left apical systolic murmur was noted on physical exam. B6 CBC showed mild thrombocytopenia (121k on automated count), and no abnormalities on serum chemistry. B6 was then presented to B6 on 10/13/18 for a reevaluation of her murmur. Chest radiographs revealed generalized moderate to severe cardiomegaly with normal pulmonary vasculature and lung fields. A limited ultrasound of the heart reportedly revealed dilation of all four heart chambers with poor myocardial contractility. B6 was then referred to B6 Cardiology for suspected grain-free diet related DCM. Her diet was switched to Purina ProPlan dry kibble and she was started on taurine (500 mg PO BID) and L-carnitine supplementation (1g PO BID). For the last 3 months, B6 has had an occasional single dry, non-productive cough once weekly when playing with her puppy housemate. B6 has not experienced any lethargy, decreased appetite, exercise intolerance, respiratory distress or fainting. B6's resting respiratory rate has been between 13 to 24 breaths per minute since 10/13/18.

B6 was adopted from a shelter in B6 three years ago and was estimated to be one year old at that time. B6 experienced diarrhea and vomiting in the first 2 months after adoption and was started on a grain-free, chicken-free diet. B6 diarrhea and vomiting resolved after the diet switch. Her diet history is as follows: Nature's Variety Instinct Limited Ingredient Lamb (11/2015 - 11/2017); Blue Buffalo Turkey + Potato or Lamb + Potato (11/2017 - 8/2018); American Journey Lamb + Sweet Potato Limited Ingredient Grain-Free (8/2018 - 10/2018). B6 has had no other significant medical history since adoption and is not on any prescription medications. She is eating, drinking, urinating and defecating normally and has had no episodes of vomiting. B6 is on Heartgard and Nexgard parasite prevention and up to date on all vaccines.

Current Diet: Purina Pro Plan Adult Lamb and Rice - dry kibble
Current Medications: None
Current Supplements: Taurine 500mg q12hr (GMC brand tablets), L-carnitine 1000mg q12hr (GMC brand tablets)

PHYSICAL EXAM FINDINGS:

RESULTS OF DIAGNOSTIC TESTS:
B6

PENDING DIAGNOSTIC TESTS:

B6

ASSESSMENT:

Thank you for entrusting us with [B6] today. Today, [B6] was diagnosed with dilated cardiomyopathy (DCM). DCM is a disease that affects the muscle of the heart and causes a decrease in the contractility (pumping ability) of the heart. Because the heart is unable to pump with enough force to move blood adequately forward into circulation, a volume overload occurs and the heart dilates to accommodate it. Subsequently, the chambers of the heart become enlarged and the mitral valve leaflets are pulled slightly apart, resulting in back-flow of blood (mitral regurgitation) and the heart murmur auscultated on [B6] physical exam. [B6] echocardiogram today showed mild to moderate dilation of her heart chambers, mild mitral valve regurgitation, and mildly diminished pumping ability of her heart.

While the exact mechanism of DCM is currently unknown, dietary deficiencies in the amino acids taurine and carnitine, genetics, infectious and inflammatory conditions, and toxins have all been linked to DCM. Since B6 is an atypical breed to develop primary (hereditary) DCM and has been on a grain-free diet for the last 3 years, we are concerned for a possible diet-associated DCM. This is a diagnosis of exclusion, so to rule out other causes, blood was drawn today for a troponin level and for thyroid testing. Troponin is a biomarker for damage to the muscle of the heart and is elevated in cases of myocarditis, which can be caused by many things including infectious or inflammatory disease. [B6] troponin level was normal, so an infectious or inflammatory cause of her DCM is unlikely. Thyroid testing was also submitted today, as hypothyroidism can be another cause of DCM.

There has been recent unpublished data suggesting a link between some grain-free diets and cardiomyopathy. Although some of these cases seem related to taurine/carnitine deficiency, others do not, and the reason for this link is not yet clear. Although the mechanism has not been confirmed, one hypothesis is that phytic acid, produced by legumes and lentils (common ingredients in grain-free diets) decreases the absorption of taurine and other essential nutrients from the intestines into the bloodstream. Some animals will show reversibility of their heart disease with supplementation of taurine and carnitine and initiation of a grain-containing diet.

INSTRUCTIONS FOR CARE
B4, B6

In order to help expedite medication refills, please visit us online at [B4, B6] and select Pet Owners Pharmacy Refills.
Admission date: Wednesday, October 17, 2018

Reason for visit: Murmur evaluation, suspect dilated cardiomyopathy (DCM)

Diagnosis/Problem: Dilated cardiomyopathy, suspect diet related

Treatments and diagnostic tests performed: Troponin level (pending), taurine level (pending), T4/TSH (pending), platelet count, echocardiogram

Medications: _______________________________________________________________________________________________________________________________________________________________________________________________________________

Instructions for care: Continue to monitor ___ B6 ___ for increased respiratory rate and effort, exercise intolerance, fainting, lethargy, decreased appetite, coughing, and abdominal distension. If you note any of these signs, ___ B6 ___ should be evaluated by a veterinarian immediately. Continue to monitor ___ B6 ___ resting respiratory rate by counting her number of breaths per minute while she is laying down or sleeping. A normal resting respiratory rate for a dog is less than 30-40 breaths per minute.

Plan for next evaluation: Please schedule an appointment with ___ B4, B6 ___ Cardiology in 3 months by calling ___ B4, B6 ___

Thank you for allowing us to care for you and your pet. If you have any questions or concerns, please do not hesitate to call the ___ B4, B6 ___ Cardiology Service at ___ B4, B6 ___. For prescription refills, ____________

Owner requests full report (Full Summary Automatically Sent To Primary DVM)

This is the full report to be sent to the primary DVM

Faculty: ___ B4, B6 ___

Residents: ___ B4, B6 ___

Clinical Technicians: ___ B4, B6 ___

Research Technician: ___ B4, B6 ___

Client Services: ___ B4, B6 ___
# Endocrinology

## Endocrine Results

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L = Low Result; H = High Result; ⊗ = Critical Result; ^ = Corrected Result; ★ = Interpretive Data; # = Result Footnote
Date: 10/10/18

Current diet:

Brand: American Journey Lamb & Sweet Potato

Variety: Limited Ingredient Grain-Free

Is this diet Grain-free? Yes

How long has your pet eaten this food? 3 months (Aug 18 - Oct 18)

Are there other pets in your house eating this food? Yes, puppy version for 5 mo.

Other diets eaten in the last 3 years and dates:

(Nov 17-Nov 18) Blue Buffalo - different versions of basic, lifesource 4 freedom (mostly basics)
(Nov 15-Nov 17) Nature's Variety Instinct Limited Ingredient Lamb

- First 2 months after adoption tried 2 or 3 foods that caused major diarrhea & vomiting so claimed allergic to chicken and started on grain-free, chicken-free diet. No more D or V.

Other food (treats, rawhides, table food):


- Have given Better Belly chews, dental chews (mile bone, proinext, Nylabone NutrDent)

Supplements (e.g. fish oil, CoQ10, vitamins etc) None.
Would like referral for echocardiogram ASAP. Suspect grain-free diet related DCM. Client amenable to referral. On grain free diet past 3-4 years. New heart murmur first noted last week at a different veterinary office. Seen today by our hospital first time for second opinion. Grade 2-3/6 L systolic murmur, NSR. Respiratory: WNL, no crackles/wheeze. Eupnic. Does not appear to be in CHF. Not currently on any medications aside from Nexguard and Heartguard. Advised Taurine 500mg PO BID and L carnitine-1 gram PO BID and change to diet containing grains while awaiting echo. Discussed monitoring for signs of impending CHF and when to seek emergency care.

Chest rads- Generalized moderate to severe cardiomegaly. Lungs appear WNL.

Brief cardiac US (by me)- All 4 chambers appear subjectively enlarged/dilated. Myocardium appears subjectively thin with POOR contractility. No pericardial effusion detected. Suspect DCM.
Patient History Report

Clinic: B6

Patient: B6

ID: B6

Tag: B6

Species: Canine, Mixed breed

Sex: female/spayed

Age: 4 yrs, DOB B6

Weight: 35.7 lbs

Color: Black/tan markings

Last visit: 10/13/2018

Referred By:

Tel: Fax

Medical Record Entries:

10/15/2018

Referral - SW[B6] fit into red slot- 1 month

-save diet and bring in to appointment - Change diet to one with grain in it

Taurine - 40mg/kg 640mg/day (250 and 500mg, too)

Consultation with specialist - Sent to Cardiology:

Wish like referral for echocardiogram - B6 PASAP; suspect grain-free diet related DCM. Client unable to refer. On grain-free diet past 3-4 years. New heart murmur first noted last week at a different veterinary office. Seen today by our hospital first time for second opinion. Grade 2/6 systolic murmur, NSR. Respiratory: WNL, no rales/bruits. Does not appear to be in CHF. Not currently on any medications except for Heartguard and Nexgard. Advanced Taurine 640mg PO BID and L-carnitine - 1 gram PO BID and change to diet containing grains while awaiting echo. Discuss periodic monitoring for signs of impending CHF and when to seek emergency care.

Consultation with specialist - Cardiology:


Bloodwork performed recently by another vet hospital - WNL per owner (Copies unavailable today - Saturday).

Ultrasound Consult Fee - Cardiac US. All 4 chambers appear subjectively
enlarged/dilated. Myocardium appears subjectively thin with poor contractility. No pericardial effusion detected. Suspect DCM.

**Radiographs Two Views -** 3 view thorax. Generalized moderate to severe cardiomegaly. Lungs appear WNL. Suspect DCM.

**Weight in lbs.** 35.7

**Examination/Office Call**

Chief Complaint: second opinion, heart murmur

History: 2nd opinion - heart murmur. Adopted approx. 2 years ago, think she was around 3 months at time of adoption. Pretty healthy past few months - had diarrhea occasionally in first year, improved once she eliminated chicken and grains from the diet. 1 week ago - diagnosed with a heart murmur for the first time at B6. Prior to that, has been to multiple vets and they have never mentioned a heart murmur. Occasionally coughs, mostly when excited (when pulling on the leash/collar, but also sometimes when playing off-leash).

Diet: American Journey Salmon and sweet potato (grain-free). Has always been on a grain-free diet.

On Heartguard and Nexguard. Gives every month, regularly.

**B6**

**MIXED BREED**

**Owner**

**Patient History Report** 10/13/2018 - B6
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B6

10/02/2018

SOAP Wellness Visit

S: Presenting Complaint: B6 is here for a wellness exam. Current on vaccines, no concerns, E/D ok, no WD

M: Medications received: None

P: Preventatives received: Nexgard and Heartgard

D: Diet: American Journey

O: Weight: 35.6 lbs

PHYSICAL EXAM

B6

DIAGNOSTICS

CBC/Chem: NSF

A: Healthy pet. Murmur very mild and not a concern at this time

P: Dental cleaning will be important for maintaining heart health

10/02/2018 Lab Value Temperature: 101.20

10/02/2018 Service Exam - Pet Wellness QTY 1 Provider: B6

Comprehensive Diagnostic

10/02/2018 02:51 PM

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TBIL
BUN
CA
PHOS
CRE
GLU
NA+
K+
TP
GLOB

0.01-0.6 mg/dL
7.25 mg/dL
8.6-11.8 mg/dL
2.2-6.6 mg/dL
0.3-1.4 mg/dL
60-110 mg/dL
138-190 mmol/L
3.7-5.6 mmol/L
5.4-6.2 g/dL
2.3-5.2 g/dL

Abaxis VetScan HMS
10/02/2018 02:45 PM

WBC
RBC
HGB
HCT
MCV
MCH
MCHC
PLT
PCT
MPV
PDWs
PDWc
RDWs
RDWc
LYM
MON
NEU
LY%
MO%
NE%
EOS
EO%
BAS
BA%

6.00-17.00 x 10^9/L
5.50-8.50 x 10^12/L
12.0-18.0 g/dL
37.00-65.00 %
6.0-77 ll
19.5-24.5 pg
31.0-39.0 g/dL
185-500 x 10^9/L
3.9-11.1 ll
5.0-15.0 ll
3.00-12.00 x 10^9/L
14.0-20.0 %
1.00-4.60 x 10^9/L
0.20-1.50 x 10^9/L
0.00-0.60 10^9/L
0.00-0.40 10^9/L

Page 3 of 5

10/15/2018 11:30AM (GMT-04:00)
B6

WBC Hist

RBC Hist

EOS Hist

PLT Hist

09/25/2018  LINK Records Cont.

09/25/2018  LINK Records

B6 CANINE

B6 MIXED BREED DOG

B6 BLACK & TR

B6

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Provider: B6

B6: CANINE: MIXED BREED DOG
BLACK & TA

Page 1 of 2

10/15/2018 11:35AM (GMT-04:00)
**SOAP**

**Wellness Visit**

**S:** Presenting Complaint: B6 is here for a wellness exam. Current on vaccines, no concerns. E/D ok, no V/D

**Medications received:** None

**Preventatives received:** Nexgard and Heartgard

**Diet:** American Journey

**O:** Weight: 35.6 lbs

**PHYSICAL EXAM**

**DIAGNOSTICS**

CBC/Chem: NSF

**A:** healthy pet, murmur very mild and not a concern at this time

**P:** dental cleaning will be important for maintaining heart health

---

**Lab Value**  
**Temperature:** 101.2°F

**Service**  
**Exam - Pet Wellness**  
**QTY:** 1

**Provider:** B6

---

**LINK**  
**Records Cont.**

**09/25/2018**

---

**LINK**  
**Records**

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For any questions on B6's health, please call B6.
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Patient History Report

Client: B6
Phone:
Address:

Species: Canine
Age: 3 yrs. 8 mos.
Color: Black/Tan
Sex: Spayed Female
Breed: Mixed

Date Type Staff History

7/30/2018 P B6

7/27/2018 P B6

Signed Consents - TENTATIVE

7/23/2018 TC B6

Signed Estimate/Drop Off - TENTATIVE

7/20/2018 TC B6 PDVM - TENTATIVE B6

CANINE VACCINES & LAB- ** Please type below when vaccines or tests were actually Given at B6 - Not when they are due **

*** RECEPTION FULL NAME (NOT YOUR INITIALS) OF WHO PUT IN PDVM OF DATES VACCINES GIVEN : B6

10/15/2018 11:35AM (GMT-04:00)
## Patient History Report

**Client:**

**Phone:**

**Address:**

**Patient:** B6

**Species:** Canine

**Age:** 3 Yrs. 8 Mos.

**Sex:** Spayed Female

**Breed:** Mixed

**Color:** Black/Tan

### Staff History

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**Reason for visit:** O lacerated L cranial flank fold while grooming

**DVM:**

**Wt:** 35.2

**Exam:**

**Test:**

**Date:** 8/29/2018 6:37 PM
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**Patient History Report**

**Client:**

- **Address:**

**Patient:** B6

- **Species:** Canine
- **Age:** 3 Yrs. 8 Mos.
- **Color:** Black/Tan
- **Species:** Canine
- **Breed:** Mixed
- **Sex:** Spayed Female
- **Date:** 8/29/2018

**Temp/Pulse/Resp:** 101.8 / 130 / 40
**Patient History Report**

**Client:**
- **Phone:**
- **Address:**

**Patient:** B6
- **Species:** Canine
- **Age:** 3 Yrs, 8 Mos.
- **Color:** Black/Tan

**Breed:** Mixed
- **Sex:** Spayed Female

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<tr>
<td>7/19/2018</td>
<td>V</td>
<td>B6</td>
<td></td>
</tr>
</tbody>
</table>

- **7/19/2018 B**
- **7/19/2018 B**
- **7/19/2018 B**
- **7/19/2018 B**
- **7/19/2018 B**
- **7/19/2018 B**
- **7/19/2018 B**
- **7/19/2018 B**

**10/15/2018 11:35AM (GMT-04:00)**

FDA-CVM-FOIA-2019-1704-001631
Patient History Report

Patient: B6
Species: Canine
Age: 3 Yrs. 8 Mos.
Color: Black/Tan
Breed: Mixed
Sex: Spayed Female

Date Type Staff History
8/1/2016 C B6 RR - FINAL 08/01/2016

7/30/2016 C B6 Canine Exam - CLOSED 08/29/2016

To be completed by Technician

Reason for visit: to establish relationship for Bravecto
History (Subjective):

To you/your pet, having any problems?


To be completed by DVM

Exam (Objective):

Nose and Throat
- Normal
- Did Not Exam
- Abnormal Remarks:

Mouth/Teeth/Gum
- Normal
- Did Not Exam
- Abnormal Remarks:

Eyes and Ears
- Normal
- Did Not Exam
- Abnormal Remarks:

Cost and Skin
- Normal
- Did Not Exam
- Abnormal Remarks:

Lymph Nodes
- Normal
- Did Not Exam
- Enlarged Remarks:
- Abnormal Remarks:

Musculoskeletal
- Normal
- Did Not Exam
- Nail Trim
- Abnormal Remarks:
Patient History Report

Client: 
Phone: 
Address: 

Patient: B6
Species: Canine
Age: 
Color: Black/Tan
Breed: Mixed
Sex: Spayed Female

Date Type Staff History

<table>
<thead>
<tr>
<th>Nervous System</th>
<th>Heart and Lungs</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Normal [ ] Did Not Examine</td>
<td>[ ] Normal [ ] Did Not Examine</td>
</tr>
<tr>
<td>[ ] Abnormal Remarks:</td>
<td>[ ] Heart Murmur Grade [ ] Murmur Comments:</td>
</tr>
<tr>
<td>[ ] Abnormal Remarks:</td>
<td>[ ] Abnormal Remarks:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GI Tract/Abdomen</th>
<th>Urinary and Genitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Normal [ ] Did Not Examine</td>
<td>[ ] Normal [ ] Did Not Examine</td>
</tr>
<tr>
<td>[ ] Abnormal Remarks:</td>
<td>[ ] Abnormal Remarks:</td>
</tr>
</tbody>
</table>

To be Completed by DVM (Unless they are really backed up)

Vital Signs:

To be completed by Technician

Wellness Services:

Rabies: 1 yr [ ] 2yr [ ] Retag [ ] [ ] UTD [ ] Declined [ ]
DHPP: 1yr [ ] 2yr [ ] [ ] [ ] UTD [ ] Declined [ ]
Lepto: [ ] Annual [ ] UTD [ ] Declined [ ]
Bordetella: [ ] 1yr [ ] UTD [ ] Declined [ ]

Note: Don't forget the Accept or Declined boxes!

To be completed by DVM:

Assessment: Add Diagnoses Description

healthy pet

Plan: examination for Bravecto, will have vx as a tech appt in a couple months.

NT today.

7/30/2016 P B6

1.00 pack of Bravecto Chews > 22.0 lbs (1534)
Rx #: 31588 0 Of 0 Refills Filled by: [ ] B6
Give 1 chew by mouth every 12 weeks for prevention of fleas and ticks. GIVE WITH FOOD. FOR VETERINARY USE ONLY. KEEP OUT OF REACH OF CHILDREN.
# Patient History Report

**Client:**
- Name: [Redacted]
- Phone: [Redacted]
- Address: [Redacted]

**Patient:** B6
- **Species:** Canine
- **Age:** 3 Yrs., 8 Mos.
- **Color:** Black/Tan
- **Breed:** Mixed
- **Sex:** Spayed Female

<table>
<thead>
<tr>
<th>Date</th>
<th>Type</th>
<th>History</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/30/2016</td>
<td>C</td>
<td>B6</td>
</tr>
<tr>
<td>7/30/2016</td>
<td>B</td>
<td>B6</td>
</tr>
<tr>
<td>7/30/2016</td>
<td>V</td>
<td>B6</td>
</tr>
</tbody>
</table>

## CANINE VACCINES
- DHPP: Date Given: 09/24/2015
- DHPP Booster: Yes
- DHPP: Date Given: 09/24/2015
- DHPP Booster: Yes
- DHPP: Date Given: 09/24/2015
- DHPP Booster: Yes
- DHPP: Date Given: 09/24/2015
- DHPP Booster: Yes

## CANINE RABIES
- Date Given: 09/24/2015
- Mr: Boehringer Ingelheim
- Date Given: 09/24/2015
- Mr: [Redacted]

## LEPTO
- Date Given: [Redacted]
- Date Given: [Redacted]

## BORDETELLA
- Date Given: 09/24/2015
- Intranasal: Yes
- Oral: Yes
- Injectable: Yes

## LAB/HYGIENE
- DEWORMING
  - Date Given: 09/24/2015
  - Type: Pyrantel Pamoate
  - Date Given: [Redacted]
  - Type: [Redacted]

- FECAL
  - Date Given: [Redacted]
  - Negative: [Redacted]
  - Positive: [Redacted]

## CANINE HEARTWORM TEST
- Date Given: 09/24/2015
- Negative: [Redacted]
- Positive: [Redacted]
Patient History Report

Client:  
B6

Patient:  
B6
Species: Canine

Breed: Mixed  
Age: 3 Yrs. 8 Mos.  
Sex: Spayed Female  
Color: Black/Tan

Date  Type  Staff  History  
7/30/2016 B  B6  
7/30/2016 B  B6  
7/30/2016 B  B6  
7/19/2016 V  B6  

Weight: 35.00 pounds

B6

Page 9 of 9  Date: 8/29/2018 6:37 PM

FDA-CVM-FOIA-2019-1704-001635
### Reminder Letter Report

Sorted by Client ID

<table>
<thead>
<tr>
<th>Client ID</th>
<th>Client Name</th>
<th>Report ID</th>
<th>Report Date</th>
<th>Rep. Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>B6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Canine Echocardiography Report

Patient Name: B6
Medical Rec #: 231020
DOB: 23/10/20
Age: 3 years
Sex: F
Sonographer: B4, B6

Date of Exam: B6
Breed: Mixed breed
Weight: 16 kg
BSA: 0.64 m²
HR: BP-sys:

Report Status: READ
Diagnosis: Suspect Grain Free Diet Associated DCM, Decreased left ventricular systolic function; Left ventricular dilation
Study Details: 2D Echo/Doppler/Color Doppler. The images were of adequate diagnostic quality. The patient was awake.

Additional Comments:
Dog presents for asymptomatic heart murmur.

Normal Canine M-mode values (in cm) for 15 kg dogs.

Tissue Doppler: E', A'
Aortic Valve:
VMax
Pk Grad
AoV

Mitral Valve:
Mn Grad
P1/2T
MV Area

Tricuspid valve:
TV E Max
TV Mn Grad
P 1/2 T
TV VTI

Pulmonic valve:
Vmax
Pk Grad
PV AT
PV ET
PV AT/ET

CLINICIAN INTERPRETATION:

ECHO SUMMARY:

CV Exam:
Cardiac auscultation revealed a systolic murmur of grade II-III/VI intensity loudest at the left apex.

Radiographs:
RDVM radiographs. No evidence of pulmonary edema. Left sided cardiomegaly.

Recommendations: Cause of dog's murmur is Mitral valve insufficiency due to MV annular stretch. MV anatomy is normal.
Since B6 is an atypical breed for DCM and has been on grain free diet for last 3 years, we are concerned for possible diet associated DCM. Other causes are possible such as idopathic, infectious/inflammatory, ischemic or hypothyroidism. Cardiac troponin and thyroid testing are pending. Blood for infectious disease has been banked if troponin is markedly elevated. Taurine concentrations are also pending but dog has been on new diet and taurine for last 4-5 days.

Recommend continuing with taurine 40 mg/kg per day and carnitine. Suggest adding pimobendan 5 mg am, 2.5 mg pm and recheck echo in 3 months. If changes are reversible then diet associated DCM is likely cause.
All Medical Records

Species: Canine
Sex: Male (Neutered)

Breed: Golden Retriever

B6

Referring Information

Initial Complaint:
Scanned Record

Initial Complaint:
New B6 DCM study

SOAP Text B6 12:08PM B6

Disposition/Recommendations
**Cummings Veterinary Medical Center**

### Lab Results Report

**Species:** Canine  
**Breed:** Golden Retriever  
**Sex:** Male (Neutered)  
**Age:** 10 Years Old

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>Reference Range</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Troponin I Research - FHSA</td>
<td>B6</td>
<td>0 - 0.08</td>
<td>mg/dl</td>
</tr>
</tbody>
</table>

Printed Friday, 3/22
B6
ECG from cardio
All Medical Records

Client: B6
Patient: B6
Address:

Breed: Boxer
DOB: B6
Species: Canine
Sex: Male (Neutered)

Referring Information

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: **B6**

Veterinarian: **B6**

Patient ID: 433149

**Lab Results Report**

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>Reference Range</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Troponin I Research - FHSA</td>
<td><strong>B6</strong></td>
<td>0 - 0.08</td>
<td>mg/dl</td>
</tr>
</tbody>
</table>

Printed Tuesday, December 04, 2018
B6
CARDILOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet'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)

   Example: Poor | Excellent

   Poor

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.

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

<table>
<thead>
<tr>
<th>Food (include specific product and flavor)</th>
<th>Form</th>
<th>Amount</th>
<th>How often?</th>
<th>Fed since</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutro Grain Free Chicken, Lentil, &amp; Sweet Potato Adult</td>
<td>dry</td>
<td>1 1/2 cup</td>
<td>2x/day</td>
<td>Jan 2018</td>
</tr>
<tr>
<td>85% lean hamburger</td>
<td>microwaved</td>
<td>3 oz</td>
<td>1x/week</td>
<td>Jan 2015</td>
</tr>
<tr>
<td>Pepperoni original beef flavor</td>
<td>treat</td>
<td>1/4</td>
<td>1x/day</td>
<td>Aug 2015</td>
</tr>
<tr>
<td>Rawhide</td>
<td>treat</td>
<td>6 inch twist</td>
<td>1x/week</td>
<td>Dec 2015</td>
</tr>
<tr>
<td>Earthborn - MEADOWPEST</td>
<td>O2H</td>
<td>1/2 inch twist</td>
<td>2x/day</td>
<td>Feb 2016</td>
</tr>
</tbody>
</table>

   *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:

<table>
<thead>
<tr>
<th>Supplement</th>
<th>Brand/Concentration</th>
<th>Amount per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taurine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carnitine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antioxidants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multivitamin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish oil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coenzyme Q10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please list): Vitamin C</td>
<td>Nature's Bounty</td>
<td>500 mg tablets - 1 per day</td>
</tr>
</tbody>
</table>

   Example: Vitamin C 500 mg tablets - 1 per day

6. How do you administer pills to your pet?

   □ I do not give any medications
   □ I put them directly in my pet's mouth without food
   □ I put them in my pet's dog/cat food
   □ I put them in a Pill Pocket or similar product
   □ I put them in foods (list foods): BOLDGOF or CHEESE
B4, B6
B6

Date of report: 12/30/2018
Date of procedure: B6

Secondary Surgeon: B6, BVSc
Procedure(s) performed: Right caudal maxillary mass excision

Specimens obtained:
Right maxillary mass for histopathology
Patient Name: B6
Signalment: 6 years old Black/Tan Male (Neutered) Doberman Pinscher

Patient ID: 320320

Appointment Date: 1/2/2019

Diagnosis:
1. Right maxillary soft tissue sarcoma—fibrosarcoma

Procedures:
1. Physical examination
2. Complete blood count
3. Blood chemistry profile
4. Urinalysis

Medications:

Discharge Instructions:
1. Continue all cardiac medications as prescribed by the Cardiology Service.

Diet:
Please continue feeding from the diet you have discussed with the Cardiology department.
B6
B6

* Cummings Veterinary Medical Center offers a free support group for caregivers of companion animals with cancer. For more information please visit our website: http://vetmed.tufts.edu/oncology

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 (508-857-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

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

<table>
<thead>
<tr>
<th>Case</th>
<th>66</th>
<th>Owner</th>
<th>B6</th>
<th>Discharge Instructions</th>
</tr>
</thead>
</table>

FDA-CVM-FOIA-2019-1704-003176
Outside Prescription Log

1. Date: 1/2/19
   Clinician: B6
   Prescription: B6
   Pharmacy sent to: B6
   Completed by: B6
   Origin of request:
   Caps #30: 1 cap PO q24h, 1 refill

2. Date: 1/3/19
   Clinician: B6
   Prescription: B6
   Pharmacy sent to: B6
   Completed by: B6
   Origin of request:
   Give 1 cap PO Q12hrs with food; 3 refills

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:
<table>
<thead>
<tr>
<th>Date</th>
<th>Clinician:</th>
<th>Prescription:</th>
<th>Pharmacy sent to:</th>
<th>Completed by:</th>
<th>Origin of request:</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Discharge Instructions

**Appointment date:** 1/30/2019 10:04:21 AM

**Medications:** Continue all of [B6] medications as previously prescribed by our cardiology and oncology departments.

**History:** [B6] presented today for a consultation regarding his maxillary mass (fibrosarcoma). It was debulked with our department and sent for histopathology on [B6]. Based on its composition, [B6] was evaluated by our oncology department and metronomic chemotherapy (cyclophosphamide) was initiated on 1/2/19. Since the surgery, you report that the mass has returned and growing larger.

**Follow Up:** Please email Dr. [B6] when you are ready to schedule surgery.

[B6]@tufts.edu

Please contact the Surgery Liaison @ (508) 887-4794 to arrange your next appointment.

If you have any problems or questions, please contact Dr. [B6] DVM, DACVS as soon as possible. If it is an emergency, contact the emergency service @ (508) 887-4623.

**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.

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B6

Patient ID: 320320

Canine

B6  Years Old  Male {Neutered}

Doberman Pinscher

Black/Tan  BW: Weight (kg) 40.00

Canceled
Patient Name: B6
Signalment: B6 | Years Old Black/Tan Male
          | (Neutered) Doberman Pinscher

Patient ID: 320320

Contact Clinician: B6 | DVM, DACVS
Alternate Clinician: B6 | DVM
Student: B6 | V19

Discharge Instructions

Admit Date: B6 | 7/4/20
Discharge Date: B6

Diagnosis:
1. Right maxillary oral fibrosarcoma

Procedures:
1. Tumor excision
2. von Willebrand's factor testing
3. Baseline bloodwork
4. Chest radiographs (x-rays)
5. Cardiology Consult

Medications:
Continue: B6 can continue to receive his medications as prescribed by the cardiology service. You may give them to him tonight with a small amount of soft food.

Diet: Please feed B6 soft food.
Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (608-887-4629) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

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B6 B6

Discharge Instructions
Radialagy Request & Report

Patient

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

Owner

Name: B6
Address: B6

Patient ID: 320320
Date of request: B6

Attending Clinician: B6 J DVM, DACVS
Student: B6 V19

Date of exam: B6

Patient Location: Ward/Cage: B ward Run 4
Weight (kg): 40.00

Sedation

☒ Inpatient
☒ Outpatient Time:
☒ Waiting
☒ Emergency

BAG
OBAG
1/2 dose OBAG
DexDomitor/Butorphanol
☐ Anesthesia to sedate/anesthetize

Examination Desired: Met check under pre-med before surgery

Presenting Complaint and Clinical Questions you wish to answer:
Admit to B Ward, Collect Deposit

Pertinent History:
Oral fibrosarcoma debulked on B6 second debulking surgery today
History of DCM and Atrial Fibrillation

Findings:
Conclusions:
- Faint right middle lung lobe interstitial to alveolar pattern. This may represent a focus of pneumonia. Correlate to thoracic auscultation. Follow-up radiographs are recommended to monitor.
- Mild generalized cardiomegaly with moderate left-sided enlargement without evidence of cardiac decompensation. This is consistent with reported DCM. Echocardiography can be considered for further evaluation as clinically indicated prior to anesthesia.
- Mild diffuse bronchial pattern may represent chronic lower airway disease (allergic, infectious or parasitic etiologies) or age related changes. Correlate with clinical history.
- No evidence of thoracic neoplasia.

Radiologists
Primary: B6, DVM
Reviewing: B6, BVS, DACVR

Dates
Reported: 2/20/2019
Finalized: 2/28/2019
Patient: B6
Male (Neutered)
Canine Doberman Pinscher
Patient ID: 320320

SURGERY REPORT

Date of report: B6
Date of procedure: B6

Attending Clinician: B6

Primary Surgeon: Dr. B6
Student: B6, V19

Procedure(s) performed: Right caudal maxillary mass debulking

Report:

Specimens obtained:
Right maxillary mass for histopathology

Concerns:
aspiration
Discharge Instructions

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

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

Diagnoses:
Dilated cardiomyopathy (DCM), asymptomatic
Atrial and ventricular arrhythmia
Oral fibrosarcoma

Case summary:
Thank you for bringing B6 to Tufts for evaluation of his heart. Upon echocardiogram (ultrasound of the heart) today, his DCM is stable. There were no significant differences in comparison to findings from previous echocardiogram. Electrocardiogram was also similar but showed slightly less frequent arrhythmia (abnormal heart rhythm), more specifically some atrial and fewer ventricular premature contractions, and slower heart rate so we will continue his medication. Since B6 is enrolled in the study on DCM, and we submitted some blood work for that study which will give us other markers of heart health. We will plan to call you with those results.

We are sorry to hear that his mouth is causing him discomfort and decreased appetite. We are sending you home with an appetite stimulant and some anti-diarrheal medication to help improve his comfort at home. It is ok to dissolve his medication to give in a liquid slurry if that works better for him. We recommend avoiding putting his pills in his food.

Monitoring at home:
- We would like you to occasionally monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. Given that B6 is a large breed dog, his respiratory rate should be no more than 35 breaths
per minute at rest, and it may be much lower. 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 a dose of furosemide (Lasix). If difficulty breathing is not improved by within 30-60 minutes after giving extra furosemide then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

**Recommended Medications:**

We discussed tips for getting medications into [B6](#). You can crush or dissolve his tablets right before you give the medications if you find it easier to give them this way. You can use small amounts of appetizing foods like low-sodium peanut butter, cream cheese, cake frosting, and marshmallows to hide pills in. If you are unable to get all of his oral medications in to him, we want you to prioritize his Pimobendan and Amiodarone medications.

**Diet Suggestions**

**Diet and supplement 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/).

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

- We recommend switching 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/news-events/cvm-updates/hum613365.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School's Pet Medicine blog can further explain these findings (http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).

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

**Dry Food Options:**
- Royal Canin Early Cardiac (veterinary diet)
- Royal Canin Boxer
- Purina Pro Plan Adult Weight Management
- Purina Pro Plan Bright Mind Adult Small Breed Formula

**Canned Food Options:**
- Hill’s Science Diet Adult Beef and Barley Entree
- Hill’s Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
- Royal Canin Mature 8+

**Exercise Recommendations**

Limited activity is recommended, but can still be allowed to play. Short leash walks are ideal. If you find that B6 lagging behind or needs to stop on a walk, then this is 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. Please be aware that dog’s with significant arrhythmia, as is B6 case, are at risk of sudden death as a result of fatal arrhythmia, and we worry that high intensity activity can increase this risk.

**Recheck Visits:** A recheck visit is scheduled for Monday June 10th at 4PM. At this visit we will want to check breathing effort and heart function with an echocardiogram, ECG and a blood test as part of the DCM study.

Thank you for entrusting us with care. He is such a good boy and we hope that the entacy helps his appetite. Please contact our Cardiology liaison at (508)-887-4696 or email us at cardiology@tufts.edu for scheduling and non-emergent questions or concerns.

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

**Prescription Refill Disclaimers:**

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/cevs/clinical-studies

**Case:**

**Owner:**

**Discharge Instructions**
Nutritional Tips for Pets with Heart Disease

Low sodium, high quality pet treats

Notes:
1. Most other dog treats are high in sodium.
2. If your pet has other medical conditions, these treats may not be appropriate. Talk to your veterinarian if you have questions or make an appointment with the Nutrition Service.

<table>
<thead>
<tr>
<th>Product</th>
<th>Calories per treat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dogs</strong></td>
<td></td>
</tr>
<tr>
<td>Hill’s Science Diet Baked Light Biscuits with Real Chicken Small Dog Treat</td>
<td>8</td>
</tr>
<tr>
<td>Hill’s Science Diet Baked Light Biscuits with Real Chicken Medium Dog Treat</td>
<td>34</td>
</tr>
<tr>
<td>Hill’s Science Diet Soft Savories Peanut Butter &amp; Banana, Beef &amp; Cheddar, or Chicken &amp; Yogurt Dog Treat</td>
<td>25-27, depending on flavor</td>
</tr>
<tr>
<td>Hill’s Ideal Balance Soft-Baked Naturals with Chicken &amp; Carrots, Duck &amp; Pumpkin, or Beef &amp; Sweet Potato Dog Treat</td>
<td>12-13, depending on flavor</td>
</tr>
<tr>
<td>Purina Beyond Natural Salmon Dog Biscuit Treat with Oats or Chicken &amp; Barley</td>
<td>27-29, depending on flavor</td>
</tr>
<tr>
<td>Purina Alpo Variety Snaps Little Bites (beef, chicken, liver, lamb, beef, bacon, cheese, peanut butter)</td>
<td>16</td>
</tr>
<tr>
<td>Purina Alpo Variety Snaps Big Bites (beef, chicken, liver, lamb)</td>
<td>58</td>
</tr>
<tr>
<td>Royal Canin Original Canine treat</td>
<td>5</td>
</tr>
<tr>
<td><strong>Cats</strong></td>
<td></td>
</tr>
<tr>
<td>Royal Canin Original Feline treat</td>
<td>2</td>
</tr>
<tr>
<td>Fancy Feast Duos Natural Rotisserie Chicken Cat treat</td>
<td>2</td>
</tr>
<tr>
<td>Fancy Feast Duos Tuna with Accents of Parsley Cat treat</td>
<td>2</td>
</tr>
</tbody>
</table>

Taste enhancers to make your pet’s food tastier to increase food intake

Safe and effective appetite stimulants are now available for dogs and cats. Please talk to your veterinarian if your pet is not eating well, not eating ideal foods, or is losing weight.

Notes:
1. All foods in this list should be prepared without salt
2. These taste enhancers should be added in small amounts. If your pet eats too much of them, they will unbalance the diet and increase your pet’s risk for nutritional deficiencies.

**Dogs**
- Honey or maple syrup
- Homemade chicken, beef, or fish broth (made without salt; avoid all deli meats and rotisserie chicken). Avoid store bought broths because even the low sodium brands are too high in sodium.
- Sugar (brown or white) – Domino pourable light brown sugar is a good option
- Vanilla or fruit yogurt – One option that dogs seem to like is Yoplait Custard Yogurt (caramel or vanilla flavors). If you try other brands, just be sure the sodium is less than 100 mg per 100 calories (the Yoplait is 95 mg per 170 calories which comes out to 56 mg sodium per 100 calories). Also avoid yogurts with artificial sweeteners.
- Maple syrup. Low salt brands include Log Cabin All Natural, Maple Grove Farm 100% pure maple syrup, or Stop and Shop Original Syrup
- Applesauce (be sure they have less than 50 mg sodium per serving)
- Ketchup (no salt added). Examples include Hunts or Heinz no salt added
- Pasta sauce (no salt added). Examples: Francesco Rinaldi no salt added or Enrico’s no salt added
- Frosted Mini Wheats Original – these can be crumbled on his food
- Lean meats, cooked (chicken, turkey, beef, or fish) – not deli/sandwich meats/cold cuts, rotisserie chicken, and any canned fish or meat
- Eggs, cooked
Dogs (continued)
- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium).
  Avoid all canned soups unless labeled as no salt added
- Low-salt breakfast cereal - the label should read, "very low sodium food" or contain less than 20 mg sodium per serving. A good option is Frosted Mini Wheats Original or Little Bites Original
- Fresh vegetables/fruit. Examples include carrots, green beans, apple, orange, banana (avoid grapes, raisins, onions, garlic)
- Low sodium canned dog foods

Cats
- Lean meats, cooked (chicken, turkey, beef, or fish) – not sandwich meats/cold cuts, canned tuna, or rotisserie chicken
- Eggs, cooked
- Homemade chicken, beef, or fish broth (even low sodium store-bought broths are too high in sodium)
- Low sodium canned cat foods

Foods to avoid
- Fatty foods (meat trimmings, cream, ice cream)
- Baby food
- Pickled foods
- Bread
- Pizza
- Condiments (ketchup, soy sauce, barbecue sauce, etc – unless they are unsalted or no salt added)
- Sandwich meats/cold cuts (ham, corned beef, salami, sausages, bacon, hot dogs)
- Rotisserie chicken
- Most cheeses, including "squirtable" cheeses
- Processed foods (such as, potato mixes, rice mixes, macaroni and cheese)
- Canned vegetables (unless "no salt added")
- Potato chips, packaged popcorn, crackers, and other snack foods
- Soups (unless homemade without salt)
- Most commercial pet treats

Tips for administering medications
Foods commonly used to administer your pet’s pills can provide a large amount of additional salt to your pet’s diet. Preferable ways to give medications include:
- Have one of our staff show you how to give medications without using food
- Insert medications into one of the following foods:
  **Dogs or cats**
  - Low-sodium canned pet food
  - Home-cooked meat such as chicken or hamburger (made without salt); not lunch meats
  - Whipped cream (Reddi Wip)
  - Marshmallows
  - Greenies Pill Pockets
    - Dog chicken, hickory smoke, or peanut butter flavors; cat chicken or salmon flavor
    - Avoid grain-free duck and pea which is high in sodium
    - Try to use the smallest size possible (ideally, the cat sized Pill Pockets, even for dogs) and as few as possible to avoid excessive salt.
      - Caution: Not all similar products from other companies are low in sodium
  - Soft fruit, such as banana, orange, melon, or strawberries (avoid grapes)
  - Peanut butter (only if labeled as "no salt added") – examples include Smucker’s Natural Creamy Peanut Butter with No Salt Added or Teddie All Natural Smooth Unsalted Butter
  - Frosting (should be less than 75 mg/serving and contain no artificial sweeteners or xylitol). Examples include Duncan Hines whipped vanilla frosting, Betty Crocker whipped vanilla frosting

You may find our Petfoodology post called, “Pill-popping pets” helpful for additional ideas:
http://vetnutrition.tufts.edu/2018/09/foods_for_giving_pills/
Date: 3/7/2019

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

Cardiology Resident: B6

Cardiology Technician:
- B6
- VT (Cardiology)
- CVT

Presenting Complaint: Recheck DCM/arrhythmia; DCM study

Concurrent Diseases:
- Hx of oral fibrosarcoma incompletely removed 2/2019 after failing to respond to metronomic chemotherapy.
- History of Anaplasma
- History of von Willebrand disease
- History of skin allergies
- History of elevated ALT

General Medical History:
- Has been doing okay on and off; owner thinks that he is painful and has been picking out pills. Owner is getting tramadol liquid from vet. Owner has not been able to get heart medication in for 2 days except 1 enalapril yesterday. Owner wants to know if possible to do compounding into a liquid for medication.
- Still wants to go for walks twice a day. Appetite has decreased but owner suspects it is because of pain related to oral mass. Diarrhea/soft stool for the past week and seems to be improving. Owner thinks the oral mass is infected based on smell. Owner asks about compounding liquid metronidazole. Couple weeks ago vomited a couple of times right after eating but resolved on its own.
- Owner wants to know about appetite stimulants.

Diet and Supplements:
- Only willing to eat pure beef/lamb, not interested in vegetables. Owner is trying to incorporate regular
dog food (one of the recommend low sodium diets we recommend but can't remember which one). No supplements

Cardiovascular History:
Prior CHF diagnosis? No
Prior heart murmur? No
Prior ATE? no
Prior arrhythmia? Yes
Monitoring respiratory rate and effort at home? Not daily, always below 17/min
Cough? 2 coughs yesterday for the first time but none since then
Shortness of breath or difficulty breathing? No
Syncope or collapse? No
Sudden onset lameness? No
Exercise intolerance? No

Current Medications Pertinent to CV System:

B6

Cardiac Physical Examination: General PE: generalized shaking, painful swelling on R side of mouth (did not fully evaluate mouth due to pain), increased R submandibular and prescapular LN, multiple cutaneous masses
MM Color and CRT: pink, CRT=2
BCS (1-9): 6
BW (kg): 38.1 kg
Heart rate: 72
Respiratory rate: 20
Temp (if possible): NP

Muscle condition:
- Normal
- Moderate cachexia
Mild muscle loss

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

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

Arterial pulses:
- Weak
- Fair
- Good
- Strong

Arrhythmia:
- None
- Sinus arrhythmia
- Premature beats

Gallop:
- Yes
- No
- Intermittent

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

Abdominal exam:
- Normal
- Hepatomegaly
- Abdominal distension

Problems & Differential Diagnoses:
History of DCM and APCs/VPCs
Painful R mouth- R/O infection vs. regrowth tumor
Diarrhea- R/O- medication side effects vs. stress colitis vs. neoplasia

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

Echocardiogram Findings:
General/2-D Findings:
Deepler findings:
Trace MR and TR

Mitral inflow:
- Summated
- Normal
- Delayed relaxation

ECG findings:
NSR with frequent APCs and occasional isolated VPCs

Assessment and recommendations:
Echocardiogram reveals similar advanced DCM compared to previous exam. Patient is not eating well lately; suspect related to oral mass, but chemistry panel submitted to assess renal and liver values. Recommend prioritizing pimobendan and amiodarone until taking meds better. Sent home with a sample of Entyce. If appetite improves, strongly recommend feeding one of the recommended dog food diets rather than home cooked, just in case this could be playing a role in his heart disease. Continue to have furosemide on hand in case of increased RR/RE. BNP and troponin submitted for study. Recheck echo and blood work in another 3 months for the study.

Final Diagnosis:
DCM
Ventricular and supraventricular ectopy
Oral fibrosarcoma

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

ACVIM Classification:
- A
- B1
- B2

M-Mode
IVSd
LVIDd
LVPWd
IVSs
LVIDs
LVPWs
EDV (Teich)
ESV (Teich)
HR
EF A-L LAX
LVEF MOD LAX
SV A-L LAX
SV MOD LAX
CO A-L LAX
CO MOD LAX

Doppler
MR Vmax
MR maxPG
MV E Vel
MV Dec T
MV Dec Slope
MV A Vel
MV E/A Ratio
E'
E/E'
A'
S'
AV Vmax
AV maxPG
PV Vmax
PV maxPG

B6

B6

BPM
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%
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ml
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l/min
m/s
mmHg
m/s
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ms
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mmHg
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mmHg
Client and Pet Registration Form

Client Name: B6
Pet Name: B6
Spouse/Partner: B6
Patient ID: 320320
Address: B6
Date of Birth: B6
City, State, Zip: 66
Age: 86 years old
Home Phone: B6
Breed: Doberman Pinscher
Work Phone: B6
Color: Black/Tan
Cell Phone: B6
Sex: Male (Neutered)
Email: B6
Weight: (kg) 38.10 kg
Pager:
Rabies Date:

Referring Veterinarian: B6

Agreement and Consent:
• I agree to pay for all services rendered to my pet at the end of today's examination.
• I understand that payment is required at the time of service.
• I understand that the cost of the initial exam does not cover any further diagnostics, treatments, or medications that may be necessary for my pet.
• I understand that if further diagnostics or treatments are recommended by the doctor I may request an estimate of those charges first.
• I understand that I have the right to refuse any treatments, diagnostics, or medications that have been recommended to me by the doctor.

Signature: __________________________ Date: 3/18/2019
You and your doctor will be provided with a report from the doctor for every examination performed on your pet at B6. Thank you for trusting us to care for your pet!
B6

Patient Discharge Summary

Client Name: B6
Referring Veterinarian: B6

Patient Name: B6
Patient ID: 320320
Species: Canine
Breed: Doberman Pinscher
Age: 6 Years Old
Weight: Weight (kg) 38.10 kg
Check-in date: 3/18/2019 1:49:45 PM

Veterinary Medical Team: DVM, DACVAA

Diagnosis: Cancer pain

Case Summary:
You brought B6 to see me for advice about his pain. You are mainly concerned because his appetite declined (which has been helped by the B6) and it was difficult to get pills into him, but also because he seemed to have paroxysms of pain, where he exhibited shaking and it interrupts his sleep (and yours). He had not been anything for pain since you discontinued the metronomic therapy for his cancer - there was B6 (tablets) once a day in that protocol. Then Dr. B6 suggested you try a compounded dose of B6 and it has made a major difference. She also recommended a hemp supplement oil, which you have not started yet. He does not do well on gabapentin. You are afraid to give too much of the B6. Currently he is eating mainly salmon fillets and dog cookies. You are doing an amazing job trying to separate his medication administration from his feeding times / locations.

He likes to go for walks several times a day. His other quality of life indicators are his engagement with you, and his sleep patterns.

He has reluctance to go up the stairs and you help him, but on the B6 one day he did it on his own.

I discussed methods to treat his pain, and how to monitor him for how he is feeling.

Patient Care Instructions:

B6
Medications:

Dispense: B6
Continue: B6

Follow-up Instructions:
I can make additional recommendations going forward. I will send you the comfort diary to use if you choose.

Please do not hesitate to email me with questions or concerns and we can set up a time to talk by phone.

You are truly honoring his well being above all and it was a pleasure to meet both of you.

B6  DVM, DACVAA  Discharge Date: 3/18/2019
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 bill may vary considerably from this estimated cost.

<table>
<thead>
<tr>
<th>Description</th>
<th>Low Qty</th>
<th>Med Low Estimate</th>
<th>Med High Estimate</th>
<th>High Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor Removal (Simple)</td>
<td>1.00</td>
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<tr>
<td>Anesthesia Work-Up</td>
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<tr>
<td>PVHS/BS/AZO - FHSA</td>
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<tr>
<td>Daily Professional Care, General Ward</td>
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<tr>
<td>Anesthesia, Disposables, Agents</td>
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<td>1.00</td>
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<td>Hospitalization: Day Board (Dog)</td>
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<td>Anesthesia 1 Hr/30 M</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
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</tr>
</tbody>
</table>

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. Further, agree to pay the balance of the charges when this patient 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.
REFERRAL FORM
TUFTS UNIVERSITY
Cummings School of Veterinary Medicine
Henry and Lois Foster Hospital for Small Animals
Hospital for Large Animals
200 Westboro Road, Route 30
North Grafton, MA 01536
508-899-5395

Service to Which Referred: ____________  Appointment Date: ____________  Time: ____________

OWNER INFORMATION:
Name: B6  Daytime Phone: B6  Evening Phone: ____________
Address: B6  City: B6  State: B6  Zip Code: B6

PATIENT INFORMATION:
Registered Name/ID: B6
Species: CANINE  Breed: Boxer  Sex: MN  Age: B6

CASE HISTORY
Chief Concern/Provisional Diagnosis: B6
Vaccination History: Attached
Other History: Did have mass removed from chest 3/28/13 (Hospital attached)
Diagnostic Test Results (if possible, please attach results): Bloodwork attached

Are Radiographs enclosed? ____________
Current Therapy & Medication (include dosages): ____________

Special Comments/Requests: Was scheduled for US hospital B6 Suggested not go directly to Tufts

REFERRING VETERINARIAN INFORMATION
Name: B6  Clinic/Hospital: B6
Phone: B6  Fax: B6
Address: B6  City: B6  State: B6  Zip Code: B6

If an animal is being referred which has had lab work done at B6 please include copies of the lab results or the B6 accession number. If you are faxing us information about a clinical case which has been referred, please use fax number B6.
**MEDICAL NOTE TEMPLATE INFORMATION**

**Patient:** B6  
**Species:** Canine  
**Breed:** Boxer  
**Sex:** Neutered Male  
**Status:** TENTATIVE  
**Date:** 10/01/2013  
**Weight:** 57.5 pounds

**SOAP**

Enter Office Visit:

History: Last month o changed food, changed back to original food, stool was formed for first time in a long time today. Having some trouble eating, not interested at first, o has started by hand feeding to get him to eat the rest. Gagging like he wants to vomit or have hairball, nothing produces. Loosing weight, breathing irregularly, heart seems to beat out of chest. Was bit by o's aunt's dog two weeks ago.  

S: BAR  

**Temp:** 98.5  
**Pulse:** 55  
**Resp:** 32

Eyes: Normal conjunctiva, sclera, corneas, palpebrae

Ears: NSF

Nose/Throat: NSF

Mouth/Teeth: No tartar, No gingivitis.

**MM:** Pink, cvt <2, moist

Cardiovascular: No murmur, strong synchronous pulses.

Respiratory: Lungs clear bilaterally.

Abdomen: Soft, non-painful

PLN: NSF

Urogenital: NSF

Musculoskeletal: No lameness, no crepitous or pain in stifles, hocks, elbows, or carpi.

Nervous System: Normal CP, PLR, menace, palpebral reflex. No ataxia.

Skin/Hair Coat: No fleas or flea dirt, no lesions

A:DDX: Open, cardiac or electrolyte:


GI: NSF
### Detailed Lab Results

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference Range</th>
<th>Low</th>
<th>Normal</th>
<th>High</th>
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<tbody>
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<td>BUN/UREA</td>
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<td>Ca</td>
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<tr>
<td>Chloride</td>
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<td>Potassium</td>
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**Species:** Canine

**Breed:** Boxer

**Weight:** 57.5 pounds

**Client:** B6

**Patient:** B6

**Sex:** Neutered Male

**Age:** B6

**Lab ID:** INCLINIC

**Template:** IDEXX VetLab In-clinic Laboratory

**Staff:** B6

**Status:** Posted

**Req ID:** 7373 - Tuesday

**10/01/2013 15:23**

**10/01/2013 08:38:59**
### Detailed Lab Results

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**Client:** B6  
**Patient:** B6  
**Species:** Canine  
**Breed:** Boxer  
**Weight:** 57.5 pounds
### Detailed Lab Results

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**Patient:** B6  
**Client:** B6  
**Species:** Canine  
**Breed:** Boxer  
**Sex:** Neutered Male  
**Age:** 2 Yrs. 10 Mos  
**Weight:** 57.5 pounds
Patient: B6
Species: Canine
Breed: Boxer
Sex: Neutered Male
Weight: 57.5 pounds

Enter Office Visit:

History: Exam:

Page 1 of 1
Date: 10/01/2013 14:08
10/01/2013 15:23

Client: B6
Patient: B6

Archived RDVM B6

Canine Boxer Neutered Male 69.5 pounds (3/29/2013)

3/29/2013 B6 Comment
Closed - 4/1/2013
### Detailed Lab Results

**Patient:** B6  
**Client:** B6  
**Sex:** Neutered Male  
**Age:** B6  
**Species:** Canine  
**Breed:** Boxer  
**Weight:** 57.5 pounds

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**Lab Comments:** WBC Abnormal Distribution
Detailed Lab Results

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Detailed Lab Results

Patient: B6  Sex: Neutered Male  Age: B6
Client: B6  Species: Canine  Breed: Boxer  Weight: 57.5 pounds

Lab ID: IDEXX  IDEXX Reference Laboratory
Template: Miscellaneous
Staff: B6
Status: Posted
Req ID: B188 - Friday  3/29/2013 12:22:00

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COMMENTS

RE: 2007 PATHOLOGIST PATHOLOGIST

B6
Detailed Lab Results

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COMMENTS: COMMENTS

B6
### Reminder Letter Report

**Sorted by Client ID**

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**Client:** B6

**Patient:** B6

**Archived RDVM:** B6

**Date:** 10/01/2013

**Phone:** B6

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**Page 1 of 1**

**Date:** 10/1/2013

---

**Page 24/213**
## Veterinary Medical Team

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<tr>
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<td>Attending (Faculty) Clinician</td>
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<td>Senior Student</td>
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## Diagnoses

- **Final diagnoses**: 3rd degree AV block with pacemaker implantation 10/13
- **Procedures**: pacemaker interrogation, ECG
- **Recommendations**: Recheck in 3 months for echocardiogram and resetting of pacemaker

## Professional Report

Thank you for referring **B6** to Tufts Cardiology service. **B6** had his 3 month post pacemaker implantation recheck examination today. The owners report he is doing very well at home. The pacemaker is capturing well, but the battery life appears to be only about 3-5 1/2 years, so we turned down the output slightly to try to prolong this. We will recheck this in 3 months, at which point we will also do a recheck echocardiogram to assess heart size, and hopefully turn down the output a bit more to prolong battery life further.

## Client Report

Thank you for bringing **B6** to Tufts Cardiology service for his 3 month post pacemaker implantation recheck. We are glad to hear that **B6** has been doing very well at home. Today, we checked the output on his pacemaker, and found that it is working the way we would like it to, and that his heart is nearly 100% reliant on the pacemaker. While it is controlling his heart rate well, the projected battery life is about 5-5 1/2 years on his current settings. We lowered the output slightly to try to prolong the battery life. We would like to see **B6** back for a recheck exam to revisit the battery life as well as an echocardiogram (ultrasound of the heart) in 3 months. It is safe to use flea/tick preventative and heartworm preventative on **B6**. At this time, you can begin to slowly increase his level of exercise. Leashed runs and hikes are safe activities, but we recommend that you avoid excessive exercise and avoid jumping or fetching activities.

It was great to see **B6** again, he is such a good patient! If you have any further questions or concerns, please feel free to give us a call!

## Patient Care Instructions

2/7/2014 3:49:20 PM

S227632/Case Summary/MedRec Copy

John E. Rush, DVM, MS, Tufts Cardiology
Follow Up Instructions

Please continue to monitor ... for any signs of decreased heart rate including counting heart beats (we would like his heart rate to be at or a bit greater than 60 beats/min), weakness, collapse, or difficulty breathing. If you note any of these changes, please contact us immediately.

Please schedule a recheck appointment for a cardiac exam, pacemaker check and echocardiogram in 3 months.

John E. Rush, DVM, MS, DACVIM (Cardiology), DACVECC
Date: 2/7/14  Problem:  

Home Instructions:  

Follow-up visits  

Owner to call Clinician:  

Medication Dispensed:  

Amount  

Size  

Instructions:  

Physical Exam:  

Temp:  

Pulse:  

Respirations:  

Weight:  

Body condition score (1-9):  

Procedures Performed and Future Plan:  

---

FORM 290 (Rev 5/98) RE-EXAMINATION  

MEDICAL RECORDS
### Client Information
- **Client:** B6
- **Case#:** B6
- **Number:** B6

### Patient Information
- **Name:** B6
- **Species:** CANINE
- **Breed:** BOXER
- **Sex:** CM
- **DOB:** B6

### Dates
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### Personnel
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<td>John E. Rush, DVM, MS, DACVIM (Cardiology), DACVECC</td>
<td>Attending (Faculty) Cardiologist</td>
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### Case Abstract
- **3rd degree AV block.** Permanent pacemaker implanted October 2013.

### Cardiology Findings

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<tr>
<th>Type</th>
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<td>1-IV/VI over mitral valve - incirmitent</td>
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<td>Transient heart sounds</td>
<td>Bruit de coton</td>
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<td>Other auscultatory findings</td>
<td>Clear</td>
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<td>Pcrkrs</td>
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<td>Jugular veins</td>
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<td>Mucous membranes</td>
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<td>Captured down to 0.25 V. Changed output from 3.5 to 2.0 V. Minimal evidence of rate responsive feature, tried to adjust.</td>
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### Body condition score (9)

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### Assessment and Recommendations
- **Third degree AV block and pacemaker implantation.** Good pacemaker function with battery life of 5 to 5.5 years.

2/8/2014 9:51:52 AM
S227632/Cardiology Report/ModRec Copy
John E. Rush, DVM, MS,
Recommend recheck in 3 months to evaluate pacemaker function, battery life and rate responsiveness; likely also recheck echo then, as heart was originally dilated.

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

- **Diagnosis Read Feb 7, 2014 3:18 pm**

**Basic Operation**
- **Mode:**
- **Magnet Response:**

**Rates**
- **Base Rate**
- **Rest Rate**
- **Max Sensor Rate**

**Refractories & Blanks**
- **Ventricular Refractory**
- **Rate Resp. V. Refr.**
- **Shortest Ventricular Refractory**

**Capture & Sense**
- **AutoCapture**
- **Pulse Amplitude**
- **Pulse Width**
- **Amplitude Monitoring**
- **Sensitivity**

**Leads**
- **Lead Type**
- **Pulse Config**
- **Sense Config**
- **Lead Monitoring**
- **Lower Limit**
- **Upper Limit**

**Patient Data**
- **Patient Name**
- **Patient ID**
- **Implant Date**
- **Lead Model**
- **Manufacturer**
- **Model**
- **Date**
- **ADAPTOR**
- **OTHER**

**FastPath® Summary**

---

**Heart Rate Histogram**

- **Pericard (VP)**
- **Sensed (RB)**

**Events**
- **VP Counts:**
  - 100%

**Site Info**

- **Patient:** B6
- **Device:** Merlin® PCS (919916, 3330)

---

**Site Info**

- **Site:**

---

**Site Info**

- **Site:**

---

**Site Info**

- **Site:**
Client: 
Patient: B6

Archived Records 10/1/13-10/4/13 (PART ONE) & 10/11/13-2/7/14

Zephyr® SR 5620 (R7203104 prb.7) • TUFFS VET SCHOOL - Cardiology

Test Results

Ventricular Capture Test

This Session: < 0.25 V @ 0.4 mA(B)
Safety Margin: > 12.0 : 1 @ 5.00 V

Zephyr® SR 5620 (R7203104 prb.7) • TUFFS VET SCHOOL - Cardiology

Battery

Voltage 2.78 V

Remaining Longevity

Magnet Rate

Current Impedance

Ventricular Lead

Test Results page 1 of 1

Feb 7, 2014 3:23 pm

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**Ventricular Capture Test**

**Test Results** (Last Session: Oct 2, 2013)

- Capture
- Sense
- Lead Impedance

**FastPath® Summary**

- **No Alerts**

**Zephyr® SR 5620** (RF20315/Mp9.7)

- **TUFTS VET SCHOOL - Cardiology**
- **Ventricular Capture Test**

- **Session:** <0.25 V @ 44 ms (B)
- **Safety Margin:** >14.0 V @ 3.50 V
- **Last Session:** No previous results

Clanent: B6

Patient: B6

Archived Records 10/1/13-10/4/13 (PART ONE) & 10/11/13-2/7/14
**Basic Operation**
- Mode
- Magnet Response
- Sensor
- Threshold
- Measured Avg
- Slope
- Max Sensor Rate
- Reaction Time
- Recovery Time

**Rates**
- Base Rate
- Rest Rate
- Max Sensor Rate
- Hysteresis Rate

**Refractories & Blank:**
- Ventricular Refractory
- Rate Resp. V. Ref.
- Shortest Ventricular Refractory

---

**Stored EGM Configuration**
- Sampling Option
- Number of Stored Episodes
- Channel
- EGM Configuration
- EGM Recording Range

**Episode Triggers**
- High Ventricular Rate Trigger
- Magnet Placement Trigger

---

**Archived Records 10/1/13-10/4/13 (PART ONE) & 10/11/13-2/7/14**
Client: B6
Patient: B6

Archived Records 10/1/13-10/4/13 (PART ONE) & 10/11/13-2/7/14

---

**TUFTS UNIVERSITY**
Foster Hospital for Small Animals
200 Westboro Road
North Grafton, MA 01536-1893
1-508-839-5395

**Document:** Case Summary  
**Copy To:** MedRec  
**Status:** FINAL  
**Finalized:** by B6 on 10/11/2013

---

**Client Information**

<table>
<thead>
<tr>
<th>Client#</th>
<th>Name</th>
<th>Address</th>
<th>City</th>
<th>Zip</th>
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<tbody>
<tr>
<td>B6</td>
<td></td>
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**Patient Information**

<table>
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<tr>
<th>Case#</th>
<th>Name</th>
<th>Species</th>
<th>Breed</th>
<th>Sex</th>
<th>DOB</th>
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<tbody>
<tr>
<td>B6</td>
<td></td>
<td>CANINE</td>
<td>BOXER</td>
<td>CM</td>
<td></td>
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**Dates**

<table>
<thead>
<tr>
<th>Description</th>
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<tbody>
<tr>
<td>Technician Appointment</td>
<td>10/11/2013</td>
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**Veterinary Medical Team**

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>B6</td>
<td></td>
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**Diagnoses**

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Recommendations</th>
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</thead>
<tbody>
<tr>
<td>recheck ECG, suture removal</td>
<td>recheck in 2-3 months</td>
</tr>
</tbody>
</table>

---

**Client Report**

B6 came in today for a recheck ECG and to have his sutures taken out. The incision looks good, although slightly red around the area, we applied another neck bandage to keep on him for a couple days. His ECG showed that his pacemaker is working well.

Thank you for bringing B6 today. He is such a love!

---

**Patient Care Instructions**

You are allowed to leash walk only, for about 10-15 minutes. Please continue to restrict other activity, such as chasing toys, running, jumping on furniture, etc.

---

**Follow Up Instructions**

Please come back in 2-3 months for a pacemaker computer check and an ECG.

---

10/11/2013 3:31:18 PM  
S227632/Case Summary/MedRec Copy

---

Page 51/213
 archived records 10/1/13-10/4/13 (part one) & 10/11/13-2/7/14

Tufts University Hospital for Small Animals
200 Westboro Rd.
North Grafton, MA 01536
508-839-5395

Date: 10/11/13
Problem: recheck
Clinician: 

Home Instructions:

Follow-up visits
Owner to call Clinician:

Medication Dispensed

Amount
Size
Instructions

History: antibiotics gone
on prednisone stay calm
bandage not staying on well

Physical Exam: Temp
Pulse
Resp
Weight
Body condition score (1-9)

Procedures Performed and Future Plan:

Culture removal

Form #355 (Rev 002) RE-EXAMINATION

MEDICAL RECORDS
Client: B6

Patient Informaion
Client#: B6
Name: B6
Address:
City:
Zip:
Home#: 86
Work#: 86

Case Information
Case#: B6
Name: B6
Species: CANINE
Sex: CM
Breed: BOXER
DOB: B6

DOB: B6

Veterinary Medical Team

<table>
<thead>
<tr>
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<th>Title</th>
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<tbody>
<tr>
<td>B6</td>
<td>Emergency Clinician</td>
</tr>
<tr>
<td>B6</td>
<td>Senior Student</td>
</tr>
<tr>
<td>B6</td>
<td>Primary Clinician</td>
</tr>
<tr>
<td>John E. Rush, DVM, MS, DACVIM (Cardiology), DACVECC</td>
<td>Attending (Faculty) Surgeon</td>
</tr>
<tr>
<td>B6</td>
<td>Senior Student</td>
</tr>
<tr>
<td>B6</td>
<td>Attending (Faculty) Clinician</td>
</tr>
</tbody>
</table>

To the Referring Veterinarian
Dear B6

Diagnoses
Final diagnosis: 3rd degree AV block
Procedure: echocardiogram, ICD, pacemaker implantation
Recommendations: sutures removal and EKG in 7-10 days

Case Progress Notes (ICU Transfer Sheet)
Time and Date Admitted: 01 Oct 2013 4:15 pm
Transfer Date: 02 Oct 2013
Admitting Clinician: B6
Transferred to (Clinician): B6
Patient Location: ICU R5

Estimate and Financial Notes: B6

History and Physical Exam Summary: B6 is a CM boxer who presented to Tufts from his rDVM for a slow heart rate, went to his rDVM last week mild lethargy. No signs of heart disease were reported during this visit. Over the next week his signs continued so he went back to his rDVM today who found a heart slow heart rate and sent him to Tufts for a cardiology consult. The owner reports that Warren has otherwise been healthy aside from chronic allergies. He has not had any syncopal episodes or fainting spells.

Patient Condition:
S-OAR TO-1028, P-50, R-rant, CRT<2, MMs pale pink and tacky

10/2/2013 1:58:44 PM
S227632/CASE Summary/MedRec Copy

Page 67/213
EENT: Clear eyes, mild dental tarter, clear nose, mild debris AU
PLNs: No peripheral lymphadenopathy appreciated
Heart/Circulatory: III/VI systolic murmur, gallop rhythm, hyperdynamic apical beat and femoral pulses
Lungs: clear
Abd: soft, non painful
UG: externally unremarkable CM
MSE: Ambulatory x4
INTEG: small skin focal areas of alopecia on the muzzle, alopecia behind the ears bilaterally
Neuro: QAR, mentally appropriate, full exam not performed
RECTAL: NP

Initial and Current Therapy:
1) Telemetry
2) [B6]

Diagnostic tests completed and pending:
1) Cardiology consult: 3rd degree AV block, dilated cardiac chambers, start treatment with minocycline while awaiting 4DX results
2) 4DX: Pending
3) CBC: Pending
4) CHEM: Pending

Prognosis Given Owner: Stable.

Client and Referring Veterinarian Communication Status: Will admit overnight for telemetry monitoring and transfer to our cardiology service in the morning.
*Not sure what else you talked to them about*

Oct 2, 2013

CV: HR = 64, 3rd degree AV block, III/VI systolic murmur and gallop heard on left side, snappy femoral pulses (systolic murmur), jugular vein distended to 3/4 of the neck
Lungs: RR = 36, no respiratory effort, normal breath sounds
Recent diagnostic tests:
4dx - all negative
CBC - no abnormal findings
Chem - slight hypoproteinemia (5.4 g/dl), hypoglobulinemia (1.9 g/dl), elevated ALT (99)

A1: 3rd degree AV block - r/o myocarditis vs. fibrosis
A2: alopecia - r/o allergic skin disease vs. endocrine
A3: hypoglobulinemia - hepatic insufficiency vs. PLE vs. hemorrhage
A4: elevated ALT - decreased cardiac output vs. artifact (hemolysis) vs. liver disease vs. endocrine vs. drug-induced

P:
Pacemaker placement today
discontinue minocycline?

Recent History: On telemetry overnight, pacemaker placed 10/2/13, no evidence of ventricular tachycardia overnight, eating well
A1: 3rd degree AV block - resolved
A2: alopecia - r/o allergic skin disease vs. endocrine
A3: short runs of v-tach - resolved
A4: seroma formation under chin

Professional Report

Same to Tufts after you noticed that his heart rate was too slow. We confirmed 3rd degree AV block, and echocardiogram showed typical changes to dogs with bradycardia. A pacemaker was placed the next day, and has been doing well. He was tested negative for tick-borne diseases, and UA was unremarkable. B6 seems to be younger than a typical dog with 3rd degree AV block, so we're still suspicious that some infection started this off. So there is a chance in the future that his rhythm may recover.

Thank you for your referral. Please contact us with any questions or concerns. A copy of the cardiology report will be faxed to you.

Sincerely,

[Signature]

cardiologist resident

To Our Client

Dear B6 Family,

Client Report

Presented to the Tufts in third degree AV block. AV block is a condition of the heart where the electrical impulses that are responsible for contraction of the heart fail to be conducted from the atria to the ventricles. In a normal heart, the atria and ventricles would contract the same number of times, allowing blood to move through the heart in a forward direction. In the case, his atria contract multiple times for every one contraction of the ventricles. This results in a significantly slower heart rate and lower volume of blood that gets pumped to the body. An echocardiogram showed that the heart still has good contractile function. The best treatment for AV block is a pacemaker. Following placement of a pacemaker the prognosis is good. B6 will require more frequent rechecks initially, but can later be spaced further out.

A pacemaker was placed on Wednesday 10/2. The surgery went very well. Thursday morning color and pulses were much better. B6 was tested for tick borne diseases as they can often be a cause for AV block. He
was negative for the tests. Spontaneous AV block in a young Boxer is uncommon and there is often an infectious cause whether or not we can identify it.

We are sending B6 home with a course of antibiotics to reduce the chance that his incisions get infected. B6: suture should be removed in 7-10 days, this can be done with your primary care veterinarian. At that time, an EKG should be checked just to make sure everything's working properly. In 3 months we want to see him here at Tufts to check his pacemaker function and maybe make adjustments to the pacemaker.

B6 will be going home with a neck bandage. Because he tends to scratch at his neck, we will need you to rewrap his neck several times so the bandage stays in place until the sutures come out. Please only use a harness to leash walk him and do not put a collar on while the sutures are still in place.

If you have any questions or concerns between now and your recheck appointment, please do not hesitate to call.

**Patient Care Instructions**

**Medications and Treatments**

**Itemized Medications**

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<th>strength</th>
<th>units</th>
<th>qty</th>
<th>formulation</th>
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<th>refill</th>
<th>meddose</th>
<th>status</th>
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<td>B6</td>
<td>B6</td>
<td>B6</td>
<td>B6</td>
<td>B6</td>
<td>None</td>
<td>afternoon</td>
<td>Dispense</td>
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**Follow Up Instructions**

1. Please have B6 suture removal in 7-10 days, and recheck an EKG. This can be done with your primary care veterinarian. If you would like it done here, you can make an appointment can be made by calling 508-887-4696.

2. We want B6 to return here to see us for programming of the computer/pacemaker in 2-7 months.

B6 (Resident in cardiology)
Client: B6

Patient: B6

 Archived Records 10/1/13-10/4/13 (PART ONE) & 10/11/13-2/7/14

Tufts University
Foster Hospital for Small Animals
200 Westboro Road, N. Grafton, MA 01536
508-839-5385

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<th>MIDDLE INITIAL</th>
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<th>COLOR</th>
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Length of time you have owned your pet:

Has your pet ever traveled or resided outside of New England?  □ Yes □ No
If yes, where/when:

Other Pets:

Diet:

Feeding:

Number of feedings per day:

Date of last Fecal Test:

□ Tested – Date: ____________________________

□ Not Tested

Vaccination History:

Type: ____________________________ Date: ____________________________

Other:

Date of last Heartworm Test:

□ Tested – Date: ____________________________

□ Not Tested

Heartworm Prevention:

□ Daily □ Monthly □ Not Given

Presenting Complaint:

(DO NOT WRITE BELOW THIS LINE)

History: last week allergies brought to room thought labeled
breathing not eating as much
having diarrhea brought to room this morning
no fainting or weakness - a little less active.

MEDICAL HISTORY / ADMISSION
**Tufts University**  
Foster Hospital for Small Animals  
200 Westboro Road, N. Grafton, MA 01536

---

### PHYSICAL EXAMINATION

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<th>Date:</th>
<th>01 Oct 13</th>
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<tr>
<td>Time:</td>
<td>4:15pm</td>
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<tr>
<th>Body Condition (1-9)</th>
<th>Body Weight</th>
<th>Temperament</th>
<th>Temperature</th>
<th>Pulse</th>
<th>Respiratory</th>
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<td>419</td>
<td>Normal</td>
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<td></td>
<td></td>
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<tr>
<td>S = ideal</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>S = obese</td>
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<th>Eyes</th>
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<th>Mucous Membranes</th>
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<td>N.A.F.</td>
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<tr>
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<td>(11)</td>
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</table>

**Describe abnormal, using code numbers as above, for systems**

- **ALG: Anemia on muzzle behind ears**
- **SV: Systolic murmur, gallop rhythm, hyperdynamic pulses + A2/P2 + 3rd degree AV block on EKG**
- **T: Tachy pulse, CRT 2, Bradycardia**

**A:**
- Systolic murmur, gallop rhythm, hyperdynamic pulses + A2/P2 + 3rd degree AV block on EKG

**P:**
- Cardiac conduction
- Pacemaker

---

*Page 79/213*
PATIENT DISCHARGE CHECKLIST

Date of Discharge: 10/1/13
Time of Discharge: A.M. 5:30 P.M.
Discharged by (please print) B6

Circle One: STUDENT WARD ATTENDANT ICU/TECH CLINICIAN

Check List:
- Animal is Clean
- Showed incision/wound to owner
- Removed ECG pads
- Catheter has been removed
- Instructed owner to remove Pressure Wrap
- Reviewed Discharge/Medication Orders
- Returned owners' medication (brought from home)

Comments:

FRONT DESK DISCHARGE

Discharged by (full name) Clinician

DISCHARGE ORDERS COMPLETE
ORDERS IN RECORD
RECORD IN DISCHARGE
BILLING FOLDER IN RECORD
PHARMACY COPY PULLED
MEDICATION DISPENSED FROM PHARMACY
(Do not dispense left-over medication from Ward)

YES NO Client Wait Time
YES NO
YES NO
YES NO N/A (day case)
YES NO N/A
YES NO GIVEN TO OWNER
IV CATHETER SITE(S): Left jugular
DATE PLACED: 10/1/13
INITIALS: [redacted]

CLINICAL SUMMARY: 3rd degree AV block

DATE: 10/1/13
CAGE No. [redacted]
DIE: Bivalent water ad lib
VANCO 500 mg q12h
<table>
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<tr>
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**Archived Records 10/1/13-10/4/13 (PART ONE) & 10/11/13-2/7/14**
Archived Records 10/1/13-10/4/13 (PART ONE) & 10/11/13-2/7/14

TUFTS UNIVERSITY
POSTER HOSPITAL FOR SMALL ANIMALS
200 Westboro Road, N. Grafton, MA 01536

B6

IV CATHETER SITE(S): Cephalic
DATE PLACED: 10/1/13
INITIALS:

CLINICAL SUMMARY: 3rd degree AV block

* NO NECK LEADS *

DATE: 10/2/13
CAGE #: 16725
DIET: 'NO DIET. WATER OK
WEIGHT: 20.5 lbs

HOME PHONE NO.

DAILY RECORD

PAGE 1 OF 2
IV CATHETER SITE(S): ........................................... DATE PLACED: ...........................................
INITIALS: ...........................................

CLINICAL SUMMARY: ...........................................

DATE: 10/2/13 CAGE #: BOXER DIET: CANINE
WATER: FL - WEIGHT: 25.7 kg

TREATMENT PLAN
RECORD OBSERVATIONS

MONITORING

STUDENT: ...........................................

CLINICIAN: ...........................................

HOME PHONE NO.: ...........................................

DAILY RECORD

PAGE 2 OF 7

TUFTS UNIVERSITY
FOSTER HOSPITAL FOR SMALL ANIMALS
300 Westboro Road, N. Grafton, MA 01536

B6
IV CATHETER SITE(S): L cephalic
DATE PLACED: 10/1/13
INITIALS: 

CLINICAL SUMMARY:
 pacemaker placed 10/2/13, d/t AV block (complete)
 X NO NECK LEADS

DATE: 10/2/13
CAGE #: ICU 25
DIET: 
WATER: F/C
WEIGHT: 25.1 kg

TREATMENT PLAN
RECORD OBSERVATIONS

MONITORING

DAILY RECORD

Page 89/213
IV CATHETER SITE(S): C cephalic DATE PLACED: 10/1/13 INITIALS: 
CLINICAL SUMMARY: pacemaker placed 10/2/13 - complete AV block
DATE: 10/4/13 CAGE#: ICU #5 DIET: WATER: E/C WEIGHT: 24.8 XG
From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROSTEIN>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 2/25/2019 2:19:28 PM
Subject: DCM - More from L Freeman 2/25/2019 0915
Attachments:

Acana lamb and apple dry: Lisa Freeman - EON-380747; Wellness Core grain-free ocean fish dry-Wellness core grain free turkey: Lisa Freeman - EON-380742; Wellness CORE Grain-Free Ocean Whitefish dry-Wellness Core grain free turkey: Lisa Freeman - EON-380743

Note: 380742 & 380743 are from the same household. Other dogs in household – 2 not tested yet & 1 normal BNP

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

FDA U.S. FOOD & DRUG ADMINISTRATION

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From: Rotstein, David <O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD­DROTSTEI>
To: Carey, Lauren; Ceric, Olgica; Glover, Mark; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Peloquin, Sarah; Queen, Jackie L; Rotstein, David
Sent: 2/26/2019 12:01:05 PM
Subject: DCM cases 2/26/2019 0700
Attachments: Instinct Original Grain Free Recipe (unknown protein source) EON-380789; Merrick Classic Real Beef + Green Peas Recipe with Ancient Grains Adult Dry Dog Food: EON-380855; Taste of The Wild - Salmon grain free: EON-380783; Taste of The Wild PREY (unknown formula): EON-380774; Wellness Complete Health Fish and Sweet Potato dry: Lisa Freeman - EON-380848

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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Influence of mercury and selenium chemistries on the progression of cardiomyopathy in pygmy sperm whales, *Kogia breviceps*

Colleen E. Bryan a,b,*, W. Clay Davis a, Wayne E. McFee c, Carola A. Neumann d, Jennifer Schulte d, Gregory D. Bossart c, Steven J. Christopher a

a Analytical Chemistry Division, National Institute of Standards and Technology, Hollings Marine Laboratory, 331 Fort Johnson Road, Charleston, SC 29412, USA
b Marine Biomedicine and Environmental Science Center, Medical University of South Carolina, 221 Fort Johnson Road, Charleston, SC 29412, USA
c Center for Coastal Environmental Health and Biomolecular Research, National Ocean Service, National Oceanic and Atmospheric Administration, 219 Fort Johnson Road, Charleston, SC 29412, USA
d Department of Cell and Molecular Pharmacology and Experimental Therapeutics, Medical University of South Carolina, 173 Ashley Avenue, MSC-505, Charleston, SC 29425, USA
e Georgia Aquarium, 225 Baker Street, Atlanta, GA 30313, USA

HIGHLIGHTS

- More than half of stranded pygmy sperm whales exhibit signs of cardiomyopathy.
- Hg and Se balance and oxidative stress may influence progression of cardiomyopathy.
- Adults have significantly greater Hg:Se liver molar ratios than younger age classes.
- Hg:Se molar ratios were greater in males and increased with heart disease progression.
- Protein oxidation was greater in males and increased with heart disease progression.

ABSTRACT

More than half of pygmy sperm whales (*Kogia breviceps*) that strand exhibit signs of cardiomyopathy (CMP). Many factors may contribute to the development of idiopathic CMP in *K. breviceps*, including genetics, infectious agents, contaminants, biotoxins, and dietary intake (e.g. selenium, mercury, and pro-oxidants). This study assessed trace elements in *K. breviceps* at various stages of CMP progression using fresh frozen liver and heart samples collected from individuals that stranded along US Atlantic and Gulf coasts between 1993 and 2007. Standard addition calibration and collision cell inductively coupled plasma mass spectrometry (ICP-MS) were employed for total Se analysis and pyrolysis atomic absorption (AA) was utilized for total Hg analysis to examine if the Se/Hg detoxification pathway inhibits the bioavailability of Se. Double spike speciated isotope dilution gas chromatography ICP-MS was utilized to measure methyl Hg and inorganic Hg. Immunoblot detection and colorimetric assays were used to assess protein oxidation status. Data collected on trace elements, selenoproteins, and oxidative status were evaluated in the context of animal life history and other complementary histological information to gain insight into the biochemical pathways contributing to the development of CMP in *K. breviceps*. Cardiomyopathy was only observed in adult pygmy sperm whales, predominantly in male animals. Both Hg:Se molar ratios and overall protein oxidation were greater in males than females and increased with progression of CMP.

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B4
Pathobiochemistry

Selenium protein identification and profiling by mass spectrometry: A tool to assess progression of cardiomyopathy in a whale model

Colleen E. Bryan a,*, Gregory D. Bossart b, Steven J. Christopher a, W. Clay Davis a, Lisa E. Kilpatrick c, Wayne E. McFee d, Terrence X. O’Brien e

a Chemical Sciences Division, National Institute of Standards and Technology, Hollings Marine Laboratory, 331 Fort Johnson Road, Charleston, SC 29412, USA
b Georgia Aquarium, 225 Baker Street NW, Atlanta, GA 30313, USA
c Biomolecular Measurement Division, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899, USA
d Center for Coastal Environmental Health and Biomolecular Research, National Ocean Service, National Oceanic and Atmospheric Administration, 219 Fort Johnson Road, Charleston, SC 29412, USA
e Department of Medicine, Division of Cardiology, Medical University of South Carolina, Carolina 25 Courtenay Dr. ART 7063 and the Office of Research and Development, Ralph H. Johnson Veterans Administration Medical Center, Charleston, SC 29425, USA

ARTICLE INFO

Keywords:
Selenium
Selenoprotein
Cardiomyopathy
Kogia breviceps
ICP-MS
LC-ESI-MS/MS

ABSTRACT

Non-ischemic cardiomyopathy is a leading cause of congestive heart failure and sudden cardiac death in humans and in some cases the etiology of cardiomyopathy can include the downstream effects of an essential element deficiency. Of all mammal species, pygmy sperm whales (Kogia breviceps) present the greatest known prevalence of cardiomyopathy with more than half of examined individuals indicating the presence of cardiomyopathy from gross and histopathology. Several factors such as genetics, infectious agents, contaminants, biotoxins, and inappropriate dietary intake (vitamins, selenium, mercury, and pro-oxidants), may contribute to the development of idiopathic cardiomyopathy in K. breviceps. Due to the important role Se can play in antioxidant biochemistry and protein formation, Se protein presence and relative abundance were explored in cardiomyopathy related cases. Selenium proteins were separated and detected by multi-dimension liquid chromatography inductively coupled plasma mass spectrometry (LC-ICP-MS), Se protein identification was performed by liquid chromatography electrospray tandem mass spectrometry (LC-ESI-MS/MS), and Se protein profiles were examined in liver (n = 30) and heart tissue (n = 5) by SEC/UV/ICP-MS detection. Data collected on selenium proteins was evaluated in the context of individual animal trace element concentration, life history, and histological information. Selenium containing protein peak profiles varied in presence and intensity between animals with no pathological findings of cardiomyopathy and animals exhibiting evidence of cardiomyopathy. In particular, one class of proteins, metallothioneins, was found to be associated with Se and was in greater abundance in animals with cardiomyopathy than those with no pathological findings. Profiling Se species with SEC/ICP-MS proved to be a useful tool to identify Se protein pattern differences between heart disease stages in K. breviceps and an approach similar to this may be applied to other species to study Se protein associations with cardiomyopathy.

B4

http://dx.doi.org/10.1016/j.jtemb.2017.05.005

Received 14 September 2016; Received in revised form 18 May 2017; Accepted 19 May 2017

0946-672X/ Published by Elsevier GmbH.
Comparison of reactive oxygen scavenging systems

Microtiter plate assay for the measurement of glutathione and glutathione disulfide in large numbers of biological samples, Anal. Biochem. 190 (2) (1990) 360-365.


Subcellular distribution of heavy metals in stranded dolphins from the Mediterranean sea (Southern Italy), J. Environ. Monitor. 5 (2003) 1459-1467.


**Lab Results IDEXX CARDIOPET proBNP 9/10/18**

- **Client:** B6
- **Species:** CANINE
- **Breed:** DOBERMAN_PINCH
- **Gender:** MALE
date of B6

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Reference Range</th>
<th>Low</th>
<th>Normal</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARDIOPET proBNP - CANINE</td>
<td>B6</td>
<td>0-900 pmol/L</td>
<td></td>
<td></td>
<td>B6</td>
</tr>
</tbody>
</table>

**Comments:**

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.
Cardiology Consultation

Date: B6
Weight: Weight (kg) 32.00
Requesting Clinician: B6 DVM (Resident – Emergency & Critical Care)

Attending Cardiologist:

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

Cardiology Resident:

B6

Thoracic radiographs available for review?

☐ Yes – in SS
☐ Yes – in PACS
☐ No

Patient location: ER

Presenting complaint and important concurrent diseases: 8 y.o doberman presenting for acute onset soft cough after exercise and at rest, worse at night. Owners report coughing episodes have been getting more frequent over the past 3 days. Grade IV/VI right sided systolic murmur ausculted on exam. Had scheduled appointment to be seen with cardiology 9/20/18 based on arrhythmia heard at rDVM.

*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/II
☐ IV/VI
Murmur location/description: systolic right apical

<table>
<thead>
<tr>
<th>JUGULAR VEIN</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Arterial pulses:
- Weak
- Fair
- Good
- Strong

Arrhythmia:
- None
- Sinus arrhythmia
- Premature beats

Gallop:
- Yes
- No
- Intermittent

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

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

B6
**ECG findings:**

| B6 |

**Radiographic findings:** Lung parenchyma with interstitial pattern in perihilar area. Cardiomegaly with pronounced LV and LA enlargement. Pulmonary vessels mildly dilated.

**Assessment and recommendations:** Findings consistent with DCM and active congestive heart failure. Simpson and sphericity index revealed advanced LV dilation and enlarged LA are consistent with advanced DCM. Recommend B6 in order to improve systolic function, cardiac output and decrease LA pressure. TR revealed mild PHT, for which we expect that treating CHF will help to improve pulmonary circulation. Radiographs revealed interstitial pattern consistent with incipient pulmonary edema. TID is recommended in the first 24 hours of hospitalization (if kidney values are normal) and decrease to BID tomorrow. CBC/chem, NTproBNP and Taurine levels are recommended. Telemetry monitoring during hospitalization as patient had many isolated ventricular ectopies during the exam. In case of couplets, triplets, NSVT or R/T, recommend B6. Low sodium diet (ideally a main stream brand) should be started and explain to owners that grain free diet is contra-indicated at this point. Kidney levels should be evaluated in daily basis during hospitalization and recheck ECG tomorrow in case arrhythmias are still frequent.

**Treatment plan:**

| B6 |

**Final Diagnosis:**

L-CHF secondary to DCM

**Addendum:**

| B6 | Patient did well overnight, rare episodes of cough and respiratory rate stayed stable |

**Heart Failure Classification Score:**

**ISACHC Classification:**

- Ia
- Ib
- IIIa
- IIIb

**ACVIM CHF Classification:**

- A
- B1
- B2
- C
- D

---

**FDA-CVM-FOIA-2019-1704-007836**
Discharge Instructions

Admit Date: B6 12-5-2558 AM
Check Out Date: B6

Case Summary
Diagnosis:
1. Dilated cardiomyopathy with active congestive heart failure.

Case Summary:
Thank you for bringing B6 to Tufts ER for evaluation of his persistent cough. You reported that he suddenly developed a cough three days ago and that it is worse after exercise or when he is resting at night. On presentation he was bright and alert. His vital signs (heart rate, respiratory rate, and temperature) were all within normal limits. He had an audible bilateral heart murmur. He coughed when his trachea was palpated lightly.

Based on his breed and clinical presentation, we opted to do radiographs and have an emergency consult with the cardiology department because of concerns of dilated cardiomyopathy (DCM). This is a common condition for this breed. Also, grain-free diets may predispose animals to developing dilated cardiomyopathy or make a pre-existing disease to get worse.

On his cardiology consult, ultrasound showed significantly decreased contraction of the heart, confirming dilated cardiomyopathy. EKG showed occasional abnormal heartbeats originating from the ventricle. Based on the results of his radiographs and cardiology consult, B6 was started on diuretics to relieve some of the fluid building up in his lungs. He was also started on, B6, which increases the strength of heart contractions. As grain free diet can affect absorption of some nutrients, Taurine supplementation was started. He was placed on an EKG overnight to determine if any arrhythmias are present.
Patient Care Instructions:

1. Exercise restrictions: Do not allow to overexert himself. He may still go for short walks and play with his sister but avoid strenuous activity like hiking or chasing squirrels which may overexert his heart.

2. Diet: We recommend to discontinue the grain free diet - a sheet that has suggestions for diet and low sodium treats can be found on the HeartSmart website (http://vet.tufts.edu/heartsmart/diet/). We recommend as dry options:
   - Royal Canin Early Cardiac;
   - Royal Canin Boxer;
   - Purina ProPlan Adult Weight Management.

Medications:

Recheck visits: Please come in for your scheduled cardiology appointment on September 29th at 1PM as a re-check appointment.

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

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/cvmg/clinical-studies

<table>
<thead>
<tr>
<th>Case</th>
<th>B6</th>
<th>Owner</th>
<th>B6</th>
<th>Discharge Instructions</th>
</tr>
</thead>
</table>

FDA-CVM-FOIA-2019-1704-007839
Sorry - 1 more document (diet history)
Lisa

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

-----Original Message-----
From: noreply.safetyreporting@hhs.gov <noreply.safetyreporting@hhs.gov>
Sent: Saturday, September 22, 2018 6:34 PM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: Safety Report ID 243513 Submission Confirmation

Your initial Pet Food Safety Report, Submitted by: Lisa Freeman, ID 243513, was successfully submitted on 9/22/2018 6:33:37 PM EST to the FDA, and it was issued an Individual Case Safety Report Number (ICSR) of 2055229.

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.
## Cardiology Diet History Form

**Please answer the following questions about your pet:**

**Pet's name:** B6  
**Owner's name:** B6  
**Today's date:** 9/20/18

1. **How would you assess your pet's appetite?** (Mark the point on the line below that best represents your pet's appetite. Example: Poor: __________________________ Excellent: __________________________)

<table>
<thead>
<tr>
<th>Poor:</th>
<th>Excellent:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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's weight changed?** (Check one)

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

4. **Please list below ALL pet foods, treats, snacks, dental chews, rawhide, and any other food item that your pet currently eats. Please include the brand, specific product, and flavor so we know exactly what you are feeding.**

   **Food (include specific product and flavor)** | **Form** | **Amount** | **How often?** | **Fed since**
   --- | --- | --- | --- | ---
   Nutro Grain-Free Chicken, Lentil, & Sweet Potato Adult | _ | 1 1/2 cup | 2x/day | Jan, 2016
   65% lean hamburger | last 2 bags RED microwave | 3 oz | 1x/day | Jan, 2016
   Pepperoni original beef flavor | before max-3 bags-yenn | tree: | 1/2 | 1x/day | Aug, 2015
   Rawhide | | treat: | 6 inch twist | 1x/day | Dec, 2015
   Taste of the wild | _ | dry | 3 cups | 1x/day | 2012
   Premium classic, mature & adult | _ | 4 cups | 1x/day | 2018 Sep
   Baby carrots & baby carrots | _ | treat | 2-4 | 1x/day | 2018
   Green pepper & other veggies + fruit | _ | treat | 1-2 | 1x/day | 2010
   KG Granola Factory, various treats | _ | B-10 week | 2013

   *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

   - [ ] Yes: Please list, which ones and give brands and amounts:
     - [ ] Brand/Concentrate
     - [ ] Nature's Bounty
     - [ ] [Example: Vitamin C]

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):

---

**Before Diagnosis (All Taste of the Wild)**

- Last 1-2 bags were to the Southeast Canyon
- Before that, fed 3-4 bags of Pacific Stream
- Before that, Pacific Stream

---

**FDA-CVM-FOIA-2019-1704-007843**
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

Veterinary Cardiology Service
Tufts University Cummings School of Veterinary Medicine

Please note: This account is not monitored on weekends, holidays, or evenings (after 5pm). Please allow 24-48 business hours for a reply. For immediate service during business hours, please call the liaison office at 508-887-4696. If you need to speak with the Emergency Service, please call 508-839-5395.

Foster Hospital for Small Animals
200 Westboro Road
North Grafton, MA 01536
http://www.tufts.edu/vet/
508.887.4696 phone
508.887.4363 fax

Hello -

Thank you for using the Amino Acid Laboratory at UC Davis, School of Veterinary Medicine.
Please find attached the results for your patient. You will note that we are now using a new submission form. The new form requests some additional information that may be useful in interpreting your results. Please note, with the recent increase in the number of dogs screened for taurine deficiency, we are seeing some dogs with values within the lower reference ranges (or above the “no known risk for deficiency range”) yet are still exhibiting changes in cardiac function.

In addition to our new submission form, we have also attached 2 handouts developed by our cardiology service at UC Davis for your information. The first is a general handout on dilated cardiomyopathy in dogs. The second is a handout specifically focused on Golden Retrievers, a breed that has been over-represented in the association between grain-free diet consumption and dilated cardiomyopathy.

We hope your clinic finds this information helpful. Veterinarians are always welcome to contact our laboratory for assistance in evaluating your patient’s results.

Thank you -

The Amino Acid Laboratory  
Department of Molecular Biosciences  
School of Veterinary Medicine  
University of California, Davis

Phone: 530-752-5058  
Email: ucd.aminoacid.lab@ucdavis.edu
Thanks, Lisa.

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

-----Original Message-----
From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Saturday, September 22, 2018 6:37 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: FW: Safety Report ID 243513 Submission Confirmation

Sorry - 1 more document (diet history)
Lisa

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Board Certified Veterinary NutritionistTM
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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
Sample Submission Form

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


Vet/Tech Contact: B6
Company Name: Tufts Cummings School of Vet Med - Clinical Pathology Laboratory
Address: 200 Westboro Road
North Grafton, MA 01536

Email: clinpath@tufts.edu; cardiovet@tufts.edu
Tel: 508-887-4669
Fax: 508-839-7936

Billing Contact: B6
TAX ID: B6
Email: B6

Patient Name: B6
Species: canine
Owner’s Name: B6

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

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

Reference Ranges (nmol/ml)

<table>
<thead>
<tr>
<th></th>
<th>Plasma</th>
<th>Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat</td>
<td>80-120</td>
<td>&gt;40</td>
</tr>
<tr>
<td></td>
<td>300-600</td>
<td>&gt;200</td>
</tr>
<tr>
<td>Dog</td>
<td>60-120</td>
<td>&gt;40</td>
</tr>
</tbody>
</table>
|       | 200-350| >150 ]
Doberman Pinscher Dilated Cardiomyopathy (DCM) Genetic Testing

Dilated cardiomyopathy mutation (DCM) is a form of heart disease in the Doberman pinscher dog. It is an inherited disease, and our laboratory has identified two mutations responsible for the development of DCM. Dogs that are positive for both mutations are at the highest risk of developing DCM.

**Owner Name:** B6

**Dog's Name:** B6

**ID #:** 320320

Below is an explanation for each possible test result so you can better understand all the possible results and make informed breeding decisions:

<table>
<thead>
<tr>
<th>Test Result</th>
<th>Description</th>
<th>Breeding Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Result for both DCM1 and DCM2:</td>
<td>The absence of both mutations in a Doberman indicates that the risk of developing DCM is low. It is still possible for a dog to develop heart disease. However, a negative result for both DCM1 and DCM2 indicates that a dog does not have either mutation known to cause DCM.</td>
<td>Dogs are positive for DCM1 should NEVER be bred to a dog that is positive for NCSU DCM 2 since this will lead to dogs that are highest risk of developing DCM. Dogs that are positive homozygous for DCM1 should ideally not be bred.</td>
</tr>
<tr>
<td>Positive result for NCSU DCM1 only:</td>
<td>About 40% of dogs with this mutation will develop DCM. Dogs that are positive for only DCM1 will not necessarily develop significant heart disease.</td>
<td>Dogs are positive for DCM1 should NEVER be bred to a dog that is positive for NCSU DCM 2 since this will lead to dogs that are highest risk of developing DCM. Dogs that are positive homozygous for DCM1 should ideally not be bred.</td>
</tr>
<tr>
<td>Breeding recommendations:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive Result for NCSU DCM2 only:</td>
<td>About 50% of dogs with this mutation will develop DCM. Dogs that are positive for only DCM2 will not necessarily develop significant heart disease.</td>
<td>Dogs are positive for DCM2 should NEVER be bred to a dog that is positive for NCSU DCM1 (PDK4) since this will lead to dogs that are highest risk of developing DCM. Dogs that are positive homozygous for DCM2 should ideally not be bred.</td>
</tr>
<tr>
<td>Breeding recommendations:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive result for both NCSU DCM1 and NCSU DCM2:</td>
<td>Dogs that positive for BOTH DCM1 &amp; DCM2 are at a very HIGH risk of developing DCM and should be carefully monitored by your veterinarian for signs of disease. Annual evaluation by a cardiologist with an echocardiogram and Holter monitor after 3 years of age is recommended.</td>
<td>Dogs that positive for both DCM1 &amp; DCM2 are at the HIGHEST risk of developing DCM and should ideally not be bred since they can pass both traits on. They should never be bred to a dog that is positive for either test.</td>
</tr>
<tr>
<td>Breeding recommendations:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As always, breeding decisions should be made carefully. Removal of a significant number of dogs from the breeding population could be very bad for the Doberman Pinscher breed. Remember that dogs that carry this mutation may also carry other important good genes that we do not want to lose from the breed.
Initial Complaint:
Vomiting

Exam:
Subjective (S): BAR

Objective (O)

H/L: No murmurs, arrhythmias or adventitious lung sounds

Referral Diagnostics: Blood work (not available at ER visit)

Diagnostics Completed:

Diagnostics Pending:
Requested feces be collected and put on hold for possible salmonella testing
EDTA and serum on hold in ER fridge

Treatments Completed:
SOAP Text  Feb 16 2015 3:34PM  B6

2/16/2015 3:34:42 PM EXAM, GENERAL

Subjective (S)
No vomiting overnight, kept NPO. QAR and nervous this morning.

Additional history:

H/L: NSR, NMA, fpss; eupneic, normal BV sounds bilaterally

Assessment (A)
2/17/2015 7:35:35 AM

SOAP Text Feb 17 2015 5:35PM

2/17/2015 6:17:50 PM EXAM, GENERAL

Subjective (S)
Looks brighter this morning. No vomiting, but still having large bowel diarrhea. No interest in food. Owner says that B6 is normally a picky eater.

Objective (O)

H/L: NSR, NMA, fpss; normal BV sounds bilaterally

Diagnostics:

Assessment (A)

Plan (P)
SOAP Text Feb 18 2015 8:49AM - B6

2/18/2015 8:49:54 AM EXAM, GENERAL

Subjective (S)
BAR. Ate boiled hamburger and rice at owner visit last night continued to eat purina EN throughout the night. No vomiting noted. Still has some _, but stool is becoming more formed.

Objective (O)

H/L: NSR, NMA, fpss; normal BV sounds bilaterally

Assessment (A)

Plan (P)

2/18/2015 9:29:02 AM
Prescribed - B6
Instructions:

Initial Complaint:
Emergency

SOAP Text Feb 20 2015 8:41AM - B6

2/20/2015 12:51:27 PM NEW VISIT (ER)
Doctor: B6
Student: B6
Presenting complaint: B6
On car ride here: vomited small amount of fluid/foam

Past pertinent medical history:

Dietary history:
Type of food: Boiled hamburger and rice
Amount per feeding:
Feedings per day:

Visit is a referral: No
Bloodwork completed prior to arrival: None

Exam:

Objective (O)
H/L: HR: 120, NMA, NSR, PSS. RR: 36, eupenic, normal BV sounds

Referral Diagnostics: None

Diagnostics Completed:

Abdominal Radiographs: Normal abdomen

Abdominal US:

Diagnostics Pending: None

Treatments Completed:

Assessment (A)

Plan (P)
Additional requests submitted:

Estimate given: $  
Deposit collected: $
Medications currently administered at home: B6

Dietary history:
Type of food: Raw diet since weaning
Amount per feeding:
Feedings per day:

Visit is a referral: Yes  No
Bloodwork completed prior to arrival:

Exam: B6

Objective (O)

Treatments Completed: B6

Assessment (A)

Plan (P)

Communication Summary:

Additional requests submitted:

Estimate given: $  Deposit collected: $
Initial Complaint:
recheck

Initial Complaint:
Emergency

5/2/2015 11:05:54 PM NEW VISIT (ER)
Doctor: B6
Student: B6
Presenting complaint: B6

Past pertinent medical history:

Medications currently administered at home:
Visit is a referral: No
Bloodwork completed prior to arrival: No

Exam:

Objective (O)

H/L: HR 96, NMA, NSR, SSP, RR 28, normal effort, normal BV sounds bilaterally
Abd: soft, non painful, gas filled loops
UG: intact female, normal externally, no discharge
MSI: ambulatory x 4, no ectoparasites, normal hair coat
Neuro: mentally appropriate, full exam not performed
Rectal: mucoid discharge, otherwise WNL

Referral Diagnostics:
None
Diagnostics Completed:
Ocular exam
Diagnostics Pending:
None
Treatments Completed:
None

Assessment (A)

Plan (P)

Communication Summary:
Initial Complaint:
Emergency

SOAP Text
9:09:46 AM: TS (FHSA) 6.8
9:09:46 AM: PCV ** 50
11:19:13 AM NEW VISIT (ER)

Doctor: B6
Student: B6

Presenting complaint: ADR this morning
Referral visit? No
Diagnostics completed prior to visit: None

HISTORY: B6 presented to Tufts ER for ADR this morning. Not really willing to get out of bed and hunched/shaky.

Signalment: B6

Current history: B6
Prior medical history: No concerns
Current medications: None
Diet: 
Vaccination status/flea & tick preventative use: 
Travel history: None

EXAM:

BCS: B6
Hydration:

EENT: B6
C/V: NSR, NMA, fpSS.

ASSESSMENT:
A1: ADR r/o dilated cardiomyopathy vs pyometra vs primary GI
A2: DCM
PLAN:
- Thoracic radiographs; mild cardiomegaly with mild right ventricular enlargement
- Cardiology consult

Diagnostics completed:

Diagnostics pending:

Client communication:

Deposit & estimate status:

Resuscitation code (if admitting to ICU):

SOAP approved (DVM to sign):

Initial Complaint:

Subjective

EXAM, GENERAL

4 yo intact female presenting for spay. Referred from cardio- echocardiogram shows LV dilation, ECG-occassional VPCs, currently on Doing well at home.

Objective (O)

H/L: HR 100, NSR, NMA, fpss. Lung fields clear with normal BV sounds. No crackles/wheezes
Assessment (A)
A1: Healthy female presenting for spay
A2: LV dilation with occasional VPCS - r/o early DCM - on carvediolol

Plan (P)

SOAP completed by: B6
SOAP reviewed by:

Initial Complaint:

SOAP Text Apr 20 2018 7:57AM B6

Subjective

EXAM, GENERAL
B6 4 yo intact female doberman presenting for B6 Referred from cardio-
echocardiogram shows LV dilation, ECG - occasional VPCs, currently on B6 gave morning dose
do carvediolol

Current medications:
B6

Subjective (S)
B6

Objective (O)
B6

Assessment (A)
A1: Intact female presenting for r/o early DCM
A2: LV dilation with occasional VPCS

Plan (P)

SOAP completed by
SOAP reviewed by:

Addendum:

Subjective
EXAM, GENERAL
now A 4 yo female spayed doberman who presented for
Referred from cardio - echocardiogram shows LV dilation, ECG- occasional VPCs, currently on

Overnight Update:

Recent Diagnostics:
Current medications:

Subjective (S)

Objective (O)

H/L: Normal sinus rhythm, no murmur heard. Femoral pulses strong and synchronous. Lung fields clear with normal BV sounds. No crackles/wheezes

Assessment (A)
A1: 1 Day post-
A2: LV dilation with occasional VPCS- r/o early DCM--

Plan (P)

SOAP completed by:
Initial Complaint:
Chief Special-recheck

Subjective
EXAM, GENERAL

Recent Diagnostics:

Current medications:

Subjective (S)

Assessment (A)
A1: 3 Day post-  B6  inappetent, quiet, intermittent trembling at home—r/o mild nausea vs discomfort vs other
A3: LV dilation with occasional VPCS—r/o early DCM—stable, or  B6

Plan (P)

SOAP completed by  B6

Initial Complaint:
Tech - ECG

SOAP Text  May 7 2018 10:58AM - Rush, John
Initial Complaint:
Recheck - B6

SOAP Text  Dec 11 2018 10:40AM - B6

Disposition/Recommendations
CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet:

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

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

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

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

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

   **Food (include specific product and flavor)** | **Form** | **Amount** | **How often?** | **Dates fed**
   --- | --- | --- | --- | ---
   Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult | dry | 1 1/2 cup | 2x/day | Jan 2016-present
   95% lean hamburger | microwaved | 3 oz | 1x/week | June - Aug 2016
   Pepperoni original beef flavor | treat | 1/2 | 1x/day | Sept 2016-present
   Rawhide | treat | 6 inch twist | 1x/week | Dec 2018-present
   Taurine (pills) | | | | Jan 1972-
   Carnitine (pills) | | | | Jan 1972-
   Antioxidants (pills) | | | | Jan 1972-
   Multivitamin (pills) | | | | Jan 1972-
   Fish oil | | | | Jan 1972-
   Coenzyme Q10 | | | | Jan 1972-
   Other (please list) | | | | Jan 1972-

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

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

   **Brand/Concentration** | **Amount per day**
   --- | ---
   Taurine | Nature’s Bounty
   Carnitine | 500 mg tablets – 1 per day
   Antioxidants | Nature’s Bounty
   Multivitamin | Nature’s Bounty
   Fish oil | Nature’s Bounty
   Coenzyme Q10 | Nature’s Bounty
   Other (please list) | Nature’s Bounty

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

Page 4/14
Client: B6
Patient: B6

Idexx NT-proBNP 5/3/2019

<table>
<thead>
<tr>
<th>Client:</th>
<th>B6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species:</td>
<td>CANINE</td>
</tr>
<tr>
<td>Breed:</td>
<td>LABRADOR RETRIE</td>
</tr>
<tr>
<td>Gender:</td>
<td>FEMALE</td>
</tr>
<tr>
<td>Age:</td>
<td>5Y</td>
</tr>
</tbody>
</table>

**Comments:**

"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."
<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Reference Interval</th>
<th>Assay Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultra-Sensitive Troponin I Fasting</td>
<td>B6</td>
<td>≤0.06</td>
<td>05/31/19</td>
</tr>
</tbody>
</table>

**Comments:**

**GI Lab Contact Information**

Phone: (979) 862-2861  
Fax: (979) 862-2864  
Email: gilab@cvm.tamu.edu  
vetmed.tamu.edu/gilab
CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6
Owner's name: B6
Today's date: 5/3/2019

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

Example: Poor: __________ Excellent: __________

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Food (include specific product and flavor)</th>
<th>Form</th>
<th>Amount</th>
<th>How often?</th>
<th>Dates fed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutro Grain Free Chicken, Lentil, &amp; Sweet Potato Adult</td>
<td>dry</td>
<td>1 1/2 cup</td>
<td>2x/day</td>
<td>Jan 2018-present</td>
</tr>
<tr>
<td>95% lean hamburger</td>
<td>microwaved</td>
<td>3 oz</td>
<td>1x/week</td>
<td>June - Aug 2016</td>
</tr>
<tr>
<td>Pepperoni original beef flavor</td>
<td>treat</td>
<td>1/2</td>
<td>1x/day</td>
<td>Sept 2016-present</td>
</tr>
<tr>
<td>Rawhide</td>
<td>treat</td>
<td>6 inch twist</td>
<td>1x/week</td>
<td>Dec 2018-present</td>
</tr>
<tr>
<td>Purina Pro Plan</td>
<td>treat</td>
<td>1/2</td>
<td>2x/day</td>
<td>Jan 2019-present</td>
</tr>
<tr>
<td>Wholesome Dog Biscuit</td>
<td>treat</td>
<td>1</td>
<td>3x/week</td>
<td>Jan 2019-present</td>
</tr>
<tr>
<td>Wholesome Dog Biscuit</td>
<td>treat</td>
<td>1</td>
<td>3x/week</td>
<td>Jan 2019-present</td>
</tr>
<tr>
<td>Wholesome Dog Biscuit</td>
<td>treat</td>
<td>1</td>
<td>3x/week</td>
<td>Jan 2019-present</td>
</tr>
</tbody>
</table>

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

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

☐ Yes ☐ No

If yes, please list which ones and give brands and amounts:

- Taurine: ☐ Yes ☐ No
- Carnitine: ☐ Yes ☐ No
- Antioxidants: ☐ Yes ☐ No
- Multivitamin: ☐ Yes ☐ No
- Fish oil: ☐ Yes ☐ No
- Coenzyme Q10: ☐ Yes ☐ No
- Other (please list):

Example: Vitamin C Nature's Bounty 500 mg tablets - 1 per day

3. How do you administer pills to your pet?

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

Page 4/14
Client: B6
Patient: B6

Idexx NT-proBNP 5/3/2019

Client: B6
Species: CANINE
Gender: FEMALE

CardioPET proBNP - CANINE

Test: CardioPET proBNP
Species: CANINE

Lab: IDX

Reference Range: 0 - 900 pmol/L
Result: 900 pmol/L

Comments:

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.
<table>
<thead>
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<th>Reference Interval</th>
<th>Assay Date</th>
<th>Comments</th>
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<tr>
<td>Ultra-Sensitive Troponin</td>
<td>B6</td>
<td>&lt;0.06</td>
<td>05/31/19</td>
<td></td>
</tr>
</tbody>
</table>

Comments:
This is a Dr. Freeman report (follow-up)-not sure if this is one that you were working on.

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

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From: PFR Event <pfreventcreation@fda.hhs.gov>
Sent: Sunday, February 24, 2019 6:57 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>
Subject: Solid Gold Mighty Mini Beef: Lisa Freeman - EON-380716

A PFR Report has been received and PFR Event [EON-380716] has been created in the EON System.

A "PDF" report by name "2063119-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 "2063119-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-380716
ICSR #: 2063119
EON Title: PFR Event created for Solid Gold Mighty Mini Beef Sweet Potato and Apple grain free dry; 2063119

<table>
<thead>
<tr>
<th>AE Date</th>
<th>01/02/2019</th>
<th>Number Fed/Exposed</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Best By Date</td>
<td></td>
<td>Number Reacted</td>
<td>1</td>
</tr>
<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
</tbody>
</table>
**Product information**

**Individual Case Safety Report Number:** 2063119

**Product Group:** Pet Food

**Product Name:** Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry

**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.

**Submission Type:** Initial

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

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

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

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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sender information**

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

**Owner information**

[B6] USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-380716

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=12&issueId=397725

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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.
A PFR Report has been received and Related PFR Event [EON-390030] has been created in the EON System.

A "PDF" report by name "2067990-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 "2067990-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390030  
**ICSR #:** 2067990  
**EON Title:** Related PFR Event created for Solid Gold Mighty Mini Beef Sweet Potato and Apple grain free dry; 2067990

<table>
<thead>
<tr>
<th>AE Date</th>
<th>Number Fed/Exposed</th>
<th>Best By Date</th>
<th>Number Reacted</th>
<th>Animal Species</th>
<th>Outcome to Date</th>
<th>Breed</th>
<th>Age</th>
<th>District Involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/02/2019</td>
<td>1</td>
<td></td>
<td>1</td>
<td>Dog</td>
<td>Better/Improved/Recovering</td>
<td>Chihuahua</td>
<td>9 Years</td>
<td>PFR-New England DO</td>
</tr>
</tbody>
</table>

**Product information**  
**Individual Case Safety Report Number:** 2067990  
**Product Group:** Pet Food  
**Product Name:** Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry  
**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
Submission Type: Followup
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Better/Improved/Recovering
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
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<th>Best By Date</th>
</tr>
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<tbody>
<tr>
<td>Solid Gold Mighty Mini Beef, Sweet Potato, and Apple grain free dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This report is linked to:
Initial EON Event Key: EON-380716
Initial ICSR: 2063119

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-390030

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=407302&parentIssueTypeId=12

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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.
Client: B6

**CARDIOLOGY DIET HISTORY FORM**

**Pet's name:** B6

**Owner's name:** B6

**Today's date:** 4/5/19

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

   Example: Poor — Excellent

   Poor — Excellent

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

   □ Eats about the same amount as usual □ Eats less than usual □ Eats more than usual

   □ Seems to prefer different foods than usual □ Other

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

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

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

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

   **Food (include specific product and flavor)**
   **Form**
   **Amount**
   **How often?**
   **Dates fed**

   **Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult**
   Dry 1 ½ cup 2x/day Jan 2016-present

   **95% lean hamburger**
   Microwaved 3 oz 1x/week June-Aug 2016

   **Pupperoni original beef flavor**
   Treat ½ 1x/day Sept 2016-present

   **Rawhide**
   Treat 6 inch twist 1x/week Dec 2016-present

   **Rise case - Cat Freedom (1/4 case)**
   Treat 1x/day

   **Solid Gold Mighty Mini-Sweet Potato**
   Dry 1/4 cup Split 2x Daily

   **Royal Canin - Farley Canina**
   Dry 1/4 cup Split 2x Daily

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

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

   □ Yes □ No

   If yes, please list which ones and give brands and amounts:

   **Brand/Concentration**

   **Amount per day**

   **Taurine**
   □ Yes □ No

   **Creatine**
   □ Yes □ No

   **Antioxidants**
   □ Yes □ No

   **Multivitamin**
   □ Yes □ No

   **Fish oil**
   □ Yes □ No

   **Coenzyme Q10**
   □ Yes □ No

   **Other (please list)**

   **Example: Vitamin C Nature's Bounty**

   Nature's Bounty 500 mg tablets - 1 per day

3. **How do you administer pills to your pet?**

   □ I do not give any medications

   □ I put them directly in my pet's mouth without food (liquid)

   □ I put them in my pet's dog/cat food

   □ I put them in a Pill Pocket or similar product

   □ I put them in foods (list foods)
**Client:** B6  
**Patient:** B6  

**NT-proBNP 4/5/19**

<table>
<thead>
<tr>
<th>Test</th>
<th>Method</th>
<th>Reference Range</th>
<th>Low</th>
<th>Normal</th>
<th>High</th>
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<tr>
<td>CARDIOPET proBNP - CANINE</td>
<td>B6</td>
<td>0 - 900 pmol/L</td>
<td>B6</td>
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</tr>
</tbody>
</table>

**Comments:**

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.
Test Result Reference Interval Assay Date
Ultra-Sensitive Troponin I Fasting B6 ng/mL ≤0.06 05/31/19
Amino Acid Laboratory Sample Submission Form
Amino Acid Laboratory, 1089 Veterinary Medicine Drive, Davis, Ca 95616
Telephone: 530-752-5058, Fax: 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

Veterinarian Contact: B6

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

Address: 200 Westboro Road, North Grafton MA 01536

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

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

Billing Contact: B6

Billing Contact Phone: 508-887-4267 Email: B6

Patient Name: B6

Species: Canine

Breed: Chihuahua

Owner’s Name: B6

Current Diet: Solid Gold veterinary

Sample type: Plasma Whole Blood Urine Food Other

Test: Taurine Complete Amino Acids Other: __________

Taurine Results (lab use only)
Plasma: __________ Whole Blood: B6 Urine: __________ Food: __________

<table>
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<tr>
<th></th>
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<th>Whole Blood (nMol/ml)</th>
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<tr>
<td></td>
<td>Normal Range</td>
<td>No known risk for deficiency</td>
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<tr>
<td>Cat</td>
<td>80-120</td>
<td>&gt;40</td>
</tr>
<tr>
<td>Dog</td>
<td>60-120</td>
<td>&gt;40</td>
</tr>
</tbody>
</table>

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

Result: B6

Reference Interval: ≤0.06

Assay Date: 03/06/19

Comments:
<table>
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<tr>
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Comments:

Gi Lab Contact Information

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

Email: gilab@cvm.tamu.edu

vetmed.tamu.edu/gilab
### Test Results

- **Test:** Ultra-Sensitive Troponin I Fasting
- **Result:** B6
- **Reference Interval:** ≤0.06
- **Assay Date:** 03/06/19

### Comments:

---

**GI Lab Contact Information**

Phone: (979) 862-2861  
Fax: (979) 862-2864  
Email: gilab@cvm.tamu.edu  
vetmed.tamu.edu/gilab
Gastrointestinal Laboratory
Dr. J.M. Steiner
Department of Small Animal Clinical Sciences
Texas A&M University
4474 TAMU
College Station, TX 77843-4474

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

GI Lab Assigned Clinic ID: 11405

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

Phone: 508 887 4669
Fax: 950 839 7936

Animal Name: B6
Owner Name: B6
Species: Canine
Date Received: Mar 06, 2019

Tufts University-Clinical Pathology Lab
Tracking Number: B6

Test Result Reference Interval Assay Date
Ultra-Sensitive Troponin I Fasting B6 ≤0.06 03/06/19

Comments:

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Phone: (979) 862-2861
Fax: (979) 862-2864
Email: gilab@cvm.tamu.edu
vetmed.tamu.edu/gilab
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<td>( \leq 0.06 )</td>
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Fax: (979) 862-2864

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Fax: (979) 862-2864

Email: gilab@cvm.tamu.edu  
vetmed.tamu.edu/gilab
**Gastrointestinal Laboratory**  
**Dr. J.M. Steiner**  
**Department of Small Animal Clinical Sciences**  
Texas A&M University  
4474 TAMU  
College Station, TX 77843-4474

Website User ID: clinpath@tufts.edu  
GI Lab Assigned Clinic ID: 11405

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<th>Dr.</th>
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<th>Phone:</th>
<th>508 887 4669</th>
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<tbody>
<tr>
<td>Attn:</td>
<td>B6</td>
<td>Fax:</td>
<td>9 508 839 7936</td>
</tr>
<tr>
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<td>200 Westboro Road</td>
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</tr>
<tr>
<td></td>
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<td>Animal Name:</td>
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**Test Result Reference Interval Assay Date**

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

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#### GI Lab Contact Information

**Phone:** (979) 862-2861  
**Fax:** (979) 862-2864  
**Email:** gilab@cvm.tamu.edu  
**Website:** vetmed.tamu.edu/gilab
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Phone: (979) 862-2861  
Fax: (979) 862-2864

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

---

**Website User ID:** clinpath@tufts.edu  
**GI Lab Assigned Clinic ID:** 11405  
**Phone:** 508 887 4669  
**Fax:** 9 508 839 7936

---

**Animal Name:**  
**Owner Name:**  
**Species:**

**Date Received:** Mar 06, 2019

---

**Tufts University-Clinical Pathology Lab**

**Attn:** B6  
200 Westford Road  
North Grafton, MA 01536  
USA

---

**FDA-CVM-FOIA-2019-1704-008169**
**Test Result Reference Interval Assay Date**

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**Comments:**

---

**GI Lab Contact Information**

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

Internal Medicine Conference

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

Ongoing studies

**Cobalamin Supplementation Study**- Dogs and cats with cobalamin deficiency with normal PLI, and either normal or low (consistent with EPI) TLI to compare the efficacy of oral vs parenteral cobalamin supplementation. Contact Dr. Chang at chchang@cvm.tamu.edu 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 >400µg/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
From: PFR Event <pfreventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification;
Sent: 11/10/2018 6:44:26 PM
Subject: Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food
Attachments: 2058695-report.pdf; 2058695-attachments.zip

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

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

Below is the summary of the report:

**EON Key:** EON-370755  
**ICSR #:** 2058695  
**EON Title:** PFR Event created for Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food; 2058695

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<th>Number Fed/Exposed</th>
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<tr>
<td>Animal Species</td>
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<td>Outcome to Date</td>
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<tr>
<td>Breed</td>
<td>Retriever - Golden</td>
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<td></td>
</tr>
<tr>
<td>Age</td>
<td>[B6] Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR{B6}DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**

**Individual Case Safety Report Number:** 2058695  
**Product Group:** Pet Food  
**Product Name:** Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon & Peas Formula Dry Dog Food  
**Description:** Low taurine level, eating Wellness Simple grain free for 3 months prior to testing and Wellness Core Low fat Grain Free food for 3 years before that. Taurine level was [B6] Echo showed NO DCM  
**Submission Type:** Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Unknown
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Wellness Simple Limited Ingredient Diet Grain-Free Healthy Weight Salmon &amp; Peas Formula Dry Dog Food</td>
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</table>

Sender information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-370755

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=387724

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

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

Dr. B6

B6 is a 6-year-old FS golden retriever belonging to B6 who presented to the B6 for a cardiac evaluation.

Cardiac Diagnosis: Normal echocardiogram.

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

Cardiology Exam:

CV: I/VI left apical systolic heart murmur. Regular rhythm. Strong and synchronous pulses. B6

Echocardiogram Subjective Findings: B6

Echocardiogram Objective Findings: B6

Assessment/Recommendations: There is no evidence of significant cardiomyopathy seen on this exam. There are trace insufficiencies of the mitral and tricuspid valves, which are hemodynamically insignificant at this time. No cardiac medications are warranted at this time. Consider switching to a non-grain-free diet due to low normal contractile function.

Medications: No cardiac medications warranted at this time.

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

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

B6 DVM, DACVIM (Cardiology)
FREQUENTLY REQUESTED INFORMATION REGARDING TAURINE & DILATED CARDIOMYOPATHY IN GOLDEN RETRIEVERS

Taurine reference ranges for Golden Retrievers: The Stern Lab suggests that the following clinical reference ranges be used for Golden Retrievers and be considered for other known taurine-sensitive breeds such as Newfoundlands 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 documented disease reversal after taurine supplementation and diet change.
2. Previously published work documents taurine sensitivity 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/mL
- Normal plasma taurine: >70nmol/mL
- Marginal whole blood taurine: 200-250nmol/mL
- Marginal plasma taurine: 60-70nmol/mL
- Low whole Blood taurine: <200nmol/mL
- Low plasma taurine: <60nmol/mL

References:

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 DCM, 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 utilized for our reference ranges was generated. https://www.vetmed.ucdavis.edu/labs/aminos-acid-laboratory. 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 underscores the value of paired sampling.
Clinical Recommendations for Golden Retrievers based on taurine levels:

If taurine levels test <200nmol/mL in whole blood or <60nmol/mL in plasma

- An echocardiogram by a board-certified veterinary cardiologist is indicated
- After echocardiogram has been completed, a diet change is recommended.
  - If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - If DCM is diagnosed, prescribed supplementation with oral taurine and l-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

If taurine levels test 200 – 250nmol/mL in whole blood or 60-70nmol/mL 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 thus the value of screening should be carefully considered. If the dog is eating a diet that falls within the FDA warning or shares features 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 on the new diet should be considered.
- If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - If DCM is diagnosed, prescribed supplementation with oral taurine and l-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

If taurine levels test >250nmol/mL in whole blood or >70nmol/mL in plasma

- Diet change is recommended if you are feeding a diet that falls within the FDA warning or shares features with the diets identified in our study (see diets of concern section below)
- If your pet shows any signs of cardiac disease (trouble breathing, exercise intolerance, fainting/collapse, coughing) we recommend your veterinarian evaluate your pet.
Diets of Concern & Choosing 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 legumes like peas and lentils, white or sweet potatoes). These findings were largely recapitulated in our current study of Golden Retrievers with low taurine levels and DCM. 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 as consensus by veterinary nutritionists from around the world:
- FDA alert found here:
  - https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm

Choosing a taurine or l-carnitine supplement:

Selecting supplements should be performed based upon those that match their stated contents and are readily available for absorption. Luckily a previous publication tested multiple taurine and l-carnitine supplements. Based upon this publication our laboratory recommends the following supplements as those meeting our quality criteria. (Bragg et al. 2009 J Am Vet Med Assoc; 234(2))

Tested taurine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes

- Mega taurine caps by Twinlab (1000 capsule)
- Taurine by Swanson Health Products (500mg capsule)
- Taurine by NOW foods (500mg capsule)
- Taurine 500 by GNC (500mg tablet)

Tested L-carnitine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes

- L-carnitine 500 by Jarrow Formulas (500mg capsule)
- L-carnitine caps by Country Life (500mg capsule)
- Maxi L-carnitine by Solgar Vitamin and Herb (500mg tablet)
- L-carnitine by Puritan’s Pride (500mg tablet)

The Stern lab does not recommend the empirical supplementation of taurine or l-carnitine to dogs without evidence of DCM and/or significant deficiency. If DCM is diagnosed we typically recommend dogs over 50lbs receive 1000mg of taurine every 12hrs and dogs under 50lbs receive 500mg of taurine every 12hours. 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 prescribing the best dose for your dog.

Reporting to the FDA:

Understanding the basis of this condition requires a great deal of research and investigation. Clients 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:

https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm182403.htm

Additional questions or comments: sterngenetics@ucdavis.edu

This document last updated: Aug. 20, 2018

Page 3 of 3
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>  
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>  
Subject: FW: 800.267-FDA Case Investigation for [B6] EON-359970

Dear folks

One of the owners who reported a case mentioned to me that there is a facebook page which has information crowd-sourced from owners regarding grain-free products and DCM. She offered to send it to me and I said sure send it but I recommended she advise owners to submit reports to FDA.

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

Thank you for the information.

Again – please urge the users of the Facebook page to report their individual cases to FDA directly.

A consumer complaint can be submitted through the Safety Reporting Portal: 
https://www.safetyreporting.hhs.gov

Best Regards,

Renate Reimschuessel V.M.D. Ph.D. Director Vet-LIRN
Phone 1-240-402-5404
Fax 301-210-4685
Hi Dr. Reimschuessel,

Please find the attached Diet and Taurine Table Spreadsheet and is aware this document is being emailed to you. Out of respect for the privacy of the dog owners, I've crossed out their names.

All of the information on these pages was supplied by the individual dog owners. It is sorted by dog food brand in an effort to help members easily see which foods may be a problem and which foods produce good taurine levels. The areas highlighted in yellow represent low taurine results and the brand and formula fed at the time the blood work was performed. Not all dogs diagnosed with low taurine had echocardiograms performed, but the results are noted for those that did.

Please let me know when you receive this.

Thank you,
The one I’ve been following (behind the scenes) on FB is “Taurine-Deficient Dilated Cardiomyopathy” which is focused on the condition in Golden Retrievers (at least originally), but has expanded beyond the breed. They’re working closely with Josh Stern at UC Davis. From a glance at the data, I assume it’s the same group.

Thanks Renate! Is this a Golden Retriever group? A lot of Golden and Golden mixes.

The owner sent you the spreadsheet or is it from CVCA/UC Davis?

Martine

Dear folks
One of the owners who reported a case mentioned to me that there is a facebook page which has information crowd-sourced from owners regarding grain-free products and DCM. She offered to send it to me and I said sure send it but I recommended she advise owners to submit reports to FDA.

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.

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
To: ______________________________________
Subject: RE: 800.267-FDA Case Investigation for EON-359970

Thank you for the information.

Again – please urge the users of the Facebook page to report their individual cases to FDA directly.

A consumer complaint can be submitted through the Safety Reporting Portal:
https://www.safetyreporting.hhs.gov

Best Regards,

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

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

Hi Dr. Reimschuessel,

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Thank you,
This was sent to me by the owner of a dog that did report to FDA and has been sending me the dog’s medical records.
She mentioned the FB page. It looks like it might be the one Lee Anne has looked at since most of the bloodwork is from Davis.
Jen – has Josh Stern been in the group that we spoke with?

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

Thank you for the information.

Again – please urge the users of the Facebook page to report their individual cases to FDA directly.

A consumer complaint can be submitted through the Safety Reporting Portal:
https://www.safereporting.hhs.gov

Best Regards,

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

Hi Dr. Reimschuessel,

Please find the attached Diet and Taurine Table Spreadsheet. B6 is an B6 and is aware this document is being emailed to you. Out of respect for the privacy of the dog owners, I've crossed out their names.

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Please let me know when you receive this.

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

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>  
Subject: RE: 800.267-FDA Case Investigation for B6 [EON-359970  

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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: Palmer, Lee Anne  
Sent: Wednesday, August 1, 2018 8:16 AM  
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Reimschuessel, Renate <Reenate.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>  
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>  
Subject: RE: 800.267-FDA Case Investigation for B6 [EON-359970  

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From: Hartogensis, Martine
Thanks Renate! Is this a Golden Retriever group? A lot of Golden and Golden mixes.

Martine

From: Reimschuessel, Renate
Sent: Wednesday, August 01, 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>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Palmer, Lee Anne <Lee.Anne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: FW: 800.267-FDA Case Investigation for [B6] EON-359970

Dear folks
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Please let me know when you receive this.

Thank you,
Good afternoon,

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

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 in CHF and isn’t responding to treatment. She is a 3.5yrold, 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.

B6
to discuss next steps.

Sincerely,

[Signature]

[Contact Information]

[Logo: Like us on Facebook, Find us on Yelp]
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

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. 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. is out of the office today. Please give me a call at your earliest convenience to discuss next steps.  
Sincerely,
FREQUENTLY REQUESTED INFORMATION REGARDING TAURINE & DILATED CARDIOMYOPATHY IN GOLDEN RETRIEVERS

Taurine reference ranges for Golden Retrievers: The Stern Lab suggests that the following clinical reference ranges be used for Golden Retrievers and be considered for other known taurine-sensitive breeds such as Newfoundlands 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 documented disease reversal after taurine supplementation and diet change.
2. Previously published work documents taurine sensitivity 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/mL
- Normal plasma taurine: >70nmol/mL
- Marginal whole blood taurine: 200-250nmol/mL
- Marginal plasma taurine: 60-70nmol/mL
- Low whole blood taurine: <200nmol/mL
- Low plasma taurine: <60nmol/mL

References:


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 DCM, 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 utilized for our reference ranges was generated. https://www.vetmed.ucdavis.edu/labs/aminio-acid-laboratory. 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 underscores the value of paired sampling.
Clinical Recommendations for Golden Retrievers based on taurine levels:

If taurine levels test <200nmol/mL in whole blood or <60nmol/mL in plasma

- An echocardiogram by a board-certified veterinary cardiologist is indicated
- After echocardiogram has been completed, a diet change is recommended.
  - If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - If DCM is diagnosed, prescribed supplementation with oral taurine and l-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

If taurine levels test 200 – 250nmol/mL in whole blood or 60-70nmol/mL 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 thus the value of screening should be carefully considered. If the dog is eating a diet that falls within the FDA warning or shares features 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 on the new diet should be considered.
- If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - If DCM is diagnosed, prescribed supplementation with oral taurine and l-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

If taurine levels test >250nmol/mL in whole blood or >70nmol/mL in plasma

- Diet change is recommended if you are feeding a diet that falls within the FDA warning or shares features with the diets identified in our study (see diets of concern section below)
- If your pet shows any signs of cardiac disease (trouble breathing, exercise intolerance, fainting/collapse, coughing) we recommend your veterinarian evaluate your pet.
Diets of Concern & Choosing 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 legumes like peas and lentils, white or sweet potatoes). These findings were largely recapitulated in our current study of Golden Retrievers with low taurine levels and DCM. 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 as consensus by veterinary nutritionists from around the world:
- FDA alert found here:
  - https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm

Choosing a taurine or l-carnitine supplement:
Selecting supplements should be performed based upon those that match their stated contents and are readily available for absorption. Luckily a previous publication tested multiple taurine and l-carnitine supplements. Based upon this publication our laboratory recommends the following supplements as those meeting our quality criteria. (Bragg et al. 2009 J Am Vet Med Assoc; 234(2))

Tested taurine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes
- Mega taurine caps by Twinlab (1000 capsule)
- Taurine by Swanson Health Products (500mg capsule)
- Taurine by NOW foods (500mg capsule)
- Taurine 500 by GNC (500mg tablet)

Tested L-carnitine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes
- L-carnitine 500 by Jarrow Formulas (500mg capsule)
- L-carnitine caps by Country Life (500mg capsule)
- Maxi L-carnitine by Solgar Vitamin and Herb (500mg tablet)
- L-carnitine by Puritan’s Pride (500mg tablet)

The Stern lab does not recommend the empirical supplementation of taurine or l-carnitine to dogs without evidence of DCM and/or significant deficiency. If DCM is diagnosed we typically recommend dogs over 50lbs receive 1000mg of taurine every 12hrs and dogs under 50lbs receive 500mg of taurine every 12hours. 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 prescribing the best dose for your dog.

Reporting to the FDA:
Understanding the basis of this condition requires a great deal of research and investigation. Clients 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:
https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm182403.htm

Additional questions or comments:
sterngenetics@ucdavis.edu

This document last updated: Aug. 20, 2018
Amino Acid Laboratory Sample Submission Form

Veterinarian Contact: B6

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

Address: 200 Westboro Road, North Grafton MA 01536

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

Billing Contact: B6

Billing Contact Phone: B6

Patient Name: B6

Species: CANINE

Owner's Name: B6

Breed: English Bulldog

Current Diet: Core Wellness Grain Free

Sample type: Plasma Whole Blood Urine Food Other

Test: Taurine Complete Amino Acids Other:

Taurine Results (lab use only)

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<th></th>
<th>Plasma (nMol/ml)</th>
<th>Whole Blood (nMol/ml)</th>
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<tr>
<td></td>
<td>Normal Range</td>
<td>No known risk</td>
</tr>
<tr>
<td></td>
<td></td>
<td>for deficiency</td>
</tr>
<tr>
<td>Cat</td>
<td>80-120</td>
<td>&gt;40</td>
</tr>
<tr>
<td>Dog</td>
<td>60-120</td>
<td>&gt;40</td>
</tr>
</tbody>
</table>

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

Hi Jen
I also left you a voice message but I just heard that died suddenly. 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 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
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

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.petfooding.org
A PFR Report has been received and PFR Event [EON-372828] has been created in the EON System.

A "PDF" report by name "2059621-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 "2059621-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-372828  
**ICSR #:** 2059621  
**EON Title:** PFR Event created for Earthborn Meadow Feast dry; 2059621

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<th>AE Date</th>
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<th>Number Fed/Exposed</th>
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<td>Number Reacted</td>
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<td>Animal Species</td>
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<td>Outcome to Date</td>
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<tr>
<td>District Involved</td>
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**Product information**  
**Individual Case Safety Report Number:** 2059621  
**Product Group:** Pet Food  
**Product Name:** Earthborn Meadow Feast dry  
**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  
**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:** 5
Number of Animals Reacted With Product: 4

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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</thead>
<tbody>
<tr>
<td>Earthborn Meadow Feast dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sender information**

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

**Owner information**

B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-372828

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueld=389797

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.
A PFR Report has been received and PFR Event [EON-372834] has been created in the EON System.

A "PDF" report by name "2059624-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 "2059624-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-372834  
**ICSR #:** 2059624  
**EON Title:** PFR Event created for Earthborn Meadow Feast dry; 2059624

<table>
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<tr>
<th>AE Date</th>
<th>11/20/2018</th>
<th>Number Fed/Exposed</th>
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<tbody>
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<td>Best By Date</td>
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<td>Number Reacted</td>
<td>4</td>
</tr>
<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Boxer (German Boxer)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>3 Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
<td></td>
<td></td>
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**Product information**  
**Individual Case Safety Report Number:** 2059624  
**Product Group:** Pet Food  
**Product Name:** Earthborn Meadow Feast dry  
**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  
**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: 5
Number of Animals Reacted With Product: 4

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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</thead>
<tbody>
<tr>
<td>Earthborn Meadow Feast dry</td>
<td></td>
<td></td>
</tr>
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Sender information
Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information
B6
B6 USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-372834

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=12&issuelId=389803

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From: PFR Event <pfreventcreation@fda.hhs.gov>
To: Cleary, Michael*; HQ Pet Food Report Notification; B6
Sent: 2/24/2019 9:40:39 PM
Subject: Purina One Smart Blend Lamb and Rice dry: Lisa Freeman - EON-380707
Attachments: 2063114-report.pdf; 2063114-attachments.zip

A PFR Report has been received and PFR Event [EON-380707] has been created in the EON System.

A "PDF" report by name "2063114-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 "2063114-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380707
**ICSR #:** 2063114
**EON Title:** PFR Event created for Purina One Smart Blend Lamb and Rice dry: 2063114

<table>
<thead>
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<th>Number Fed/Exposed</th>
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<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Worse/Declining/Deteriorating</td>
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<tr>
<td>Breed</td>
<td>Doberman Pinscher</td>
<td></td>
<td></td>
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<tr>
<td>Age</td>
<td>[B6]Years</td>
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</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**
**Individual Case Safety Report Number:** 2063114
**Product Group:** Pet Food
**Product Name:** Purina One Smart Blend Lamb and Rice dry
**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
**Submission Type:** Initial
**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating
Number of Animals Treated With Product: 3
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Purina One Smart Blend Lamb and Rice dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-380707

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueld=397716

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A PFR Report has been received and PFR Event [EON-380709] has been created in the EON System.

A "PDF" report by name "2063117-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 "2063117-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380709  
**ICSR #:** 2063117  
**EON Title:** PFR Event created for Fromm Large Breed Adult dry; 2063117

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<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
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<tr>
<td>Breed</td>
<td>Poodle - Standard</td>
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<tr>
<td>Age</td>
<td>16 Years</td>
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<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
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</tbody>
</table>

**Product information**  
**Individual Case Safety Report Number:** 2063117  
**Product Group:** Pet Food  
**Product Name:** Fromm Large Breed Adult dry  
**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  
**Submission Type:** Initial  
**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 3
Number of Animals Reacted With Product: 1

<table>
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<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Fromm Large Breed Adult dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**Owner information**
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon//browse/EON-380709

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issuelId=397718

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A PFR Report has been received and PFR Event [EON-380720] has been created in the EON System.

A "PDF" report by name "2063120-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 "2063120-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-380720  
**ICSR #:** 2063120  
**EON Title:** PFR Event created for Earthborn Coastal Catch dry; 2063120

<table>
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<tr>
<th>AE Date</th>
<th>02/01/2019</th>
<th>Number Fed/Exposed</th>
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<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Stable</td>
</tr>
<tr>
<td>Breed</td>
<td>Retriever - Golden</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>[B6]Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**  
**Individual Case Safety Report Number:** 2063120  
**Product Group:** Pet Food  
**Product Name:** Earthborn Coastal Catch dry  
**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  
**Submission Type:** Initial  
**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)  
**Outcome of reaction/event at the time of last observation:** Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earthborn Coastal Catch dry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Owner information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-380720

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jsa?decorator=none&e=0&issueType=12&issueId=397729

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<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Event Description</th>
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</thead>
<tbody>
<tr>
<td>6/21/2017 8:42:45 AM</td>
<td>Eliminations</td>
</tr>
<tr>
<td>6/21/2017 9:05:55 AM</td>
<td>Respiratory Rate</td>
</tr>
<tr>
<td>6/21/2017 9:56:24 AM</td>
<td>Respiratory Rate</td>
</tr>
<tr>
<td>6/21/2017 10:20:08 AM</td>
<td>Heart Rate (1/min)</td>
</tr>
<tr>
<td>6/21/2017 10:20:17 AM</td>
<td>Temperature (F)</td>
</tr>
<tr>
<td>6/21/2017 11:20:32 AM</td>
<td>Respiratory Rate</td>
</tr>
<tr>
<td>6/21/2017 11:28:48 AM</td>
<td>Quantify IV fluids (mls)</td>
</tr>
<tr>
<td>6/21/2017 11:29:15 AM</td>
<td>Nursing note</td>
</tr>
<tr>
<td>6/21/2017 11:57:30 AM</td>
<td>Heart Rate (1/min)</td>
</tr>
<tr>
<td>6/21/2017 11:57:41 AM</td>
<td>Respiratory Rate</td>
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<tr>
<td>6/21/2017 1:34:24 PM</td>
<td>Respiratory Rate</td>
</tr>
<tr>
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<td>Heart Rate (1/min)</td>
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<tr>
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<td>Respiratory Rate</td>
</tr>
<tr>
<td>6/21/2017 2:52:19 PM</td>
<td>Respiratory Rate</td>
</tr>
<tr>
<td>6/21/2017 3:47:24 PM</td>
<td>Quantify IV fluids (mls)</td>
</tr>
<tr>
<td>6/21/2017 3:49:14 PM</td>
<td>Heart Rate (1/min)</td>
</tr>
<tr>
<td>6/21/2017 3:50:21 PM</td>
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<tr>
<td>6/21/2017 3:54:12 PM</td>
<td>Respiratory Rate</td>
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<td>6/21/2017 4:25:03 PM</td>
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</tr>
<tr>
<td>6/21/2017 4:51:03 PM</td>
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<td>Heart Rate (1/min)</td>
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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/video tape 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 $0.33% per month, which is an annual percentage rate of 4% applied to the average daily balance outstanding, with a minimum fee of $5.00.

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 the 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: 6/20/2017

________________________________________  ________________________
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
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.

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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 express 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: B6  Date: 6/20/2017

Owner's address: B6

Owner's Name Signature

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

The owner of the animal B6 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

This estimate is based upon an 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 the estimated cost.

---

Understanding that this is an estimate of the total cost of treatment, I (the owner) have read and fully understand the authorization for medical and/or surgical treatment, the reason for such medical and/or surgical treatment, and the charges associated with the treatment due to its nature,

I hereby assume financial responsibility for all charges incurred. I agree to pay 75% of the estimated costs at the time of treatment. Additional charges will be required if additional care or procedures are required. I further agree to pay the balance of the charges when the patient is released.

Preceding treatment is inclusive up to and including the estimated date of hospitalization. There will be additional expenses if hospitalization extends beyond the specified duration. I have read and understand and agree to accept the conditions of this treatment plan.

Thank you for entrusting us with the care of your pet.

Page 1/1

Printed Wednesday, June 21, 2017
Radiology Request & Report

Patient

Name: B6
Species: Canine
Golden Male (Neutered) Golden
Retriever
Birthdate: B6

Owner

Name: B6
Address: B6

Patient ID: B6
Date of request: 6/21/2017

Attending Clinician: B6
Student:

DUPPLICATE FORM

Date of exam: 6/21/2017

Patient Location: Ward/Cage: ICU R2
Weight (kg): 36.00

Sedation

☑ Inpatient
☐ Outpatient
☐ Waiting
☐ Emergency

Examination Desired:
three view thorax

Presenting Complaint and Clinical Questions you wish to answer:
Emergency - presented with upper airway obstruction, potential tieback today

Pertinent History:

Findings:

Conclusions:

Radiologists
Primary:
Reviewing:

Dates
Reported:
Finalized:

FDA-CVM-FOIA-2019-1704-008497
Biopsy Request

Doctor to serve as contact: B6
(if primary contact is not available during business hours, provide a secondary contact, as well)
Phone/pager: B6
Email: B6

Total # of anatomic sites sampled (each site will be charged separately): 1
Total # of separate containers submitted: 1

Images sent to pathpics@tufts.edu?
☐ Yes
☐ No

CASE SUMMARY (CONCISE DESCRIPTION of time sequence, therapy, summary of abnormal clinical pathology and diagnostic imaging: lesion size, margin labels/orientation if relevant):
     mass at base of tongue on left side
     acute onset gagging and nasal discharge at home followed by acute respiratory crisis and admitted here
     FNA performed as well

CLINICAL DIAGNOSES/DIFFERENTIALS:
     abscess vs. neoplasia

CONTAINER 1. (In addition to site specific history include number of tissue pieces):

CONTAINER 2. (In addition to site specific history include number of tissue pieces):

CONTAINER 3. (In addition to site specific history include number of tissue pieces):
CT Request & Report

Patient Name: B6
Species: Canine
Golden Male (Neutered) Golden Retriever
Birthday: B6

Owner Name: B6
Address: B6
Patient ID: B6
Date of Request: 6/21/2017

Attending Clinician: B6
Student: B6

Date of Exam: 6/21/2017
Patient Location: Ward/Cage: ICU R 2
Weight (kg): 36.00

Scheduling and Patient Notes: B6

Examination Desired: B6

Sedation
☑️ Anesthesia to sedate/anesthetize
☐ Desomorphine/Butorphanol
☐ Autoanesthesia

Presenting Complaint and Clinical Questions you wish to answer: Emergency

Findings: B6
Aspiration of the B6 mass was performed with no immediate complications.

Radiologists
Primary: B6
Reviewing: B6

Dates
Reported: 6.22.2017
Finalized: 6.22.2017
Patient Name: B6
Signalment: B6 Golden Male (Neutered) Golden Retriever

Owner Name: B6

Patient ID: 234674

Clinician: B6 (Resident, Emergency & Critical Care)
Clinician: B6 (Resident, cardiology)

 ER Supervisor: B6

Discharge Instructions
Admit Date: 6/20/2017 10:55:12 PM
Check Out Date: 6/26/2017

Case Summary
Diagnosis: B6

General Summary: B6
Patient Care Instructions:
Please continue to monitor B6 for any trouble breathing. We recommend keeping him calm and as quiet as possible, and avoiding the heat as much as possible. If you start to notice him making more noise please try to keep him calm and cool, and if it does not resolve then please bring him in for evaluation.

Medications:

Recheck Visits:
A recheck is recommended in about 10 days with B6 or sooner if you have concerns. Please call 508 887 4745 to schedule this appointment. At this visit we would like to check his breathing and recheck his chest x-rays. We have sent home 2 weeks of antibiotic medications, but may want to continue for longer pending how he is doing and how his x-rays look.
Thank you for allowing us to participate in his care. He is such a sweet boy and we hope that he feels good at home!

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

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

Clinical Trials:
Clinical trials are studies in which our veterinary doctors work with you and your pet to investigate a specific disease process or a promising new test or treatment. Please see our website: vet.tufts.edu/vms/clinical-studies.
Patient Name: B6
Species: Canine
Golden Male (Neutered) Golden Retriever
Birthdate: B6

Owner Name: B6
Address: B6

Patient ID: 394674
Date of request: 6/26/2017

Date of exam: 6/26
Patient Location: Ward/Cage: A run
Weight (kg): 36.00

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

Examination Desired:
3 view chest - Tech only please, dog has upper airway mass and has trouble breathing with excitement

Presenting Complaint and Clinical Questions you wish to answer:

B6

Pertinent History:

Findings:

B6
Conclusions

B6

Radiologists
Primary: B6
Reviewing: B6

Dates
Reported: 06/27/17
Patient Name: B6  
Species: Canine  
Golden Male (Neutered) Golden Retriever  
Birthdate: B6  
Address: B6  
Patient ID: B6  
Date of request: 6/21/2017  

Attending Clinician: B6  
Student:  

Date of exam: 6/21/17  
Patient Location: Ward/Cage: icu  
Weight (kg): 36.00  

Sedation  
- BAG  
- OBAG  
- 1/2 dose OBAG  
- DexDomitor/Dutorphanol  
- Anesthesia to sedate/anesthetize  

Examination Desired: Thorax 3 view  

Presenting Complaint and Clinical Questions you wish to answer:  
Emergency  

Pertinent History: Acute inspiratory crisis (suspect larynx vs oral mass) overnight  

Findings:  

Conclusions:  
- Caudodorsal gas lucency may represent atypical duodenal gas on the DV, and gastric gas on the left lateral; however the possibility of pulmonary localization cannot be excluded. In the latter case, a
pulmonary abscess or mass with central necrosis could be considered, although no soft tissue component is identified. Thoracic CT or follow-up radiographs may be considered for further evaluation.

- Normal cardiovascular structures.

A cause for acute inspiratory dyspnea is not identified.

Radiologists
Primary: B6
Reviewing: B6

Dates
Reported: 6/21/2017
Finalized: 7/6/2017
Patient Name: B6  
Signalement: B6 Gold Male (Neutered) Golden Retriever

Patient ID: 394674

Emergency Clinician: B6
Consulting Clinician: B6

Discharge Instructions

Admit Date: 1/14/2019 11:22:13 AM
Check Out Date: 1/14/2019

Case Summary
Diagnosis:
1. Lethargy: open diagnosis
2. .
3. New heart murmur: open diagnosis

Case Summary:
Thank you for bringing B6 to Tufts University Emergency Service for evaluation of lethargy and a hot spot on the tail base. On examination, B6 had normal vital parameters and a normal examination aside from a low grade heart murmur and a large hot spot on the tail base. We discussed that the lethargy is unlikely cardiac related and that further workup would start with repeat bloodwork (CBC/chemistry/urinalysis), which you elected to hold on for now. B6 was discharged with antibiotics to treat his infection and you should follow up with your primary care veterinarian if he remains lethargic.

Patient Care Instructions:

Medications:
New medications:
Start today

Recheck Visits: No recheck in the ER is necessary unless __B6__ is not doing well at home.

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 (508-817-4629) 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/vmc/clinical-studies

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<td><strong>B6</strong></td>
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Discharge Instructions

Patient
Name: B6
Species: Canine
Gold Male (Neutered) Golden Retriever
Birthday: B6

Owner
Name: B6
Address: B6

Patient ID: 394674

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

Cardiology Resident:
B6

Cardiology Technician:
B6

Veterinary Nutritionist: Dr. Lisa Freeman

Student: B6

Admit Date: 2/1/2019 1:06:44 PM
Discharge Date: 2/1/2019

Diagnoses: Dilated cardiomyopathy (DCM), Suspect mild concurrent Degenerative Mitral Valve Disease

Case Summary:
Thank you for bringing B6 to Tufts Cardiology Service for evaluation of his newly found heart murmur. On echocardiogram, we found that he does have Dilated Cardiomyopathy or 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. Thankfully, we did not see any arrhythmias on his ECG today. Additionally, we saw a moderate amount of regurgitation coming from the mitral valve. This is a common heart disease in dogs, where the heart valve thickens with age, resulting in a leak. As the leak continues, we may see worsening of the heart enlargement in the future. Signs for congestive heart failure (fluid in the lungs) will be difficulty breathing, coughing, increased breathing rate. If you notice that B6’s breathing rate is faster than normal at home we will want to have chest x-rays taken. We would like to adjust Dexter’s diet and we provided some dietary recommendations below.

Diagnostic test results and findings:
- 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. The mitral valve has a moderate amount of regurgitation.
- ECG findings: The ECG was unremarkable - no arrhythmias
- Labwork findings: We will call you when we have the results of his bloodwork. Most of it should come back...
Monitoring at home:
- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate of less than 35 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.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart website (http://vet.tufts.edu/heartsmart/at-home-monitoring/).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

**B6**

Diet suggestions:
Dogs with heart failure accumulate more fluid in their body if they eat large amounts of sodium (salt). Sodium can be found in all foods, but some foods are lower in sodium than others. Many pet treats, people foods, and supplements used to give pills often have more sodium than is desirable—a sheet that has suggestions for low sodium treats can be found on the HeartSmart website (http://vet.tufts.edu/heartsmart/diet/)

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

- The 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 ingredients or are grain-free. Therefore, we are currently recommending that dogs do not eat these types of diets.
- We recommend switching 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.
- The FDA issued a statement regarding this issue (https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm6133415.htm) and a recent article published by Dr. Lisa Freeman on the Cummings School’s Pet Foodology blog can further explain these findings (http://vetnutrition.tufts.edu/2018/06/a-broken-heart-risk-of-heart-disease-in-boutique-or-grain-free-diets-and-exotic-ingredients/).
- Our nutritionists have compiled a list of dog foods that are good options for dogs with heart disease:

**Dry Food Options:**
- Royal Canin Early Cardiac (veterinary diet)
- Purina Pro Plan Adult Weight Management
- Purina Pro Plan Bright Mind Adult Small Breed Formula

FDA-CVM-FOIA-2019-1704-008512
Canned Food Options:
Hill's Science Diet Adult 1-6 Healthy Cuisine Roasted Chicken, Carrot, and Spinach Stew
Royal Canin Mature 3+.

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.

Recheck Visits:
Thank you for enrolling B6 in our clinical study.
B6 is supposed to have an appointment here at Tufts in about 3 months - We have an appointment for him scheduled on May 9th at 10AM. We will perform an echo, ECG and bloodwork at this time.

Thank you for entrusting us with B6! 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 cardiacvet@tufts.edu for scheduling and non-emergent questions or concerns.

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

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

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

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

Case: B6
Owner: B6
Discharge Instructions
Patient ID: 394674
B6 Canine
6 Years Old Male (Neutered) Golden Retriever Gold
**Discharge Instructions**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Owner</th>
<th>Patient ID: 394674</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: B6</td>
<td>Name: B6</td>
<td></td>
</tr>
<tr>
<td>Species: Canine</td>
<td>Address: B6</td>
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</tr>
<tr>
<td>Gold Male (Neutered) Golden Retriever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birthdate: B6</td>
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</tbody>
</table>

Duplicate
Cardiology Appointment Report

Date: 2/1/2019

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

Cardiology Resident: B6

Cardiology Technician: B6

Student: B6

Presenting Complaint:
RDVM yearly revealed 2/6 heart murmur
RDVM echo- DCM with 2+ mitral regurgitation 1+ tricuspid regurgitation and mild pulmonic insufficiency
ER 1/14 for profound lethargy- declined diagnostics but wanted to see cardio sooner than scheduled appointment, diagnosed with DCM with 2+ mitral regurgitation 1+ tricuspid regurgitation and mild pulmonic insufficiency but owner didn't read label right and has been giving 500mg PO BID instead
Whole life on grain free diet
Put on a lot of weight within 2018 (84lbs in December, 80lbs today), decreased activity (secondary to owner injury vs. B6 less excited for fetching, still goes on 1-2 mile walk) - rdvm records low normal thyroid level

Concurrent Disease:
B6

General Medical History:
Attacked in face by other dog at agility class prior to adoption (1 yr)

Diet and Supplements:
Earthborne grain free 3/4 cup BID, was 1 cup BID before rdvm appt in 12/2018

B6

Cardiovascular History:
Prior CHF diagnosis? No
Prior heart murmur? II/VI diagnosed in December 2018
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:

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 to III/VI
- IV/VI

Murmur location/description: Left heart apex

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
Weak
Fair
Good
Strong

Bounding
Pulse deficits
Pulsus paradoxus
Other:

Bradycardia
Tachycardia

None
Sinus arrhythmia
Premature beats

Pronounced
Other: Faint

Yes
No
Intermittent

Pulmonary crackles
Wheezes
Upper airway stridor

Eupneic
Mild dyspnea
Marked dyspnea
Normal BV sounds

Mild ascites
Marked ascites

Normal
Hepatomegaly
Abdominal distension

Problems:
Murmur and prior dx of DCM
Here for diet study

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

Echocardiogram Findings:
General/2-D findings:

B6

Mitral inflow:
- Summated
- Normal
- Delayed relaxation
- Pseudonormal
- Restrictive
ECG findings: B6

Assessment and recommendations:
Echocardiogram reveals DCM with significant MR (which could also indicate a component of DMVD).
Recommend starting B6

Recommend changing diet to RC Early Cardiac or similar diet on the list. NT-proBNP, troponin, CBC/chem were submitted. Patient was enrolled in DCM Study. Recheck echo and blood work for study in 3, 6, and 9 months.

Final Diagnosis:
DCM with a component of DMVD

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

ACVM Classification:
- A
- B1
- B2

M-Mode
- IVSd
- LVIdd
- LVPWd
- IVSs
- LVIDs
- LVPWs
- EDV(Feich)
- ESV(Feich)
- EF(Feich)
- %FS
- SV(Feich)
- Ao Diam
- LA Diam
- LA/Ao
- Max LA
- TAPSE
- EPSS

M-Mode Normalized
- IVSdN
- LVIddN

B6

FDA-CVM-FOIA-2019-1704-008519
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<tr>
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<tr>
<td>MV A Vel</td>
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<td>m/s</td>
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<td>TR maxPG</td>
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</table>
Notice of Patient Admit

Date: 6/20/2017 10:55:12 PM
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 EHSAM is: resp distress, tarp, possible B6

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

Thank you for your referral to our Emergency Service.
6/25/2017

Dear [B6],

Thank you for referring [B6] with their pet [B6]. Please see attached discharges for further information.

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

Thank you,

[B6] (Resident, Emergency & Critical Care)
B6

6/28/2017

Dear B6,

Thank you for referring B6 with their pet B6. He presented with respiratory distress and required intubation and a brief period of ventilation. A mass was noted on B6, which was further evaluated with CT, cytology, and biopsies. The findings were consistent with inflammation and possible infection, but no neoplastic cells were seen. The owners would not pursue chemotherapy or radiation regardless, so we are treating conservatively with antibiotics and antiinflammatories. The surgical team did not feel that the area of swelling was something that they could address surgically. B6 did well with supportive care in the hospital. He left the hospital on Monday and has been reportedly breathing very well at home. If his trouble breathing recurs, the owner may elect to repeat a CT or biopsies to see if we get a different result, but hopefully he will continue to do well.

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

Thank you,

B6
B6 was presented to the Tufts Emergency Service for evaluation of lethargy that started yesterday. Examination was normal aside from a low grade heart murmur (no arrhythmia, no concern for CHF) and base. The client wished for a cardiology consult on emergency today, which could not be accommodated. Recheck bloodwork was offered, given the change in clinical status, which the client declined. We elected to treat his hot spot with B6 and he was discharged home to monitor and await his scheduled cardio consult.

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

Thank you,

B6 (Emergency and Critical Care Resident)
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
From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
To: Palmer, Lee Anne
CC: Rotstein, David; Carey, Lauren
Sent: 3/27/2018 7:39:49 PM
Subject: RE: Zignature Kangaroo Formula: B6 EON-350158

Yes-I let's take a look! I think we should check [B6] I'm curious if those aminoacid levels are normal if there is some underlying renal disease causing whole body taurine depletion.

https://academic.oup.com/alcalc/article/36/1/29/138000

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

From: Palmer, Lee Anne
Sent: Tuesday, March 27, 2018 3:25 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: FW: Zignature Kangaroo Formula: B6 EON-350158

In case of interest - taurine level low?

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Tuesday, March 27, 2018 3:20 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>
Subject: Zignature Kangaroo Formula: B6 EON-350158

A PFR Report has been received and PFR Event [EON-350158] has been created in the EON System.

A "PDF" report by name "2044632-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 "2044632-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350158
ICSR #: 2044632
EON Title: PFR Event created for Zignature Kangaroo Formula; 2044632

<table>
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<th>Number Fed/Exposed</th>
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<tbody>
<tr>
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<td>Number Reacted</td>
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<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Better/Improved/Recovering</td>
</tr>
<tr>
<td>Breed</td>
<td>Retriever - Labrador</td>
<td></td>
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</tr>
</tbody>
</table>
**Product information**

**Individual Case Safety Report Number:** 2044632  
**Product Group:** Pet Food  
**Product Name:** Zignature Kangaroo Formula  
**Description:** At the time of diagnosis (10/31/17), [B6] was a 13 year old female spayed Labrador retriever who had been maintained on a Zignature Kangaroo formula. She presented with a history of a progressive cough which, prior to presentation, became productive and she coughed up a small volume of pink foam (possible pulmonary edema). On examination she had a 2/6 left apical systolic heart murmur and on echo diagnosed with advanced dilated cardiomyopathy with severe left ventricular dilation, moderate to severe left ventricular systolic dysfunction, and moderate to severe left atrial dilation. Thoracic radiographs were suspicious for early congestive heart failure. A whole blood taurine level was submitted and was low at [B6] She was treatment with [B6] Cardiac. At her recheck in 2/26/18, [B6] heart had improved significantly with now mild dilated cardiomyopathy with normalized left atrial dimensions, mild left ventricular dilation and low normal left ventricular systolic function. The [B6] was able to be discontinued at this time.

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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zignature Kangaroo Formula</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sender information**

[B6] USA

**Owner information**

[B6] USA

To view this PFR Event, please click the link below:  
https://eon.fda.gov/eon/browse/EON-350158
To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=366527

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

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

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

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

Thank you for submitting your consumer complaint to FDA. I’m sorry to hear about the 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 the 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](http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm)
Network Procedures for Veterinarians

1. Introduction
The purpose of this Network Procedure is to facilitate basic interactions between the Vet-LIRN Program Office (VPO) and veterinarians participating in Vet-LIRN case investigations. General procedures such as information flow, sample handling procedures, submission of reports and billing for services are discussed. The focus of most Vet-LIRN case investigations is on diagnostic samples, although occasionally animal food samples will also be submitted. Animal food testing conducted after receiving a consumer complaint is typically handled by FDA’s Office of Regulatory Affairs (ORA) Laboratories or accredited laboratories.

1.1 In the case of Vet-LIRN investigations, the government is the client.
1.1.1 The government is requesting assistance in its investigation, and is requesting tests or services to be performed by your clinic during this investigation.
1.1.2 The government will pay for these services.
1.1.3 The owner is helping with the government’s investigation of a regulated product.
1.1.4 The goal of the investigation is to determine if the product is at fault and why.
1.1.5 The government’s investigation may not provide a definitive diagnosis for the patient’s illness.

2. Case Background – Consumer complaint
2.1 Vet-LIRN obtains information about the cases we investigate from 3 main sources,
2.1.1 Consumer complaints (cc) - obtained by FDA Consumer Complaint Coordinators by phone
2.1.2 Electronic consumer complaint submissions through FDA’s Food Safety Reporting Portal, and
2.1.3 Vet-LIRN partner laboratories.

NOTE: Generally, the information received in a 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.
Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

3. Communications

3.1 VPO will discuss the case with the referring veterinarian and or the owner.

3.2 VPO evaluates the case history and determines a need for follow up testing to determine if the food (or drug) is the cause of the illness or death.

3.3 VPO contacts the appropriate member laboratory(-ies) (chosen based on location and capabilities) and provides initial information

3.3.1 In some cases only partial history is available

3.3.2 Follow up information will be sent as it becomes available.

3.4 VPO proposes the tests to be conducted and prepares billing documents.

3.5 VPO makes arrangements with the veterinarian to obtain and ship samples.

3.5.1 VPO receives test results and forwards the results to the veterinarian who will then communicate the results to the owner.

4. Case history

4.1 A complete medical history is essential,

4.1.1 age, sex, breed, animal's ID/name,

4.1.2 other animals affected,

4.1.3 duration of problem, lesion distribution (diagrams or photos are welcome),

4.1.4 treatment of problem (especially dose and duration of therapy) and response to treatment.

4.1.5 concomitant drugs or dietary supplements administered (not used for treatment of the reaction, but administered for other reasons at the same time or within a short time of the problem occurrence).

4.2 Vet-LIRN Case Numbers:

4.2.1 Include Vet-LIRN case number in all correspondence.

4.2.2 E-mail: include the Vet-LIRN case number as the first part of the subject line. This will help archiving data for each case.

4.3 Electronic submission of medical records and laboratory results is preferred.

4.4 Histories can also be submitted by FAX to Vet-LIRN (301-210-4685).

4.5 Information about follow-up visits related to the investigation and additional laboratory reports should be provided as soon as possible. Phone calls are very useful for
discussing cases in depth, but should be followed up with the medical records and lab reports.

4.5.1 Due to time difference around the country, email communication is often the best way to assure information is transferred in a timely manner.

5. Services Requested by VPO

5.1 Services typically tests will fall into 3 categories:

5.1.1 Office Examination
5.1.2 Clinical laboratory samples
5.1.3 Pathology

5.2 Office Examination:

5.2.1 To evaluate the current status of the patient.
5.2.2 To obtain samples from the patient for further analysis (blood, urine, feces).

5.3 Clinical Laboratory Samples:

5.3.1 VPO may ask for repeat analysis of new samples to be run either by the veterinary hospital, or by its usual testing laboratory.
5.3.2 Typical tests include clinical hematology, microbial cultures, urinalysis, and fecal examination.
5.3.3 Additional testing may be requested and the samples sent to a Vet-LIRN network laboratory.

5.4 Pathology:

5.4.1 Either submit the entire carcass or conduct a routine necropsy examination. Record your findings in detail and submit. Histopathology and microbiological cultures as appropriate.

5.4.1.1 Describe all lesions – location, color, size, texture.
5.4.1.2 Culture lesions or intestinal contents as deemed appropriate based on the history.
5.4.1.3 Save tissues for histopathology – be sure to use 10:1 formalin to tissue mass.

5.4.2 Histopathology tissues (preserve in 10% neutral buffered formalin 10:1 ratio fixative to tissue):
Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

5.4.2.1 thyroid, thymus, lung, heart, liver, spleen, adrenal, kidney, pancreas, stomach, duodenum, jejunum, ileum, colon, urinary bladder, skeletal muscle, brain.

5.4.2.2 Request a duplicate set of H&E for submission to VPO for archiving.

5.5 Toxicology:

5.5.1 Freeze and hold tissues if there is any indication that a toxic substance may be involved:

5.5.1.1 brain (for organophosphates and carbamates),
5.5.1.2 eyes, liver, kidney, brain, stomach content, fat,
5.5.1.3 if available, serum, EDTA blood, urine.

5.5.2 Following a review of histopathology, VPO may select tissues to be analyzed and request that tissues be sent to a Vet-LIRN laboratory.

5.5.3 When the case is closed by VPO, samples can be disposed of. When in doubt, please ask.

5.5.3.1 The animal’s remains can be disposed of following the laboratories’ customary procedures.

6. Sample submissions

6.1 Normally, VPO prefers that the veterinarian, not the pet owner submit samples.

6.2 Arrangements for transport should be made with the VPO (see additional shipping instructions).

6.3 A Vet-LIRN Sample Submission Form, given by VPO to the veterinarian, should be provided to the veterinarian and should accompany all samples being sent to our Vet-LIRN laboratory, listing the recommended tests.

6.4 A Shipping Inventory Sheet, given by VPO to the veterinarian, should also be provided by VPO and should be submitted with all samples. This form will be filled out and faxed to the VPO (301-210-4685) by the receiving Vet-LIRN laboratory.

6.5 Vet-LIRN case numbers should be provided by the VPO and should be included on all samples and reports.

6.5.1 Rarely, an owner will deliver a specimen or an animal for necropsy directly to the participating laboratory. Vet-LIRN should notify the lab to expect the owner if this happens and will provide appropriate forms.
7. Sample types that Vet-LIRN may request from the Veterinarian
   7.1 Entire bodies (fresh or frozen)
   7.2 Organs from necropsy (fresh, frozen or formalin fixed)
   7.3 Clinical samples (serum, blood, urine, feces, biopsy samples, cultures)
   7.4 Food samples (open bag products from home)

8. Reporting
   8.1 All reports from Vet-LIRN testing labs are submitted to VPO.
   8.2 VPO will forward reports to the veterinarian, who should discuss the results with the owner.
   8.3 If appropriate, VPO will forward reports to the owner.

9. Communications with Owners
   9.1 General:
      9.1.1 VPO usually will have contacted the owner to request permission and assistance in the investigation.
      9.1.2 Vet-LIRN’s investigation is focused on determining if a regulated product is the cause of the animal’s illness. The testing requested by Vet-LIRN may not provide a definitive diagnosis.
      9.1.3 VPO will provide testing results to the veterinarian for communication to the owner. This ensures that:
         9.1.3.1 Owners can be counseled on the interpretation of the test results,
         9.1.3.2 Appropriate medical follow-up care based on test results can be recommended by the owner’s veterinarian.
10. Billing

10.1 Vet-LIRN VPO can only pay for services which were requested and approved by VPO. Vet-LIRN cannot pay for treatment, or for diagnostic testing outside of the scope of the investigation.

10.2 Procurement and Billing Process: The following process needs to be followed in order to adhere to government regulations.

10.2.1 The veterinarian must provide estimates so a Purchase Request can be prepared. Estimates should include items such as office visit(s), in-house diagnostic test costs, biopsy or pathology costs and additional charges such as potential shipping charges.

10.2.2 A billing contact must be provided: include name, address, telephone + fax numbers, and email.

10.2.3 Approved Purchase Request is required prior to beginning service.

10.2.4 Additional services may only be initiated after authorized by Vet-LIRN, but must first be approved by VPO with an additional Purchase Request.

10.2.5 Hospitals must provide an invoice to Vet-LIRN upon the completion of work before they can be paid. VPO is tax exempt. Taxes should be removed from all charges. The invoice must include the Vet-LIRN case number.
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.
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.
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 animal's 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 the veterinarians 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.
Subject: Re: FDA Case investigation for EON-350158

Dear Dr. Jones,

Thank you for following up on our patient. We will be sending you our complete records for 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,

VMD, DACVIM - Cardiology

On Wed, Mar 28, 2018 at 2:40 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon,

Thank you for submitting your consumer complaint to FDA. I’m sorry to hear about 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 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
CVCA - Cardiac Care for Pets

Phone: B6
Fax: B6
Email: Bcavets.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.
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.

Sincerely,

[VMD, DACVIM - Cardiology]

On Wed, Mar 28, 2018 at 2:40 PM, Jones, Jennifer L [<Jennifer.Jones@fda.hhs.gov>] wrote:

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-URN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421

fax: 301-468-5421

Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch-ucm247334.htm

---

CVCA - Cardiac Care for Pets

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.

---
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 cvcavets.com and we will forward it to our Facebook administrator.

Please note -- images are usually posted within 1 month of submission.
CVCA CONSULTATION REQUEST FORM

Date: Tuesday, October 31, 2017

Client Id #: B6   Client Name: B6

Address: B6   City: B6   State: B6   Zip: B6

Animal Name: B6   Species: Canine   Breed: Labrador Retriever

Color: Yellow   Sex: spayed female   Weight: 0Kg

Date of Birth: B6   Age: 13 Yrs. 0 Mos.

Relevant History / Physical Findings:
Cough started last Wednesday. Radiographs and blood work were performed. Radiographs revealed suspected cardiomegaly. Blood work showed mild ALP and GGT elevations. The owner made cardio-consultation on Friday however her cough got worse with pink tinged foam so [B6] was brought to [B6] for a cardiology consultation. B6 has been a healthy dog with no current medications. She is up to date on vaccination and heartworm preventative.

Current Medications:
[B6] which was stopped because her coughing got worse with those medications.
Radiographs performed at:

☑ RDVM
☐ B6

Consulting Cardiologist:

10/31/2017 CVCA Consult 2013

B6
Cardiac Evaluation Report
Exam Date: 02/26/2018

Diagnosis
• Mild, improved dilated cardiomyopathy - suspect taurine-responsive
• Mild, improved mitral and very mild tricuspid valve regurgitation as cause of heart murmur
• Normal, improved left atrial chamber dilation
• Mild, improved eccentric left ventricular chamber dilation
• Low normal, improved left ventricular contractility/heart muscle function
• Cough - suspect bronchial/primary respiratory disease

Medications

You may purchase the taurine and L-carnitine at any health food or nutrition store [www.puritanpride.com](http://www.puritanpride.com). You may also obtain the L-carnitine in bulk powder form from North Carolina State University by calling 919-513-6325.
• Continue with monthly heartworm and flea/tick control as prescribed by [B6].

Please allow 24-48 hours for CVCA to process prescription refill requests.
Refill all medications indefinitely unless directed by CVCA or your primary care veterinarian.
• Please check all medications and dosages on your discharge report against the pharmacy labels.

Please Note
• Please see our website [www.cvcavets.com](http://www.cvcavets.com) for more information about [B6] dilated cardiomyopathy.
Nutrition Recommendations:
• Continue the Royal Canin Early Cardiac diet.
• Consider fish oil supplements (omega-3 fatty acids). Her dose is approximately EPA 1220 mg and DHA 760 mg total per day. Please start at 1/2 the dose for one week, then increase to the full dose if tolerating well thereafter. Please avoid Cod liver oil and flax seed as well as products with Vit A and/or D.
For more information about fish oils, please visit -- http://vet.tufts.edu/heartsmart/diet/important-nutrients-for-pets-with-heart-disease/
• In addition to the supplements approved by Tuft's Veterinary Nutrition Service, other reputable brands include Welactin and Nordic Naturals. Swan Creek Veterinary Clinic may have additional brand recommendations.

Activity Recommendations:
• Continue normal activity as she wants and is able to do. Please allow to take more breaks and rest during activity.
• Please avoid exercise in the hot/humid weather.

At Home Monitoring:
• In order to monitor for the development of early congestive heart failure in the out-patient setting, we recommend monitoring your pet's resting respiratory rate several times a week. Normal resting respiratory rates should be less than 30 breaths per minute. Consider using a respiratory rate monitoring application to track. B6 Cardalis or BI Pharma have reliable phone applications. Please contact us if you note a persistent or progressive increase.

Future Anesthesia/Fluid Recommendations

Reevaluation
• Recheck with B6 in the next 2-4 weeks and every 6 months for wellness care as directed, close auscultation, blood pressure and complete lab tests including blood and urine testing (CBC/Chemistry/Uranalysis/Thyroid evaluation). Please forward these results when available.
• Please recheck with CVCA in 6 months for a follow up consultation/examination, blood pressure, and echocardiogram. Please contact us or schedule an earlier appointment if B6 has any problems or symptoms indicative of worsening heart disease or if recommended by B6.

We thank you for trusting in CVCA to care for B6 today. Please do not hesitate to call us with any questions or concerns.

Sincerely,
B6 developed a cough last Wednesday (10/25/17). Radiographs and blood work were performed by B6. The lab work (which is unavailable for review) reportedly showed an elevated ALP and GGT, and mild lymphopenia. Thoracic radiographs were performed which revealed cardiomegaly. B6 was treated with... All medications were stopped on Monday as her cough had worsened and she was presented to the... for a cardiac evaluation as her coughing had worsened and she had brought up a small volume of pink-tinged foam after a coughing fit. During this time there has been no evidence of lethargy and she continues to eat and drink normally at home.

PPHx: None
Meds: None
Other: Diet: changed from Zignature (Kangaroo) to Royal Canin Early Cardiac

Physical Exam Findings: 3/6 pansystolic murmur, PMI - mitral valve, regular rhythm with S3 gallop; LUNGS - clear all fields, panting, normal effort; SI, overweight body condition (BCS - B6 Pink mm; PP - SS; PLN - WNL; ABD - hepatomegaly; BAR

Echocardiographic Findings
Mild left ventricular eccentric dilation - significant improvement compared to previous exam; mild, improved centrally located mitral regurgitant jet, normal, improved left atrial dimensions on 2D imaging and on M-mode imaging, mild, low velocity eccentric low velocity tricuspid regurgitation, subjectively normal right ventricular and right atrial dimensions, normal left and right ventricular outflow velocities, low normal, improved indices of systolic function (FS% and EF% by modified Simpson's, normal EPSS, normal transmitral inflow velocities and E:A wave ratio on spectral Doppler tracings, normal TDI E:A' ratio of the lateral mitral annulus, no masses, effusions or heartworms observed.

Comments
Dear B6

Thank you for sending B6 to see us with B6 today. I am quite pleased with B6 exam today. She has had remarkable improvement in her echocardiogram with the cardiac medications, change in diet and supplementation with Taurine and L-carnitine. Her risk for congestive heart failure at this point is very low so we will be weaning B6 off the B6 while B6 monitors B6 respiratory rate. Her current cough is likely due to respiratory disease and if the cough progresses/worsens, we will consider adding in a B6 such as... Right now, with the marked improvement, B6 long-term prognosis has improved considerably. I suspect we will be able to further discontinue cardiac medications if her heart remains stable. We will continue to closely monitor B6 heart disease via serial echocardiography and institute further therapy when progression is noted. While on this course of medication, it is important to monitor the chemistry profiles and blood pressures. Hopefully, B6 will continue to do so well - she's a sweety!

We appreciate your continued referrals and the trust you place in CVCA to co-manage your cardiac patients. We look forward to working with you on this case and others. In an effort to continue to improve CVCA's service to both you and your clients, please visit our website at www.cvcavets.com and complete our online referring veterinarian survey.

Sincerely,

B6 DVM, DACVIM - Cardiology

Information for B6

CVCA B6 03/28/2018
Patient Demographics

<table>
<thead>
<tr>
<th>Patient ID: 121217B02262018</th>
<th>Accession #:</th>
<th>Alt ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOB: Age:</td>
<td>Gender: Ht:</td>
<td>Wt: 73lb 0oz BSA:</td>
</tr>
</tbody>
</table>

Institution: B6
Referring Physician:
Physician of Record:
Comments:

Performed By: B6

Study Date: 02/26/2018

Adult Echo: Measurements and Calculations

2D

- LVId (2D)
- LVpw (2D)
- EDV (2D - Teich)
- EDV (2D - Cubed)
- A4Cd
- LV Vol
- LV Length
- LV Area
- A4Cs
- LV Vol
- LV Length
- LV Area
- LVld (A4C)
- LVls (A4C)

MMode

- IVSd (MM)
- LVId (MM)
- LVpw (MM)
- IVSs (MM)
- LVIDs (MM)
- LVpw (MM)
- IVS(LVpw (MM))

- SV (MM - Teich)
- FS (MM - Teich)
- EF (MM - Teich)
- EDV (MM - Cubed)
- ESV (MM - Cubed)
- SV (MM - Cubed)
- EF (MM - Cubed)

- LVPW % (MM)
- RVIDd (MM)
- LA Dimen (MM)
- AoR Diam (MM)
- LA/Ao (MM)
- MV D-E Slope
- MV E-F Slope

- SV (A4C)
- EF (A4C)

B6

121217B02262018 02/26/2018 Created: 02:56PM 02/26/2018 1/3
EDV (MM-Teich)  B6  FS (MM-Cubed)  B6  MV EPSS  B6

Doppler

LVOT Vmax
Max PG
Vmax
RVOT Vmax
Max PG
Vmax
MV Peak E Vel
Vel
PG
MV Peak A Vel
Vel
PG

MV E/A
Med E Vel

E'/A ' Medial  B6

Med A Vel

TR Vmax
Max PG
Vmax

Other Measurements

Dimensions: Diameters
LVID/Ao (2D)
EDVI
ESVI

EF & Volume: Simpson's
Sphericity Id

Dimensions: Diameters
LVEDDN
LVID/Ao (2D)

Images

B6
Cardiac Evaluation Report
Exam Date: 10/31/2017

Diagnosis
- Advanced dilated cardiomyopathy - rule out idiopathic vs. taurine-responsive
- Mild to moderate mitral valve regurgitation as cause of heart murmur
- Trace tricuspid valve regurgitation
- Moderate to severe left atrial chamber dilation
- Severe eccentric left ventricular chamber dilation
- Moderate to severe decrease in contractility/heart muscle function
- Mild left ventricular wall thinning
- Mild right atrial and right ventricular chamber dilation
- Progressive cough - rule out: early left sided congestive heart failure vs. mainstem bronchial compression

Medications

In 2 weeks, if [B6] is eating and feeling well:

Information for [B6]
**Please Note**

- You may purchase the taurine and L-carnitine at any health food or nutrition store [www.puritanaspride.com](http://www.puritanaspride.com). You may also obtain the L-carnitine in bulk powder form from North Carolina State University by calling 919-513-6325.

Please allow 24-48 hours for CVCA to process prescription refill requests.

Refill all medications indefinitely unless directed by CVCA or your primary care veterinarian.

- Please check all medications and dosages on your discharge report against the pharmacy labels.

**Nutrition Recommendations**

- B6 is on a specialized diet which could be contributing to taurine deficiency. Please change her to a new diet, as her housemate is on a novel protein diet - consider prescription diets such as Royal Canin or Science Diet. Please discuss diet options with [B6].

- In patients with early/mild heart failure, CVCA recommends feeding a diet with less than 80 mg of sodium per 100 kcal of food (50-80 mg/100 kcal). In patients with refractory heart failure signs, further sodium restriction may be beneficial.

- For more information about sodium content of various foods, please visit:

- CVCA recommends avoiding kidney diets unless [B6] has kidney disease that warrants protein restriction.

- Diet changes should be done gradually (ie. over ~1 month) to avoid GI upset and avoided until Lucy is stable and eating well on the cardiac medications, usually about 2 weeks after starting or adjusting therapy.

- If you are interested in a consultation with a veterinary nutritionist, please visit [http://vetnutrition.tufts.edu/make-an-appointment/](http://vetnutrition.tufts.edu/make-an-appointment/)

- CVCA recommends fish oil supplements (omega-3 fatty acids) in many dogs with cardiac disease. Her dose should be approximately EPA 1220 mg and DHA 760 mg total per day. Please start at 1/2 the dose for one week, then increase to the full dose if tolerating well thereafter. Please avoid Cod liver oil and flax seed as well as products with Vit A and/or D.

- For more information about fish oils, please visit [http://vet.tufts.edu/heartsmart/diet/important-nutrients-for-pets-with-heart-disease/](http://vet.tufts.edu/heartsmart/diet/important-nutrients-for-pets-with-heart-disease/)

- In addition to the supplements approved by Tuft's Veterinary Nutrition Service, other reputable brands include Welactin and Nordic Naturals [B6].

**Activity Recommendations**

- Keep [B6] very quiet for the next 3-4 days with only brief leash walks to eliminate.

- Once her coughing has resolved [B6], may gradually resume activity as she wants and is able to do. Please allow [B6] to take more breaks and rest during activity.

- Please try avoid burst type activity, as this increases the arrhythmia risk and avoid exercise in the hot/humid weather.

- Please try to wait [B6] up for 5-10 minutes with walking prior to moderate activity and take more rests during more vigorous activity.

**At Home Monitoring**

- Monitor for signs of cough, respiratory difficulty, exercise intolerance, abdominal swelling, weakness, lethargy, etc. If you note any of these symptoms, please notify CVCA [B6] is these symptoms may indicate recurrent congestive heart failure. If you note an increase in cough, respiratory rate or effort, please feel free to give an additional dose [B6] while contacting CVCA.

- In order to monitor for the development of early congestive heart failure in the out-patient setting, we recommend monitoring your pet's resting respiratory rate several times a week. Normal resting respiratory rates should be less than 30 breaths per minute. Consider using a respiratory rate monitoring application to track [B6]. Respiration rate - Cardalis or BI Pharma have reliable phone applications. Please contact us if you note a persistent or progressive increase.

- In addition, [B6] is sadly at increased risk for sudden cardiac death due to her cardiac disease. Dobermans are particularly at risk for development of severe, sudden malignant arrhythmias that sadly may result in sudden death. However, we hope to minimize these risks with our treatment plan.
Future Anesthesia/Fluid Recommendations

B6

Reevaluation

• Please recheck with B6 in the next day or two to obtain taurine levels. Please forward these results when available.
• Please recheck with B6 in 2 weeks for a follow up examination and blood chemistry profile with electrolytes and as recommended by B6. Please forward these results when available.
• Please recheck with B6 every 4-6 months for a follow up examination and blood chemistry profile with electrolytes and as recommended by B6. Please forward these results when available.
• Please recheck with CVCA in 5 months for a follow up consultation/examination, blood pressure, and echocardiogram. Please contact us or schedule an earlier appointment if B6 has any problems or symptoms indicative of worsening heart disease or if recommended by B6.

Visit Summary

Heart Rate: B6
BP: B6 (based on MR gradient)

History:
B6 developed a cough last Wednesday (10/25/17). Radiographs and blood work were performed by B6 Veterinary Clinic. The lab work (which is unavailable for review) reportedly showed an elevated ALP, GGT and mild lymphopenia. Thoracic radiographs were performed which revealed cardiomegaly. B6 was treated with All medications were stopped on Monday as her cough had worsened and she was presented to the B6 for a cardiac evaluation as her coughing had worsened and she had brought up a small volume of pink-tinged foam after a coughing fit. During this time there has been no evidence of lethargy and she continues to eat and drink normally at home.

PPHx: None
Meds: None
Other: None
Diet: Zignature (Kangaroo)

Physical Exam Findings:

B6 H/L: Grade 2/6 left apical protosystolic heart murmur, regular rhythm, strong synchronous femoral pulses, RR: B6 breaths/min, questionable mild increase in bronchovesicular sounds bilaterally, no crackles or wheezes ausculted, eupneic

Other Diagnostics:
10/27/17 pDVM CXR: Generalized cardiomegaly characterized by widening of the cardiac silhouette and loss of the caudal cardiac waist consistent with left atrial enlargement. Slight left auricular bulge. Increased sternal contact and rounding of the right heart on the VD radiograph. Dorsal deviation of the trachea. Prominent pulmonary vasculature with a questionable mild increase in interstitial opacity in the caudodorsal lung fields which may suggest early congestive heart failure/pulmonary edema.

Echocardiographic Findings

Severe left ventricular eccentric hypertrophy with apical rounding and increased sphericity, mild-moderate centrally
located mitral regurgitant jet, moderate-severe secondary left atrial dilation on 2D imaging and moderately-severely increased LA:Ao ratio on M-mode imaging, mild eccentric low velocity tricuspid regurgitation with mildly elevated estimated right ventricular pressures consistent with mild pulmonary hypertension, mild right ventricular and right atrial dilation, normal left and right ventricular outflow velocities, moderately to severely depressed indices of systolic function (FS% and EF% by modified Simpson's - LVDI, LVIS), increased EPSS, elevated transmitral inflow velocities and E:A wave ratio on spectral Doppler tracings, normal TDI E':A' ratio of the lateral mitral annulus, no masses, effusions or heartworms observed.

ECG during echocardiogram: Normal sinus rhythm. No ventricular ectopy noted.

Comments

Dear [Name],

Thank you for sending [Date] to see us with [Date] today. Sadly, [Patient Name] has dilated cardiomyopathy with moderate to severe systolic dysfunction and moderate to severe left atrial dilation. This places her at a high risk of developing congestive heart failure and with the progression in her cough I am concerned that we may be dealing with congestive heart failure at this time. We have begun therapy to control congestive heart failure, support cardiac function, slow down the progression of the heart disease and improve survival. We are now seeing more dogs on specialized diets that are developing taurine deficiency and we have discussed submission of taurine levels to evaluate whether this may be a contributing factor to [Patient Name]'s condition. [Name] is interested in pursuing this test at your clinic, taurine levels should be drawn and placed in a heparinized tube (green top) and should be frozen and submitted to Idexx (who sends it to UC Davis). It will be interesting to see if this is a contributing factor to [Patient Name]'s condition.

We will continue to closely monitor [Patient Name]'s heart disease via serial echocardiography and institute further therapy when progression is noted. While on this course of medication, it is important to monitor the chemistry profiles and blood pressures. Dogs with dilated cardiomyopathy are at a higher risk of developing ventricular arrhythmias. None were noted today; however, it will be important to monitor for arrhythmias periodically in the future. Unfortunately, the prognosis is guarded after the onset of congestive heart failure, and we discussed with the [Patient Name]'s family that the average survival is ~ 6-12 months. Survival time is highly individually variable depending on response to therapy.

We appreciate your continued referrals and the trust you place in CVCA to co-manage your cardiac patients. We look forward to working with you on this case and others. In an effort to continue to improve CVCA's service to both you and your clients, please visit our website at www.cvcavets.com and complete our online referring veterinarian survey.

Sincerely,

[Name], VMD, DACVIM - Cardiology

Information for [Name]
B6 1 yr FS Golden Retriever

Presented 9/25/2018, discussed cardiomyopathy of GRTs; been on GF diet

WB Tau-B6(Davis)
10/19/2018 cardio: screening echo b/c on GF diet and low Tau; asymptomatic
PE-nsf
Echo-occult DCM-sys dyfxn, LV dil
Tx: B6 diet change, 0.5g Tau BID, OFAs, poss L-carn

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

From: PFR Event <pfreventcreation@fda.hhs.gov>
Sent: Wednesday, October 24, 2018 4:35 PM
To: Cleary, Michael* <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; _______________________
Subject: Fromm Four-Star Nutritionals Game Bird Recipe Dog Food: B6 - EON-369265

A PFR Report has been received and PFR Event [EON-369265] has been created in the EON System.

A "PDF" report by name "2057000-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 "2057000-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-369265
ICSR #: 2057000
EON Title: PFR Event created for Fromm Four-Star Nutritionals Game Bird Recipe Dog Food; 2057000

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Product information
Individual Case Safety Report Number: 2057000
Product Group: Pet Food
Product Name: Fromm Four-Star Nutritionals Game Bird Recipe Dog Food
Description: B6 was tested to have whole blood taurine of B6 and was diagnosed with occult dialated cardiomyopathy by echo.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

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Sender information
B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-369265

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueld=386187

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.
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<tr>
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**TREATMENT AND PROGRESS**

- **B6**: Discuss colorectal surgery in left colon. Also good weight issue.
  - 101.4 > 130  R. Painting.
  - [Note: Carbon-free dust concerns.]
  - Concerned about possible liver issues.
  - 10-21-18: Sending blood to Dr. Davis for further analysis.

10-16-18: To L/M to see how visit at specialist went yesterday.

10-19-18: [Note: Medical records to follow, but no specific mention of the specialist or outcome.]
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ANIMAL NAME: B6

- very full

FDA-CVM-FOIA-2019-1704-008576
### Animal Record

**Owner's Name:**  

**Animal's Name:** B6  

**Species:** ka  

**Sex:**  

**Birthdate:** B6  

**Breed:** Golden  

**Color:**  

**Home Phone:**  

**Work Phone:**  

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### Major Problem

**MAJOR PROBLEM**

B6
DISCHARGE INSTRUCTIONS AND REFERRAL CORRESPONDENCE

Primary Veterinarian: Dr. B6

Owner’s name: B6

Phone number: B6

Patient Name: B6

Species: Canine

Sex: Spayed Female

Weight: 28.6 Kgs

Breed: Manx Ley Golden Retriever

Age: B6

Admission Date: 10/19/2016

Discharge Date: 10/19/2016

History: Presented for Screening Echocardiogram for DCM. Currently on a Grain free diet and a low Taurine level was noted on nutrition work. No signs of cardiac disease noted by the owner.
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 that 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 (150 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 procedure and treatment performed at Affiliated Veterinary Specialists, please do not hesitate to call us.
Amino Acid Laboratory Sample Submission Form

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

Veterinarian Contact: B6

Clinic/Company Name: B6

Address: B6

Email: B6

Telephone: B6

Billing Contact: B6

Patient Name: B6

Species: Canine

Breed: Golden Retriever

Owner's Name: B6

Current Diet: Fromm Game Bird Recipe with Primal raw topper and raw goats milk

Sample type: □ Plasma □ Whole Blood □ Urine □ Food □ Other

Test: □ Taurine □ Complete Amino Acids □ Other

Taurine Results (lab use only)

Plasma: □ Whole Blood: B6 Urine: □ Food: □

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<th>Whole Blood (nMol/ml)</th>
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<tr>
<td></td>
<td>Normal Range</td>
<td>No known risk for deficiency</td>
</tr>
<tr>
<td>Cat</td>
<td>80-120</td>
<td>&gt;40</td>
</tr>
<tr>
<td>Dog</td>
<td>60-120</td>
<td>&gt;40</td>
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* Please note with the recent increase in the number of dogs screened for taurine deficiency, we are seeing dogs with values within the reference ranges (or above the “no known risk for deficiency range”) yet are still exhibiting signs of cardiac disease. Veterinarians are welcome to contact our laboratory for assistance in evaluating your patient’s results.
VETERINARY MEDICINE

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/aminoc-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:

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/ucm162403.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.
FREQUENTLY REQUESTED INFORMATION REGARDING TAURINE & DILATED CARDIOMYOPATHY IN GOLDEN RETRIEVERS

Taurine reference ranges for Golden Retrievers: The Stern Lab suggests that the following clinical reference ranges be used for Golden Retrievers and be considered for other known taurine-sensitive breeds such as Newfoundlands 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 documented disease reversal after taurine supplementation and diet change.
2. Previously published work documents taurine sensitivity 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/mL
- Normal plasma taurine: >70nmol/mL
- Marginal whole blood taurine: 200-250nmol/mL
- Marginal plasma taurine: 60-70nmol/mL
- Low whole blood taurine: <200nmol/mL
- Low plasma taurine: <60nmol/mL

References:

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 DCM, 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 utilized for our reference ranges was generated. https://www.vetmed.ucdavis.edu/labs/ amino-acid-laboratory... 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 underscores the value of paired sampling.
Clinical Recommendations for Golden Retrievers based on taurine levels:

**If taurine levels test <200nmol/mL in whole blood or <60nmol/mL in plasma**
- An echocardiogram by a board-certified veterinary cardiologist is indicated.
- After echocardiogram has been completed, a diet change is recommended.
  - If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - If DCM is diagnosed, prescribed supplementation with oral taurine and l-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

**If taurine levels test 200 – 250nmol/mL in whole blood or 60-70nmol/mL 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 thus the value of screening should be carefully considered. If the dog is eating a diet that falls within the FDA warning or shares features 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 on the new diet should be considered.
- If DCM is diagnosed, this patient may need a variety of cardiac medications that would be prescribed by the attending cardiologist.
  - If DCM is diagnosed, prescribed supplementation with oral taurine and l-carnitine is recommended.
  - Reevaluation of taurine levels is warranted after three months of diet change and supplementation.
  - Cardiology reevaluation schedules will be recommended by the attending clinician pending echocardiographic findings.
  - Many Golden Retrievers with taurine-deficient DCM in our study showed slow and steady improvement over a period of 6-12 months.

**If taurine levels test >250nmol/mL in whole blood or >70nmol/mL in plasma**
- Diet change is recommended if you are feeding a diet that falls within the FDA warning or shares features with the diets identified in our study (see diets of concern section below)
- If your pet shows any signs of cardiac disease (trouble breathing, exercise intolerance, fainting/collapse, coughing) we recommend your veterinarian evaluate your pet.
Diets of Concern & Choosing 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 legumes like peas and lentils, white or sweet potatoes). These findings were largely recapitulated in our current study of Golden Retrievers with low taurine levels and DCM. 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 as consensus by veterinary nutritionists from around the world:
- FDA alert found here:
  - https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm

Choosing a taurine or L-carnitine supplement:
Selecting supplements should be performed based upon those that match their stated contents and are readily available for absorption. Luckily a previous publication tested multiple taurine and L-carnitine supplements. Based upon this publication our laboratory recommends the following supplements as those meeting our quality criteria. (Bragg et al. 2009 Am Vet Med Assoc; 234(2))

Tested taurine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes:
- Mega taurine caps by Twinlab (1000 capsule)
- Taurine by Swanson Health Products (500mg capsule)
- Taurine by NOW foods (500mg capsule)
- Taurine 500 by GNC (500mg tablet)

Tested L-carnitine supplements that test within 5% of stated contents and if applicable disintegrated within 30 minutes:
- L-carnitine 500 by Jarrow Formulas (500mg capsule)
- L-carnitine caps by Country Life (500mg capsule)
- Maxi L-carnitine by Solgar Vitamin and Herb (500mg tablet)
- L-carnitine by Puritan's Pride (500mg tablet)

The Stern lab does not recommend the empirical supplementation of taurine or L-carnitine to dogs without evidence of DCM and/or significant deficiency. If DCM is diagnosed we typically recommend dogs over 50lbs receive 1000mg of taurine every 12hrs and dogs under 50lbs receive 500mg of taurine every 12hours. 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 prescribing the best dose for your dog.

Reporting to the FDA:
Understanding the basis of this condition requires a great deal of research and investigation. Clients 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:
https://www.fda.gov/AnimalVeterinary/safetyhealth/reportaproblem/ucm182403.htm

Additional questions or comments: sterngenetics@ucdavis.edu
This document last updated: Aug. 20, 2019
June 28, 2017

Taurine-deficient Dilated Cardiomyopathy in Golden Retrievers

In the wake of many golden retrievers being diagnosed with taurine-deficient DCM, we have started to collect information to better understand the condition and help the golden retriever community. Unfortunately due to concern and panic, many owners have identified concerns and proceeded with supplementation or diet change. This approach has led to more confusion and an inability to definitively say whether some dogs have an inherited cardiomyopathy or a nutritionally derived heart disease. This makes a huge difference in the prognosis and outcome for these dogs and their possible continuation in the breeding pool. Please review the following steps regarding evaluation of taurine-deficient DCM. Our group has put this together to help get to the bottom of this issue as fast and as medically appropriate as possible.

1. If you believe your dog is at risk for taurine deficient DCM and wish to have taurine levels tested - please request a whole-blood taurine level be submitted for analysis. The laboratory that I recommend can be found here: https://www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

2. If you believe your dog is showing signs of DCM already - please seek an appointment with a board certified cardiologist to have an echocardiogram and taurine testing obtained simultaneously - do not change foods, do not supplement prior to the appointment.

3. If you receive taurine test results that come back as low - please seek an appointment with a board-certified cardiologist to have an echocardiogram performed to determine if your pet needs cardiac medications and the appropriate supplements to be used (DO NOT SUPPLEMENT OR CHANGE FOODS UNTIL YOU HAVE THE CARDIOLOGY EVALUATION COMPLETED). If you live in close to UC Davis, we can arrange research-funded cardiology evaluations for your dog if you contact us via stergenetics@ucdavis.edu.

4. If you receive cardiologist confirmed DCM results, please take an image of the food bag, ingredient list and lot number. Please also request a copy of the images from the echocardiogram from your cardiologist (ensure that you have full DICOM image copies on a CD). Please complete a full diet history form found at this link: https://www.vetmed.ucdavis.edu/sites/g/files/dqwms491/files/inline-files/Diet_History_Form_FINAL_April2017.doc Please email the image of food bag, a 3-generation pedigree, diet history form, copies of the taurine level results and medical record to stergenetics@ucdavis.edu. A member of our laboratory team will contact you to discuss our thoughts and possible request additional information, food samples or blood samples for further testing.

5. If you have any questions on how to proceed please email Dr. Stern at stergenetics@ucdavis.edu.

Kind Regards,

Joshua A. Stern, DVM, PhD, DACVIM

Joshua Stern, DVM, PhD, Diplomate ACVIM (Cardiology)
Associate Professor of Cardiology
School of Veterinary Medicine, Department of Medicine and Epidemiology,
University of California, 2108 Tupper Hall, 258 CCAH
Davis, CA, 95616. Tel: (530) 752-2475. Email: jstern@ucdavis.edu
Patient History Report

Client: B6

Patient: B6

Species: Canine

Breed: Retriever, Golden

Age: B6

Days

Phone: B6

Date: 12/28/2017

Chemistry results from IDEXX VetLab In-clinic Laboratory Requisition ID: 2953969

Test Result Reference Range

ALB = 2.3 - 4.0
ALKP = 23 - 212
ALT = 10 - 125
BUN/UREA = 7 - 27
CREA = 0.5 - 1.8
GLU = 74 - 143
TP = 5.2 - 8.2
GLOB = 2.5 - 4.5

ALB/GLOB =
BUN/CREA =

Hematology results from IDEXX VetLab In-clinic Laboratory Requisition ID: 2953969

Test Result Reference Range

HCT = 37.0 - 55.0
HGB = 12.0 - 18.0
MCBC = 30.0 - 37.5
WBC = 5.50 - 16.90
LYMPHS = 0.50 - 4.90
%LYMPHS =
%MONOS =
NEUT = 2.00 - 12.00
%NEUT =
%EOS =
%EOS =
BASO =
%BASO =
PLT =
Retics = 175 - 900
%Retics =
RBC = 5.50 - 6.50
MCV = 60.0 - 77.0
MCH = 18.5 - 30.0
RDW = 14.7 - 17.9
MPV =
PDW =
PCT =
OFFICIAL CERTIFICATE OF VETERINARY INSPECTION
FOR INTRASTATE SALE OF A DOG OR CAT

Pursuant to Section 828.20, F.S., Rule 5C-27 and Rule 5C-29, F.A.C.

Section 828.20, Florida Statutes, provides that each dog or cat offered for sale within the state must be accompanied by a current Official Certificate of Veterinary Inspection (OCV), issued by a veterinarian licensed by the state and accredited by the United States Department of Agriculture.

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<tr>
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<td>Zip:</td>
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</table>

EXPIRES 30 DAYS
FROM DATE OF ISSUANCE
Amino Acid Laboratory Sample Submission Form

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

Veterinarian Contact: ________________

Clinic/Company Name: ____________________________

Address: _________________________________________

Email: __________________________________________

Telephone: ______________________________ Fax: __________

Billing Contact: ______________________________ Email: ________________

Patient Name: __________________________ Species: Canine

Breed: Golden Retriever Owner's Name: Nicole Ritter and Eric Yard

Current Diet: Fromm Game Bird Recipe with Primal raw topper and raw goats milk

Sample type: ☐ Plasma ☑ Whole Blood ☐ Urine ☐ Food ☐ Other ______

Test: ☑ Taurine ☐ Complete Amino Acids ☐ Other: ______________________

Taurine Results (lab use only)

<table>
<thead>
<tr>
<th></th>
<th>Plasma (nMol/ml)</th>
<th>Whole Blood (nMol/ml)</th>
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<tbody>
<tr>
<td></td>
<td>Normal Range</td>
<td>No known risk for deficiency</td>
</tr>
<tr>
<td>Cat</td>
<td>80-120</td>
<td>&gt;40</td>
</tr>
<tr>
<td>Dog</td>
<td>60-120</td>
<td>&gt;40</td>
</tr>
</tbody>
</table>

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

Patient
Name: B6
Species: Canine
Gold Male (Neutered) Golden Retriever
Birthday: B6

Owner
Name: B6
Address: B6

Patient ID: 426744

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

Cardiology Resident: B6
Cardiology Technician: B6

Date: B6

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 cardiovascular@vt.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 (508-887-4696) to ensure the food is in stock. Alternatively, veterinary diets can be ordered from online retailers with a prescription/veterinary approval.

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

<table>
<thead>
<tr>
<th>Case</th>
<th>B6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Owner</td>
<td>B6</td>
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</table>

Discharge Instructions
**Patient History Report**

<table>
<thead>
<tr>
<th>Client:</th>
<th>Phone:</th>
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</thead>
<tbody>
<tr>
<td>B6</td>
<td></td>
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</tr>
</tbody>
</table>

**Client:**
- **Species:** Canine
- **Age:** B6
- **Color:** Buff
- **Breed:** Golden Retriever
- **Sex:** M Neutered

**Date Type Staff History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Type</th>
<th>Staff</th>
<th>History</th>
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<tbody>
<tr>
<td>8/21/2018</td>
<td>C</td>
<td>012</td>
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</table>

**Blood draw --> owner to send to UC for taurine level**

**Follow Up needed / recommended:**
- **None**

---

**Office Visit - CLOSED 08/29/2018**

**Blood draw - owner to send to UC for taurine level**

**Discussion Items:**
- **Blood draw, put into green top tube, owner to send to UC lab herself for. Sent home styrofoam container and ice packs since they’re 30 mins away.**
# Patient History Report

**Client:**

**Patient:**

**Species:** Cat

**Breed:** Golden Retriever

**Address:**

**Sex:** M Neutered

**Phone:** B 6

**Species:** Cat

**Breed:** Golden Retriever

**Address:**

**Sex:** M Neutered

## Date Type  Staff  History

**Reason for Visit:** TECH APPOINTMENT

Date Patient Checked Out: 08/21/18 Practice 1

1.00 Blood Draw/Pack-Doctor/MSU-CT Mals (374) by 022

<table>
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<th>Date</th>
<th>Type</th>
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<th>History</th>
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<tbody>
<tr>
<td>8/21/2018</td>
<td>B</td>
<td>012</td>
<td>Tech APPOINTMENT</td>
</tr>
<tr>
<td>8/7/2018</td>
<td>C</td>
<td>081</td>
<td>Phone &amp; Other Contact - CLOSED 08/17/2018 - Wanting to schedule blood draw to check taurine levels</td>
</tr>
</tbody>
</table>

- Client Initiated Call/Contact
- MVC Initiated Call/Contact
- UNOM
- In Person
- E-mail

Client would like to schedule a blood draw so that she can get pts taurine levels checked. Dr. B 6 says the study for golden retrievers that she wants to take would prefer a blood sample sent to them and not run through lab. It would be helpful if sample were green top (not a special blood tube). Dr. B 6 is going to outline instructions. Note to [B6] to see best way to schedule this. [B6]

3:10 instructions attached to this note, dr. says who will handle the shipping of the blood sample [B6]

8/20 [B6] pended to schedule with a tech, dr. will wait till the blood bags come in and we call her to schedule, dr. would prefer a incoming app so that she can go to lab [B6] right after the appointment to send the blood [B6]

8/21 [B6] called and schedule appt with tech [B6]
Patient History Report

Client: 
Phone: 
Address: 

Patient: B6
Species: Carolina 
Age: 
Color: B6 
Breed: Golden Retriever 
Sex: M Neutered 

Date Type Staff History

Billing: C Med note, CB Call back, OC Check-in, OM Communication, D Diagnosis, DH Declined to history, E Examination, ES Estimate, 
L Lab result, M Imageinema, P Prescription, PA/PVL Accepted, PB Problems, PF/PVL Performed, PR/PVL Recommended, 
R Correspondence, T Images, TC Test results, v Visit note, V Visit sign

B6

Page 3 of 33 Date: 8/30/2018 3:19 PM
<table>
<thead>
<tr>
<th>Date</th>
<th>Type</th>
<th>Staff</th>
<th>History</th>
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B6

Patient History Report

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<tr>
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<table>
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<table>
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<tr>
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Date: 8/30/2018 3:19 PM
### Patient History Report

**Client:**

**Phone:**

**Address:**

**Patient:**

**Species:** Cat

**Age:** 6 months

**Color:** Buff

**Breed:** Golden Retriever

**Sex:** M Neutered

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<th>History</th>
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**B6**

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**Page 5 of 33**

Date: 8/30/2018 3:19 PM
Patient History Report

Client: B6

Phone: 

Address: 

Patient: B6

Species: Canine

Breed: Golden Retriever

Age: 

Sex: Neutered

Color: Buff

Date Type Staff History

B6

Page 6 of 33 Date: 8/30/2018 3:19 PM
Patient History Report

Client: John Patient: B6
Phone: 123-456-7890 Address:
Species: Canine Age: B6 Color: Red
Breed: Golden Retriever Sex: M Neutered

Date Type Staff History

Date: 8/30/2018 3:19 PM

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Patient History Report

Client: B6

Phone: B6

Address: B6

Patient: B6

Species: Canine

Age: B6

Color: Buff

Breed: Golden Retriever

Sex: M Neutered

Date Type Staff History

B6

Page 8 of 33 Date: 8/30/2018 3:19 PM
### Patient History Report

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B6

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B6

Page 10 of 33

Date: 8/30/2018 3:19 PM
Patient History Report

Client: B6
Phone: 86
Address: 86

Patient: B6
Species: Cat
Age: B6
Color: 86
Breed: Golden Retriever
Sex: Neutered

Date Type Staff History

B6

Page 11 of 33 Date: 8/30/2018 3:19 PM
Patient History Report

Client: [Redacted]
Phone: [Redacted]
Address: [Redacted]

Patient: B6
Species: Canine
Breed: Golden Retriever
Age: [Redacted]
Color: Buff
Sex: M Neutered

Date Type Staff History

B6

Date: 8/30/2018 3:19 PM
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**Patient History Report**

- **Client:**
  - **Phone:**
  - **Address:**

- **Patient:**
  - **Species:** Canine
  - **Age:**
  - **Color:** Buff

- **Breed:** Golden Retriever
- **Sex:** M Neutered

---

**Date:** 8/30/2018 3:19 PM
Patient History Report

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**B6**

**Species:** Canine  
**Age:** B6  
**Color:** B6  
**Breed:** Golden Retriever  
**Sex:** Neutered

---

**Notes:***

Patient History Report

Client: 
Phone: 
Address: 

Patient: B6
Species: 
Age: 
Color: 

Breed: Golden Retriever
Sex: M/Neutered

Date Type Staff History

B6

- Client Initiated Call / Contact
- A/C Initiated Call / Contact
- MOM
- In Person
- E-mail

B6 says that one of her dogs got into a Minnesota laundry soap bar last night. She says about 1/2 is missing. Note sent to B6.

B6

Page 15 of 33
Date: 8/30/2018 3:19 PM
RDVM B6

Patient History Report

Patient: B6
Species: Cat
Age: B6
Breed: Golden Retriever
Sex: M Neutered
Color: Buff

Date Type Staff History
Patient History Report

Client: 
Phone: 
Address: 

Patient: B6
Species: Canine
Age: B6
Color: Buff
Sex: M Neutered
Breed: Golden Retriever

Date Type Staff History

B6

Page 17 of 33  Date: 8/30/2018 3:19 PM
### Patient History Report

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**Patient:**
- **Species:** Canine
- **Breed:** Golden Retriever
- **Age:** B6
- **Sex:** M
- **Color:** Buff

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**Client:**
- **Phone:**
- **Address:**
### Patient History Report

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- **Age:** B6
- **Color:** Buff
- **Sex:** Neutered

### Date Type Staff History

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<th>History</th>
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**B6:**

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B (Billing), C (Med note), D (Call back), O (Check-in), OM (Communications), D (Diagnosis), DH (Declined to history), E (Examination), ES (Estimate), I (Imaging Inst), L (Lab result), M (Image views), P (Prescription), PA (PVL Accepted), PE (Problems), PF (PVL Performed), PR (PVL Recommended), R (Correspondence), T (Images), TC (Therapy notes), V (Visits)

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Date: 8/30/2018 3:19 PM
### Patient History Report

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#### Date Type Staff History

**B6**

Page 20 of 33 Date: 8/30/2018 3:19 PM
### Patient History Report

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**Patient:** B6  
**Species:** Canine  
**Breed:** Golden Retriever  
**Age:** B6  
**Color:** Bluff  
**Sex:** Neutered
### Patient History Report

**Client:**
- **Phone:**
- **Address:**

**Patient:**
- **Breed:** Golden Retriever
- **Sex:** M-Neutered

<table>
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**B6**
Patient History Report

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<th>Staff</th>
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**Patient:**
- **Species:** Canine
- **Breed:** Golden Retriever
- **Age:**
- **Sex:** M Neutered
- **Color:** Buff

**Client:**
- **Phone:**
- **Address:**

B6
Patient History Report

Client: 
Phone: 
Address:

Patient: B6
Species: Canine
Age: B6
Color: Red

Breed: Golden Retriever
Sex: M: Neutered

Date Type Staff History

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FDA-CVM-FOIA-2019-1704-008621
**Patient History Report**

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**Client:**
- **Phone:**
- **Address:**

**Patient:** B6
- **Species:** Canine
- **Age:** B6
- **Color:** Ruff
- **Breed:** Golden Retriever
- **Sex:** M Neutered

**Date:** 25/03/2018

*Page 25 of 33*
### Patient History Report

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<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

#### Patient Information

- **Species:** Cat
- **Breed:** Golden Retriever
- **Age:** B6
- **Sex:** M Neutered
- **Color:** Buff

#### Date, Type, Staff, History

<table>
<thead>
<tr>
<th>Date</th>
<th>Type</th>
<th>Staff</th>
<th>History</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Date</td>
<td>Type</td>
<td>Staff</td>
<td>History</td>
</tr>
<tr>
<td>------</td>
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</table>

**Patient History Report**

- **Client:**
- **Phone:**
- **Address:**

- **Patient:** B6
- **Species:** Canine
- **Age:** 6 months
- **Color:** Buff
- **Sex:** Neutered
- **Breed:** Golden Retriever

---


**B6**

Page 27 of 33  Date: 8/30/2018 3:19 PM
Patient History Report

<table>
<thead>
<tr>
<th>Client</th>
<th>Phone</th>
<th>Address</th>
<th>Patient</th>
<th>Species</th>
<th>Breed</th>
<th>Age</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>B6</td>
<td>Canine</td>
<td>Golden Retriever</td>
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<td></td>
<td>M-Neutered</td>
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</table>

Date: 8/30/2018 3:19 PM
### Patient History Report

<table>
<thead>
<tr>
<th>Client</th>
<th>Patient</th>
<th>Species</th>
<th>Breed</th>
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<tbody>
<tr>
<td></td>
<td>B6</td>
<td>canine</td>
<td>Golden Retriever</td>
</tr>
<tr>
<td></td>
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<table>
<thead>
<tr>
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<th>Type</th>
<th>Staff</th>
<th>History</th>
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</thead>
<tbody>
<tr>
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</table>

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**B6**

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<table>
<thead>
<tr>
<th>Date</th>
<th>Type</th>
<th>Staff</th>
<th>History</th>
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</thead>
</table>

**Patient History Report**

**Patient:** B6  
**Species:** Canine  
**Age:** B6  
**Color:** Buff  
**Sex:** M Neutered  

**B6**
### Patient History Report

<table>
<thead>
<tr>
<th>Date</th>
<th>Type</th>
<th>Staff</th>
<th>History</th>
</tr>
</thead>
</table>

**Client:**

<table>
<thead>
<tr>
<th>Phone</th>
<th>Address</th>
</tr>
</thead>
</table>

**Patient:**

| B6    | Species: Cat
|-------|----------------|
| Age: B6 | Breed: Golden Retriever
| Color: Buff | Sex: M Neutered |

**SUMMARY:**

| E: Exam
| F: Med record
| P: Exam
| P: PVL
| T: PVL
| V: Vitals
| T: Temp
| T: Lab result
| L: Image cases
| F: Prescription
| P: PVL Accepted
| P: PVL Performed
| P: PVL Recommended
| R: Correspondence
| T: Images
| T: Laboratory results
| V: Vital signs |

---

**B6**

*Page 32 of 33*  
*Date: 8/30/2018 3:19 PM*
Patient History Report

Client: B6
Phone: B6
Address: B6

Patient: B6
Species: Canine
Age: B6
Color: Buff
Sex: Neutered

Date Type Staff History

B6
Client: Veterans
Patient ID: B6
Visit ID: 

### Lab Results Report

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>Reference Range</th>
<th>Units</th>
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<tbody>
<tr>
<td>T4/TOSOH</td>
<td>B6</td>
<td>1 - 4.1</td>
<td>ug/dl</td>
</tr>
</tbody>
</table>

Accession ID: B6

Printed Friday, September 07, 2018
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: PFR Event <pfreventcreation@fda.hhs.gov>
Sent: Monday, October 01, 2018 5:05 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [B6]
Subject: Honest Kitchen whole grain turkey: Lisa Freeman - EON-367347

A PFR Report has been received and PFR Event [EON-367347] has been created in the EON System.

A "PDF" report by name "2055560-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 "2055560-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-367347  
**ICSR #:** 2055560  
**EON Title:** PFR Event created for Honest Kitchen whole grain turkey beef or chicken + Ziwi Peak (just started again) - see diet history for B6 and B6 attached; 2055560

<table>
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<th>AE Date</th>
<th>09/27/2018</th>
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FDA-CVM-FOIA-2019-1704-008632
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<th>Dog</th>
<th>Outcome to Date</th>
<th>Stable</th>
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</thead>
<tbody>
<tr>
<td>Breed</td>
<td>Retriever - Golden</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>B6 Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**

**Individual Case Safety Report Number:** 2055560

**Product Group:** Pet Food

**Product Name:** Honest Kitchen whole grain turkey, beef, or chicken + Ziwi Peak (just started again) - see diet history for [B6] and [B6] attached

**Description:** Housemate diagnosed with reduced contractile function on echo (Asymptomatic NT-proBNP tested at RDVM. Will send results)

**Submission Type:** Initial

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

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

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

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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Honest Kitchen whole grain turkey, beef, or chicken + Ziwi Peak (just started again) - see diet history for [B6] and [B6] attached</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sender information**

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

**Owner information**

[B6] USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-367347

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issuelid=384261

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

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

Failure to adhere to the above provisions could result in removal from the approved distribution list. If you think you received this email in error, please send an email to FDAReportableFoods@fda.hhs.gov immediately.
A PFR Report has been received and PFR Event [EON-364577] has been created in the EON System.

A "PDF" report by name "2054750-report.pdf" is attached to this email notification for your reference. Please note that all documents received in the report are compressed into a zip file by name "2054750-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-364577  
**ICSR #:** 2054750  
**EON Title:** PFR Event created for Honest Kitchen Whole Grain Turkey Beef or Chicken, Ziwi Peak (recently started); 2054750

<table>
<thead>
<tr>
<th>AE Date</th>
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<th>Breed</th>
<th>Age</th>
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<tbody>
<tr>
<td>Dog</td>
<td>Retriever - Golden</td>
<td>B6 Years</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>District Involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFR-New England DO</td>
</tr>
</tbody>
</table>

**Product information**  
**Individual Case Safety Report Number:** 2054750  
**Product Group:** Pet Food  
**Product Name:** Honest Kitchen Whole Grain Turkey, Beef, or Chicken, Ziwi Peak (recently started)  
**Description:** Not true DCM but reduced contractility. Taurine (whole blood)  
**Submission Type:** Initial  
**Report Type:** Adverse Event (a symptom, reaction or disease associated with the product)  
**Outcome of reaction/event at the time of last observation:** Stable  
**Number of Animals Reacted With Product:** 1
<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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<tbody>
<tr>
<td>Ziwi Peak (recently started)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Honest Kitchen Whole Grain Turkey, Beef, or Chicken</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**Owner information**

![B6](https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=381311)

USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-364577

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=381311

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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**Lab Results Report**

<table>
<thead>
<tr>
<th>Test</th>
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<th>Reference Range</th>
<th>Units</th>
</tr>
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<tr>
<td>T4/TOSOH</td>
<td>B6</td>
<td>1 - 4.1</td>
<td>ug/dl</td>
</tr>
</tbody>
</table>

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

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

Foster Hospital for Small Animals
55 Willard Street
North Grafton, MA 01536
(508) 839-5395

Printed Friday, September 07, 2018
Discharge Instructions

Patient
Name: B6
Species: Canine
   Gold Female (Spayed) Golden Retriever
Birthdate: B6

Owner
Name: B6
Address: B6

Patient ID: 626794

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

Cardiology Resident: B6

Cardiology Technician: B6

Student: B6, V19

Date: B6

Diagnoses:
Mild reduced contractile function, normal cardiac size

Clinical Findings: Thank you for bringing in for evaluation of her heart. Similar to heart is normal in size, but her contractile function is not quite as vigorous as some dogs. This could be a variation of normal for her, but it is also possible that this is an abnormality related to having been eating a grain-free diet. We recommend getting an NT-pro BNP test done when you take in for her physical examination on Monday to better assess her heart function.

Monitoring at Home: Please watch for any exercise intolerance, weakness, or collapse.

Diet Suggestions: We recommend continuing to feed a main stream brand diet with standard protein source that is not grain-free.

Exercise Recommendations: B6 can have normal exercise.

Recheck Visits: We will want to do a recheck echocardiogram in 6-12 months (on the sooner side if BNP is very high)

Thank you for entrusting us with care. She is so sweet! Please contact our Cardiology liaison at (508)-387-4696 or email us at cardiology@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information
http://vet.tufts.edu/heartsmart/
Prescription Refill Disclaimer:
For the safety and well-being of our patients, your pet must have had an examination by one of our veterinarians within the past year in order to obtain prescription medications.

Ordering Food:
Please check with your primary veterinarian to purchase the recommended diet(s). If you wish to purchase your food from us, please call 7-10 days in advance (508-857-4629) 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:

FDA-CVM-FOIA-2019-1704-008683
Amino Acid Laboratory Sample Submission Form
Amino Acid Laboratory
1089 Veterinary Medicine Drive
Davis, Ca 95616
Telephone: 530-752-5058, Fax: 530-752-4698
Email: ucd.aminoacid.lab@ucdavis.edu
www.vetmed.ucdavis.edu/labs/amino-acid-laboratory

Veterinarian Contact: B6
Clinic/Company Name: B6
Address: B6
Email: B6
Telephone: B6 Fax: B6 Email: B6
Billing Contact: B6
Patient Name: B6 Species: Dog
Breed: Golden Retriever Owner’s Name: B6
Current Diet: K-9 Naturals, RC SR, Zignaturk
Sample type: Plasma Whole Blood Urine Food Other
Test: Taurine Complete Amino Acids Other:
Taurine Results (lab use only) B6
Plasma: Whole Blood: Urine: Food:

Plasma (nMol/ml) Whole Blood (nMol/ml)

<table>
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<tr>
<th></th>
<th>Normal Range</th>
<th>No known risk for deficiency</th>
<th>Normal Range</th>
<th>No known risk for deficiency</th>
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<tbody>
<tr>
<td>Cat</td>
<td>80-120</td>
<td>&gt;40</td>
<td>300-600</td>
<td>&gt;200</td>
</tr>
<tr>
<td>Dog</td>
<td>60-120</td>
<td>&gt;40</td>
<td>200-350</td>
<td>&gt;150</td>
</tr>
</tbody>
</table>

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

* Please send results to Vet. Thank you.
Dave,
I know we're chatting Thursday about the results and next steps. Jen

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

Hi Jen
I also left you a voice message but I just heard that 3 dogs died suddenly. 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 the dogs 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
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

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
Referring Information

Initial Complaint:
New cruciate evaluation, possibly sx at rDVM.

SOAP Text Jul 8 2015 2:30PM

7/8/2015 4:58:22 PM NEW VISIT

History: 7 yo CM Dobie presenting for his right hind limb lameness. 2 weeks ago he became acutely lame on his RH after running around. He was taken to the DVM who suspected a cranial cruciate ligament rupture. rDVM did bloodwork, showed increase of ALT and started him on | ALT decreased after 2 weeks.

Exam:
Subjective

Objective

Assessment

Plan

B6

7/17/2015 7:21:04 AM EXAM, GENERAL
*** 3 doses*** - Expires: 7/16/2016 No Refills
Patient: B6

Instructions - 3.8 mg IV q6 - Expires: 7/16/2016 No Refills

Plan (P)
P1: Continue
P2: Continue
P3: Continue
P4: Feed q8
P5: water, walk, HR, RR q4
P6: BW and Temp q12
P7: Discharge 7/19/15
P8: Move to B-ward

SOAP completed by B6
SOAP reviewed by

Prescribed B6
Instructions - Give 3.6 mg IV q6 - Expires: 7/17/2016 No Refills

7/19/2015 8:19:07 AM EXAM, GENERAL
Plan (P)
P1: Discharge today
P2: Go home meds
P3: Go home meds

SOAP completed by: B6
SOAP reviewed by: B6

7/19/2015 8:26:05 AM

Initial Complaint:
Chief Recheck No Xrays

SOAP Text Oct 7 2015 3:13PM

Recheck examination:
Client: B6

Initial Complaint:
New DCM/arrhythmia (poss DCM study)

Initial Complaint:
Emergency

Initial Complaint:
Rx VW and heart disease (cardio apt 12/5)

Initial Complaint:
Drop Off Chief Surgery, Admit to B6

Subjective
EXAM, GENERAL

Subjective (S)

10 yo CM Doberman

and it has since discontinued and the odor has returned. B6 has a history of VWD and DCM which he is on medications to help manage.

Subjective (S)

BAR, nervous
mild dehydration
MM pink, Crt 0.5 seconds
Objective (O)

H/L: NMA, NSR, FPSS. Normal BVS in all lung fields, no crackles or wheezes ausculted. Eupnic.

Diagnostics Completed:

12/10/2018:

Assessment (A)

A1: 

A2: History of DCM

A3: 

A4: 

Plan (P)

P1: 

SOAP completed by: B6 V'19
SOAP reviewed by:

Disposition/Recommendations
**Lab Results Report**

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>Reference Range</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Glucose (TVETS)</td>
<td>B6</td>
<td>0 - 0 mg/dl</td>
<td></td>
</tr>
<tr>
<td>PCV for PCV/TS/AZO/BG</td>
<td>0 - 0 g/dl</td>
<td></td>
<td></td>
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<tr>
<td>TS (TVETS)</td>
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<td>BG (FHSA)</td>
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Printed Thursday, December 27, 2018
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<th>Time (min)</th>
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<td>Blood Pressure (mmHg)</td>
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**Anesthesia Record & checklist**

**Blood Type:**

- Rh Factor: Positive
- ABO Type: O
- Crossmatch: Positive

**Dosing Information:**

- IV Drip: 100 mL/h
- Oxygen: 2 L/min via nasal cannula

**Patient Monitoring:**

- Pulse Oximetry: 98%
- Non-invasive Blood Pressure: 120/80 mmHg
- ECG:
  - Heart Rate: 68 bpm
- End tidal CO2: 32 mmHg

**Surgical Site:**

- Left Femur

**Anesthesia Type:**

- General

**Anesthesia Provider:**

- Dr. Smith

**Anesthesia Assistant:**

- Nurse Johnson

**Anesthesia Technician:**

- Mr. Lee

**Anesthesia Equipment:**

- Anesthesia Machine: Model A2000
- Ventilator: Brand B8000
- Monitor: Model C2000

**Anesthesia Drug Administration:**

- Midazolam 5 mg IV
- Propofol 200 mg IV
- Fentanyl 100 mcg IV

**Anesthesia Induction:**

- Intravenous Injection
- Mask induction

**Anesthesia Maintenance:**

- Continuous IV infusion
- Supplemental O2

**Anesthesia Emergence:**

- Slow IV bolus of Midazolam
- O2 mask
- Emergence from anesthesia

**Anesthesia Discharge:**

- Stable hemodynamics
- Oxygen saturation 98%
- Vital signs within normal limits

Page 12/406
**Tufts Cummings School of Veterinary Medicine SA Anesthesia Checklist**

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<th>After Induction in Prep Area</th>
<th>Prior to Entering OR</th>
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<tr>
<td>Patient ID, procedure, &amp; procedure site confirmed</td>
<td>Radiology work-up completed</td>
<td>Phlebotomist to radiology</td>
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<td>Body weight matches patient size</td>
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<td>Wrist-up sheet reviewed &amp; signed by anesthetist</td>
<td>Cefazolin (or other antibiotic) requested and available</td>
<td>Anesthesia team</td>
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<td>Surgeon States</td>
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<td>Table where patient will spend the evening</td>
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<td>Cefazolin for other a/bi requested &amp; given within the past 60 min</td>
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This form remains with the patient throughout recovery.

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**Client:** Patient

**B6**
VETERINARY RECORDS REQUEST

DATE: 10/15/2015

ATTENTION VETERINARIAN and/or STAFF

PET OWNER: B6

PET NAME: B6

POLICY NUMBER: B6

CLAIM NUMBER: B6

INFORMATION NEEDED:

1. MEDICAL RECORDS, INCLUDING DOCTOR'S NOTES AND LAB RESULTS FROM
   6/1/2014 TO PRESENT
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Alba Holter
Client:  
Patient:  

Alba Holter

B6
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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. 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.

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 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
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 EON-358523

Dear Dr. Freeman,

Thank you for submitting your consumer complaint to FDA. I’m sorry to hear about your 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 your entire medical history (not just this event), including any referral diagnostics.

- **Phone interview** about 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
Hi Jen
I'm attaching records from re: She's also given permission for you to contact her.

I still have food in my office from

if you want any of that

Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
Professor
Cumming 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: 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 (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:
• [B6] are you able to send any updates on the Taurine testing or echocardiogram (if done?)
• [B6] 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

FDA U.S. FOOD & DRUG ADMINISTRATION
From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Friday, July 20, 2018 8:06 AM
To: Reimschuessel, Renate <Renate_Reimschuessel@fda.hhs.gov>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
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Cummings School of Veterinary Medicine
Friedman School of Nutrition Science and Policy
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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)

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Aquaculture
[http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm](http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm)
Thank you, Lisa! Enjoy your weekend, Jen

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

Lisa M. Freeman, DVM, PhD, DACVN
Board Certified Veterinary Nutritionist™
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Sent: Tuesday, July 17, 2018 11:48 AM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: 800.267-FDA Case Investigation for (EON-358523)

Dear Dr. Freeman,

Thank you for submitting your consumer complaint to FDA. I’m sorry to hear about 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 **entire** medical history (not just this event), including any referral diagnostics.

- **Phone interview** about 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: reneate.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
Hi Jen

I think you're probably right. In addition to those we've noted a few that don't have clear-cut DCM but have reduced fractional shortening. I've recorded these and will try to recheck them:

* Boxer with 3rd degree AV block but also cardiac enlargement (Earthborn diet)
* Border collieX with reduced contractile function (Merrick – I have a sample of his diet)
* Mix breed with a murmur on Zignature (no echo done)
* Catahoula with a PDA but reduced contractile function on Taste of the Wild
* German Shepherd with mitral valve disease with questionable contractile function (unknown diet)
* Boxer with reduced contractile function eating 4Health

I'm attaching B6 files. We have not heard from owners recently.

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

Hi Lisa,

I'm curious if we may be seeing a spectrum of disease with these complaints. Can you forward medical records please?

Thank you,

Jen

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

From: Reimschuessel, Renate
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)

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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.

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

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Aquaculture
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From: Jones, Jennifer L &lt;jennifer.jones@fda.hhs.gov&gt;  
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Cc: Reimschuessel, Renate &lt;renate.reimschuessel@fda.hhs.gov&gt;  
Subject: RE: 800.267-FDA Case Investigation for _____ (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:

- [B6] are you able to send any updates on the Taurine testing or echocardiogram (if done?)
- [B6] 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
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Cc: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
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 B6 B6 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

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Dear Renate
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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

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Sent: Tuesday, July 17, 2018 11:48 AM
To: Freeman, Lisa <liisaJreeman@tufts.edu>
Subject: 800.267-FDA Case Investigation for [B6] (EON-358523)

Dear Dr. Freeman,
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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
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Aquaculture
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm

FDA-CVM-FOIA-2019-1704-009110
Hi Jen,

I'll ask to send their records. I'm attaching what I have from 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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Tufts Clinical and Translational Science Institute
Tufts University
www.petfoodology.org

---

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 (EON-358523)

Thank you, Lisa.

Yes, please send 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 <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 (EON-358523)

Hi Jen

I'm still working on getting permission from owners. They may be on vacation – tough to get people at this time of year.

I also just heard that (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
From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
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http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

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Aquaculture
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm
From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFC14A6CB8E94F322906BADD-DROTSTEI>

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

Sent: 10/1/2018 8:56:50 PM

Subject: Decreased contractility with MRx-FW: Honest Kitchen Grain Free beef (love): Lisa Freeman - EON-367344

Attachments: 2055558-report.pdf; 2055558-attachments.zip

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

Sent: Monday, October 01, 2018 4:53 PM

To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ_Pet_Food_Report_Notification <HQ_Pet_Food_Report_Notification@fda.hhs.gov>; B6

Subject: Honest Kitchen Grain Free beef (love): Lisa Freeman - EON-367344

A PFR Report has been received and PFR Event [EON-367344] has been created in the EON System.

A "PDF" report by name "2055558-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 "2055558-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-367344
ICSR #: 2055558
EON Title: PFR Event created for Honest Kitchen Grain Free beef (love) fish (zeal) chicken (force) or turkey (keen). Also Instinct raw beef patties; 2055558

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<td>Number Reacted</td>
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## Animal Species Information

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<tr>
<td>Dog</td>
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<table>
<thead>
<tr>
<th>Breed</th>
<th>Retriever - Golden</th>
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<tbody>
<tr>
<td>Age</td>
<td>B6 years</td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
</tr>
</tbody>
</table>

## Product Information

**Individual Case Safety Report Number:** 2055558

**Product Group:** Pet Food

**Product Name:** Honest Kitchen Grain Free beef (love), fish (zeal), chicken (force), or turkey (keen). Also, Instinct raw beef patties

**Description:** Eating grain-free diet so owner wanted baseline echo. No clinical signs Echo showed no overt DCM but reduced contractility. Taurine low (plasma \[B6\] WB = \[B6\]) Recommended diet change and taurine supplementation

**Submission Type:** Initial

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

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

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

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

<table>
<thead>
<tr>
<th>Product Name</th>
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<th>Best By Date</th>
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<tbody>
<tr>
<td>Honest Kitchen Grain Free beef (love), fish (zeal), chicken (force), or turkey (keen). Also, Instinct raw beef patties</td>
<td></td>
<td></td>
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</tbody>
</table>

## Sender Information

Lisa Freeman  
200 Westboro Rd  
North Grafton, MA 01536  
USA

## Owner Information

B6

USA

To view this PFR Event, please click the link below:  
https://eon.fda.gov/eon/browse/EON-367344

To view the PFR Event Report, please click the link below:  
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issuelid=384258

FDA-CVM-FOIA-2019-1704-009166
This email and attached document are being provided to you in your capacity as a Commissioned Official with the U.S. Department of Health and Human Services as authorized by law. You are being provided with this information pursuant to your signed Acceptance of Commission.

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

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

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

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

Sent: 6/10/2019 8:20:57 PM

Subject: Fromm Game Bird Recipe Dog - Four-Star - Dry Grain-Free formula: B6 EON-390092

Attachments: 2068038-report.pdf; 2068038-attachments.zip

A PFR Report has been received and Related PFR Event [EON-390092] has been created in the EON System.

A "PDF" report by name "2068038-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 "2068038-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-390092  
**ICSR #:** 2068038  
**EON Title:** Related PFR Event created for Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula; 2068038

<table>
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<td>Number Reacted</td>
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</tr>
<tr>
<td>Animal Species</td>
<td>Dog</td>
<td>Outcome to Date</td>
<td>Better/Improved/Recovering</td>
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<td>Breed</td>
<td>Hound (unspecified)</td>
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<td></td>
</tr>
<tr>
<td>Age</td>
<td>B6</td>
<td>3ars</td>
<td></td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product information**  
**Individual Case Safety Report Number:** 2068038  
**Product Group:** Pet Food  
**Product Name:** Fromm Game Bird Recipe Dog · Four-Star · Dry Grain-Free formula  
**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 of 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.

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

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</tbody>
</table>

This report is linked to:
Initial EON Event Key: EON-388971
Initial ICSR: 2067510

Sender information

B6

Owner information

B6

USA

To view this Related PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-390092

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=407364&parentIssueTypeId=12

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Dear Dr. Freeman,

Thank you for submitting your consumer complaint to FDA. I'm sorry to hear about 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 entire medical history (not just this event), including any referral diagnostics.
- **Phone interview** about 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/nrm247334.htm

Phish-Pharm
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ToolsResources/Phish-Pharm/default.htm

Aquaculture
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm130892.htm
FYI-MRx in PFR show DCM w/ CHF. Is submitting reports from Tufts (in lieu of Lisa Freeman)
NFA for Vet-LIRN

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

From: PFR Event <pfreventcreation@fda.hhs.gov>
Sent: Monday, April 01, 2019 5:49 PM
To: Cleary, Michael <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>
Subject: ACANA - Heritage Red Meat Formula Dog Food (Grain-free); EON-383914

A PFR Report has been received and PFR Event [EON-383914] has been created in the EON System.

A "PDF" report by name "2065085-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 "2065085-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

**EON Key:** EON-383914  
**ICSR #:** 2065085  
**EON Title:** PFR Event created for ACANA - Heritage Red Meat Formula Dog Food (Grain-free); 2065085

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<thead>
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<tr>
<td>Number Fed/Exposed</td>
<td>2</td>
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<tr>
<td>Best By Date</td>
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<tr>
<td>Number Reacted</td>
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<tr>
<td>Animal Species</td>
<td>Dog</td>
</tr>
<tr>
<td>Outcome to Date</td>
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</tr>
<tr>
<td>Breed</td>
<td>Shepherd Dog - German</td>
</tr>
<tr>
<td>Age</td>
<td>11.5 Years</td>
</tr>
<tr>
<td>District Involved</td>
<td>PFR-New England DO</td>
</tr>
</tbody>
</table>

**Product information**  
**Individual Case Safety Report Number:** 2065085  
**Product Group:** Pet Food  
**Product Name:** ACANA - Heritage Red Meat Formula Dog Food (Grain-free)  
**Description:** 3/15/2019 - Acute onset of difficulty breathing on walk, increased resp rate, wheezing and short of breath. Diagnosed with DCM and CHF
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 2
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number or ID</th>
<th>Best By Date</th>
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</thead>
<tbody>
<tr>
<td>ACANA - Heritage Red Meat Formula Dog Food (Grain-free)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sender information

B6
USA

Owner information

B6

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-383914

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueld=401042

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MRx summaries attached.
The Message Board is worth reading-start on the last page. Good article (DeLuca et al) with Tau biosynthesis diagram (below) attached.

```
\[ \text{B5, B6} \]
```

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

From: Rotstein, David
Sent: Tuesday, January 23, 2018 7:02 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: California Natural and Zignature-Kangaroo Diets and DCM EON-345833-345835-345831-345822

Thanks---that's what I figured!

From: Jones, Jennifer L
Sent: Tuesday, January 23, 2018 7:01 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey,
I wasn’t-However, I bet it’s related to our contact from NCSU. She had a cardiologist friend in with a few cases. We can get MRx, to start!

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

From: Rotstein, David
Sent: Monday, January 22, 2018 10:06 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: California Natural and Zignature- Kangaroo Diets and DCM EON-345833-345835-345831-345822

Not sure if you were expecting these at Vet-LIRN
We received urine for Fanconi panel.

I spoke with owner today:

05/14/2015

OC-spoke with an owner. His email: [B6]

[B6], regular food is “Nature’s Recipe, Salmon”, grain free. No table scraps, no other food. The only jerky treats she ever had were Golden Rewards. He began feeding her the treats sometime in January, 2015. She was receiving them for approximately 4 months when she showed first symptoms and stopped eating. Her water intake and urination actually decreased. [B6] would eat 3-5 treats every day, and she always asked for more. The bag that owner gave to veterinarian to send to us is unopened. [B6] is Chiweenie (Chihuahua/Dachshund mix), 1.5 years old, spayed. She had absolutely no health issues before this event. She was even hit by a car, but was not hurt.

She only received [B6] but on the same day owner took her to the vet when she already showed symptoms. [B6] is primarily indoor dog, rarely goes out but is always supervised. She was never boarded.

Other pets: owner has two other dogs, they also consumed treats but are without symptoms. They are:
1. Hound mix- 85lbs.
2. Basenji mix-50 lbs.

Owner also has a Sugar Glider. Glider does not come out of the cage and is not in contact with [B6]. They also have a cat-in perfect health.

Environmental exposures: indoor, no plants, grapes or raisins, nuts, mushrooms, birds... (none of the ones from the list)
Presenting complaint: not eating for 4 days, vomited once
Diagnostics declined.
Medications: B6

04/13/2015

Presented for coughing.

12/12/2014

Presented for spaying.

11/29/2014

Presenting complaint: hit by a car, limping
Treatment: no treatment, healthy patient

Olgica Ceric, DVM, PhD
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Murrink Road, G704
Laurel, Maryland 20708
tel: 240-402-5419
tax: 301-210-4685
e-mail: olgica.ceric@fda.hhs.gov
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm

From: Ceric, Olgica
Sent: Tuesday, May 05, 2015 11:56 AM
To: Carey, Lauren; Reimschuessel, Renate; Rotstein, David; CVM Vet-LRN-OR; Queen, Jackie L; Palmer, Lee Anne

Pictures in the attachment. Chicken Jerky Recipe:
From: Carey, Lauren
Sent: Tuesday, May 05, 2015 11:53 AM
To: Reimschuessel, Renate; Rotstein, David; CVM Vet-LRN-OR; Queen, Jackie L; Palmer, Lee Anne

The actual product fed would be great to know. Golden Rewards is a brand with multiple jerky treats and combos.

From: Reimschuessel, Renate
Sent: Tuesday, May 05, 2015 8:49 AM
To: Rotstein, David; CVM Vet-LRN-OR; Queen, Jackie L; Palmer, Lee Anne; Carey, Lauren

1 year old dachshund eating 2-3 jerky treats per day sometimes instead of food. I agree – please touch base with vet – get feeding history as well – ¿Dingo?
Dog fed GR for over a year. Hard to say if related at this point.

Suggest: ICERT contact vet to see if any bloodwork or UA. (will mention freezing urine). Can go from there.

d.

A PFR Report has been received and PFR Event [EON-206801] has been created in the EON System

A "PDF" report by name "1039368-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report

**EON Key:** EON-206801  
**EON Title:** PFR Event created for Golden Reward; 1039368

To view this PFR Event, please click the link below:
[https://eon.fda.gov/eon/browse/EON-206801](https://eon.fda.gov/eon/browse/EON-206801)

To view the PFR Event Report, please click the link below:
[https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=219576](https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=219576)

**Product information**

**Individual Case Safety Report Number:** 1039368  
**Product Group:** Pet Food  
**Product Name:** Golden Reward  
**Description:** Pet stopped eating about 5-6 days ago, vomited once. receives sometimes 2-3 jerky treats/day,
sometimes replacing her meals. treated 2 days ago with antinausea meds and fluids, appetite stimulants. pet did not improve. presented today still anorexic and lethargic.

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

---

**Sender information**

B6  
USA

**Owner information**

B6  
USA

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From: Glover, Mark <MARK.GLOVER>
To: Carey, Lauren; Ceric, Olgica; Jones, Jennifer L; Nemser, Sarah; Palmer, Lee Anne; Queen, Jackie L; Reimschuessel, Renate; Rotstein, David
Sent: 5/21/2018 11:16:27 AM
Subject: RE: EON-354199 RFR Event: Dog owner

Yes please J

From: Carey, Lauren
Sent: Monday, May 21, 2018 6:46 AM
To: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: FW: EON-354199 RFR Event: Dog owner

We should probably stress to these groups that they should reports as PFRs, not RFRs. We could send a guide as to how to answer the first few questions in order to ensure they choose the PFR route. Should I enter this as a PFR?

From: RFR Event [mailto:rfreventcreation@fda.hhs.gov]
Sent: Saturday, May 19, 2018 5:48 PM
To: Lambkin, Sonya <Sonya.Lambkin@fda.hhs.gov>; orahqreportablefoodnotificationtriagegroup@fda.hhs.gov; Bataller, Neal <Neal.Bataller@fda.hhs.gov>; Johnston, Ying F <Ying.Johnston@fda.hhs.gov>; Edwards, Elizabeth <Elizabeth.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Yowell, Ruth <Ruth.Yowell@fda.hhs.gov>; ORA HAF EAST1 Reportable Food Notification <orahafeast1reportablefoodnotification@fda.hhs.gov>; Krieger, Darlene <Darlene.Krieger@fda.hhs.gov>; CFSAN Reportable Food Registry <CFSANReportableFoodRegistry@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>; Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; Weems, Shellie * <Shellie.Weems@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>; ORA OEIO RECALLS Branch <oraorecallsbranch@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; McCoig, Amber <Amber McCoig@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Subject: EON-354199 RFR Event: Dog owner

A RFR Report has been received and RFR Event [EON-354199] has been created in the EON System under ICSR # 2048088.

Reason this food is reportable: Other
Please describe Other: Associated with case of dilated cardiomyopathy
Product Name: 4Health large breed dry food

<table>
<thead>
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<th>Type of Site</th>
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<th>Food Facility Site</th>
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<tr>
<td>FDA Districts Impacted:</td>
<td>NWE</td>
<td>NWE</td>
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<tr>
<td>Organization Name:</td>
<td>Tufts Cummings School of Veterinary Medicine</td>
<td>Dog owner</td>
</tr>
</tbody>
</table>
**Address:**
200 Westboro Rd
North Grafton, MA
01536
United States

unknown unknown, MA
01536
United States

**Discovery Date:** 2018-05-18  
**Product Group:** Pet Food  
**Description:** 2 year old Great Dane with DCM and CHF. Has eaten 4Health dog food (large breed dry) since 6/2016. Taurine levels pending  
**Product Recall:** No  
**Human Symptoms Present:** No  
**Animal Symptoms Present:** Yes  
**Animal Symptoms Description:** Please see above. More details can be provided  
**Product Distribution Type:** Retail  
**Root Cause:** Not applicable

**Discovery Code:** Consumer

**Submission Type:** Initial  
**Reporting Type:** Voluntary  
**EON Key:** EON-354199  
**EON Title:** RFR Event created for 4Health large breed dry food; 2048088

To view this RFR Event, please click the link below:  
https://eon.fda.gov/eon/browse/EON-354199

To view the RFR Report, please click the link below:  
https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=9&issueId=370681

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From: Jones, Jennifer L <O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JENNIFER.JONESAA8>
To: Rotstein, David
CC: Nemser, Sarah
Sent: 10/7/2015 6:53:52 PM
Subject: RE: EVOLVE GRAIN FREE DOG FOOD TURKEY< GARBANZO BEANS & PEA RECIPE:

Dave, we don’t have records of receiving this report, and are not following up.

Jennifer Jones, DVM
Veterinary Medical Officer
FDA-CVM-Vet-LIRN
Tel: 240-402-5421

From: Rotstein, David
Sent: Wednesday, October 07, 2015 2:11 PM
To: Jones, Jennifer L
Subject: FW: EVOLVE GRAIN FREE DOG FOOD TURKEY< GARBANZO BEANS & PEA RECIPE:

Double checking—are you all doing any follow-up?

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
240-506-6763 (BB)

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From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Tuesday, October 06, 2015 6:12 PM
To: HQ Pet Food Report Notification;
Subject: EVOLVE GRAIN FREE DOG FOOD TURKEY< GARBANZO BEANS & PEA RECIPE:

A PFR Report has been received and PFR Event [EON-228487] has been created in the EON System

A "PDF" report by name "1042641-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report

EON Key: EON-228487
EON Title: PFR Event created for EVOLVE GRAIN FREE DOG FOOD TURKEY< GARBANZO BEANS & PEA RECIPE; 1042641

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-228487

To view the PFR Event Report, please click the link below:
Product information
Individual Case Safety Report Number: 1042641
Product Group: Pet Food
Product Name: EVOLVE GRAIN FREE DOG FOOD TURKEY< GARLANZO BEANS & PEA RECIPE
Description: A 6 pound 7 ounce maltese, died on after eating a bowl of Evolve Dog Food. She was well and lively in the morning per usual. When the owner returned home she appeared listless, had difficulty moving and laid down and began to cry/whimper. She was first taken to her vet where found that she had a cold body temp, blood that was not coagulating, high blood sugar and she eventually passed a bloody stool. She was dehydrated and an IV for fluids was started. She was placed in a warmer. The office was closing and I was advised to bring her to which I did right away. There had x-rays, fluid, and a transfusion amongst other interventions. Both and strongly felt poison was the cause of death. died on the night of and was not exposed to poison in her yard as there is none used and is always accompanied on walks via leash. My yard is fenced and it is in excellent condition. There is no crime per se in my neighborhood.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Died Naturally
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

Sender information

USA
Dave, we don’t have records of receiving this report, and are not following up.

Jennifer Jones, DVM
Veterinary Medical Officer
FDA-CVM-Vet-LIRN
Tel: 240-402-5421

From: Rotstein, David
Sent: Wednesday, October 07, 2015 2:11 PM
To: Jones, Jennifer L
Subject: FW: EVOLVE GRAIN FREE DOG FOOD TURKEY< GARBANZO BEANS & PEA RECIPE:

Double checking—are you all doing any follow-up?

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/ICERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
240-506-6763 (BB)

A PFR Report has been received and PFR Event [EON-228487] has been created in the EON System

A "PDF" report by name "1042641-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report

EON Key: EON-228487
EON Title: PFR Event created for EVOLVE GRAIN FREE DOG FOOD TURKEY< GARBANZO BEANS & PEA RECIPE: 1042641

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-228487

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

Individual Case Safety Report Number: 1042641
Product Group: Pet Food
Product Name: EVOLVE GRAIN FREE DOG FOOD TURKEY< GARBANZO BEANS & PEA RECIPE
Description: B6 a 6 pound 7 ounce maltese, died on B6 after eating a bowl of Evolve Dog Food. She was safely secured in my clean kitchen for the day with only the food and a water bowl at her disposal. B6 was well and lively in the morning per usual. When the owner returned home she appeared listless, had difficulty moving and laid down and began to cry/whimper. She was first taken to her vet at B6 where B6 found that she had a cold body temp, blood that was not coagulating, high blood sugar and she eventually passed a bloody stool. She was dehydrated and an IV for fluids was started. She was placed in a warmer. The office was closing and I was advised to bring her to B6 which I did right away. There B6 had x-rays, fluid, and a transfusion amongst other interventions. Both B6 of B6 and B6 B6 strongly felt poison was the cause of death. B6 died on the night of B6 B6 was not exposed to poison in her yard as there is none used and is always accompanied on walks via leash. My yard is fenced and it is in excellent condition. There is no crime per se in my neighborhood.

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

Sender information

B6
USA

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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.
No worries, thanks Alex.

Jennifer Jones, DVM
Veterinary Medical Officer

Sorry for not responding, Jen. I will call today or tomorrow.

Thanks,

Alex Scalera
Program Support Specialist

Center for Veterinary Medicine
Office of Research
U.S. Food and Drug Administration
Tel: 240-402-0888
Alexander.Scalera@fda.hhs.gov

Alex, for PO 6.
You can call the number below to pay with VISA.
Thanks,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
To: Jones, Jennifer L  
Subject: FW: FDA case follow up-EON-285648-Freeman-Nature’s Vareity

Hi Jennifer
Please see message below re: using Visa for this invoice
Thanks
Lisa

From: SAH Accounting Department  
Sent: Wednesday, November 02, 2016 9:53 AM  
To:  
Subject: FW: FDA case follow up-EON-285648-Freeman-Nature’s Vareity

Hi B6

This went to medical records and they forwarded it to me. Visa is fine. She can just call with the number. B6

Thanks,
B6

Accounting Department  
Cummings School of Veterinary Medicine at Tufts University  
55 Willard St.  
North Grafton, MA 01536  
1-508-887-4314  
Hours M-F 7am-8pm, S & S 7am-3pm

From: medrec  
Sent: Wednesday, November 02, 2016 9:43 AM  
To: SAH Accounting Department  
Subject: FW: FDA case follow up-EON-285648-Freeman-Nature’s Vareity

See email below from Dr. Freeman.

B6

Medical Records Department  
Foster Hospital for Small Animals  
Tufts University, Cummings School of Veterinary Medicine  
tel: 508.887.4636  
fax: 508.8874393  
email: medrec@tufts.edu

From: Freeman, Lisa  
Sent: Tuesday, November 01, 2016 6:42 PM  
To: medrec  
Subject: Fwd: FDA case follow up-EON-285648-Freeman-Nature’s Vareity

Hi B6 How should I respond? This is for the reimbursement for B6 blood culture that we talked about a couple weeks ago by the Fda. Thanks, Lisa

Sent from my iPhone

Begin forwarded message:

From: "Jones, Jennifer L" <Jennifer.Jones@fda.hhs.gov>  
Date: November 1, 2016 at 3:08:43 PM EDT  
To: "Freeman, Lisa" <Lisa.Freeman@tufts.edu>
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature’s Variety

Good afternoon Lisa,

My accountant asked if you’re able to be reimbursed by credit (VISA) or if a check was needed?

Thank you,
Jennifer

Jennifer Jones, DVM
Veterinary Medical Officer

From: Jones, Jennifer L
Sent: Monday, October 31, 2016 7:32 AM
To: 'Freeman, Lisa'
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature’s Variety

Sounds great! Thank you, Lisa.
Please forward me the ICSR number (confirmation number) when you submit the report. It will help us find the case after it's been submitted.

Jennifer Jones, DVM
Veterinary Medical Officer

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Friday, October 28, 2016 3:36 PM
To: Jones, Jennifer L
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature’s Variety

Thanks very much.
I’m going to have another one for you. 3 unrelated dogs in a family who’ve developed dilated cardiomyopathy. Supposedly on a commercial vegan diet and then small company’s dog food. Once I get more details, I’ll submit that one.

Best,
Lisa
Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Tufts University

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]
Sent: Friday, October 28, 2016 3:07 PM
To: Freeman, Lisa
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature’s Variety

Good afternoon Lisa,

Thank you for sending the invoices. I’ll submit them for repayment.
I’ll be on the look-out for the Medical records and the final blood culture result.
We will send the results of the food testing as soon as they are received. As a head’s up, they usually take a few weeks.
Thank you again for your help with the investigation.
Kind regards and enjoy your weekend,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Friday, October 28, 2016 10:01 AM
To: Jones, Jennifer L
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

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We’re getting written permission for release of records from the owner and will send those asap
Will I be updated on the results of the food analysis? That will be helpful information for treating this dog since she’s not doing especially well
Thanks
Lisa

Lisa M. Freeman, DVM, PhD, DACVN
Professor
Cummings School of Veterinary Medicine
Tufts University

From: Jones, Jennifer L [mailto:Jennifer.Jones@fda.hhs.gov]
Sent: Friday, October 21, 2016 11:15 AM
To: Freeman, Lisa
Cc: Nemser, Sarah; Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature’s Vareity

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In the meantime, please move forward with the Listeria blood culture and Please send a copy of the results when finished and an invoice for the blood collection/shipping/Listeria testing.
For the open product testing, an instruction document and pre-filled out laboratory submission forms are attached. Please include those in the shipment. After shipping, please send an invoice for the shipping materials and shipping.
Please email or call with any questions.
Thank you kindly,
Jennifer

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From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
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To: Nemser, Sarah; Ceric, Olgica
Cc: Reimschuessel, Renate; Jones, Jennifer L
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dear Sarah

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I’m traveling this week but can submit an estimate for blood testing on Monday.

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Cc: Reimschuessel, Renate; Jones, Jennifer L
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

Dr. Freeman,

[Broken line]

In her email below she stated that she would provide information on sending the food to the Ohio laboratory. Please let us know if that information was provided, if not we can follow up.

Please also send along an estimate for the blood testing so that we can prepare a purchase order.

Thank you very much for your assistance on this case.

Sarah

Sarah Nemser M.S.
Vet-LIRN Network Coordinator
tel: 240-402-0892
fax: 301-210-4685
sarah.nemser@fda.hhs.gov

From: Ceric, Olgica
Sent: Wednesday, October 19, 2016 2:09 PM
To: Freeman, Lisa
Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature's Vareity

If we can test blood, that would be the fastest way to get it to the lab. We will reimburse you for the charges, but we will need an estimate first, in order to prepare purchase order.

As for the food, we can test it at our network lab in Ohio, I’ll send you instructions in a separate email.

We will reimburse you for the shipping charges. You’ll just need to submit invoice (one for blood testing and shipping), once you ship the sample.

Olgica Ceric, DVM, PhD
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
tel: 240-402-5419
dia: 301-210-4685

FDA-CVM-FOIA-2019-1704-009260
Hi all
We just got a blood sample from the dog (just so happened she was coming in for a recheck today so I was fortunate to catch her primary clinician before the dog left). We typically submit our blood cultures to ___________ (I’m on the phone right now to see if they can test for Listeria. If not, can you tell me where to submit?)

We do not have the ability to easily test the food for Listeria so if you could send details on that as well, I’d appreciate it

The owner did give permission to get records sent. I’m traveling through Friday but can get those submitted to you on Monday

I’ll get someone to submit samples as soon as you provide info on labs, etc

Thanks
Lisa

---

Dear Dr. Freeman,

Thank you for the prompt response.

Do you have in-house lab available for testing the food? If so, please let me know the testing estimate.

Once you get approval from the owner to release medical records, please email them, or fax to: 301-210-4685.

Regarding Listeria, perhaps you could ask the owner if they are willing to submit blood for testing when you contact them regarding medical records? I understand your concerns regarding antibiotics, but we’d like to do it just in case.

Please reply to all when responding, my responses might be delayed since I’ll be on leave part day by the end of the week.

Thank you,
From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Tuesday, October 18, 2016 7:28 AM
To: Ceric, Olgica
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature’s Vareity

Dear Olgica
We’re happy to get permission from owners for medical records and I can get food submitted for testing next week.
My question is on the blood culture. I’m not sure when the dog will be coming back in (she was discharged late last week) and am wondering if Listeria could be cultured if dog has been on antibiotics for >1 week.
Thanks
Lisa

From: Ceric, Olgica [mailto:Olgica.Ceric@fda.hhs.gov]
Sent: Monday, October 17, 2016 1:03 PM
To: Freeman, Lisa
Cc: Nemser, Sarah; Jones, Jennifer L
Subject: FDA case follow up-EON-285648-Freeman-Nature’s Vareity

Good morning Dr. Freeman,
We received your consumer complaint and would like to request the following:
- a copy of full medical records for the dog
- blood culture for Listeria
- open bag testing for Listeria and Salmonella
FDA will pay for the testing.
We have a network of veterinary diagnostic laboratories and could send samples to one of them, unless your lab has the capabilities?
Please email (preferred) or fax (301) 210-4685 us the medical records. Please send the full medical history - not just for this illness event.
Attached are a copy of our network procedures. They describe how veterinarians help with our case investigations. I also attached an owner friendly version.
Sincerely,

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fax: 301-210-4685
e-mail: olgica.ceric@fda.hhs.gov
Web: http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm
Thank you, Lisa.
The address is:
Attn: Jennifer Jones
8401 Muirkirk Rd.
Laurel, MD 20708

Jennifer Jones, DVM
Veterinary Medical Officer

From: Freeman, Lisa [mailto:Lisa.Freeman@tufts.edu]
Sent: Wednesday, November 02, 2016 10:50 AM
To: Jones, Jennifer L; medrec
Subject: RE: FDA case follow up-EON-285648-Freeman-Nature’s Vareity

Hi Jennifer
Our medical records department is asking for your mailing address since [B6] file is rather large
Could you provide that? I’m cc’ing them here
Thanks
Lisa

Good afternoon Lisa,

My accountant asked if you’re able to be reimbursed by credit (VISA) or if a check was needed?

Thank you,
Jennifer

Jennifer Jones, DVM
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Sounds great! Thank you, Lisa. Please forward me the ICSR number (confirmation number) when you submit the report. It will help us find the case after it’s been submitted.

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Please email or call with any questions.

Thank you kindly,

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Please also send along an estimate for the blood testing so that we can prepare a purchase order.

Thank you very much for your assistance on this case.

Sarah

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Vet-LIRN Network Coordinator

tel: 240-402-0892
fax: 301-210-4685
sarah.nemser@fda.hhs.gov

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Sent: Wednesday, October 19, 2016 2:09 PM
To: Freeman, Lisa
Cc: Reimschuessel, Renate; Jones, Jennifer L; Nemser, Sarah
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I’ll get someone to submit samples as soon as you provide info on labs, etc

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Sarah Nemser M.S.  
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Do you have in-house lab available for testing the food? If so, please let me know the testing estimate.
Once you get approval from the owner to release medical records, please email them, or fax to: 301-210-4685.

Regarding Listeria, perhaps you could ask the owner if they are willing to submit blood for testing when you contact them regarding medical records? I understand your concerns regarding antibiotics, but we'd like to do it just in case.

Please reply to all when responding, my responses might be delayed since I'll be on leave part day by the end of the week.

Thank you,

Olgica Ceric, DVM, PhD
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
tel: 240-402-5419
fax: 301-210-4685
e-mail: olgica.ceric@fda.hhs.gov
Web: [http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm](http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm)

From: Freeman, Lisa
Sent: Tuesday, October 18, 2016 7:28 AM
To: Ceric, Olgica
Subject: RE: FDA case follow up-E0N-285648-Freeman-Nature’s Vareity

Dear Olgica
We’re happy to get permission from owners for medical records and I can get food submitted for testing next week.
My question is on the blood culture. I’m not sure when the dog will be coming back in (she was discharged late last week) and am wondering if Listeria could be cultured if dog has been on antibiotics for >1 week
Thanks
Lisa

From: Ceric, Olgica
Sent: Monday, October 17, 2016 1:03 PM
To: Freeman, Lisa
Cc: Nemser, Sarah; Jones, Jennifer L
Subject: FDA case follow up-E0N-285648-Freeman-Nature’s Vareity

Good morning Dr. Freeman,
We received your consumer complaint and would like to request the following:
- a copy of full medical records for the dog
- blood culture for Listeria
- open bag testing for Listeria and Salmonella
FDA will pay for the testing.
We have a network of veterinary diagnostic laboratories and could send samples to one of them, unless your lab has the capabilities?
Please email (preferred) or fax (301) 210-4685 us the medical records. Please send the full medical history -not just for this illness event.
Attached are a copy of our network procedures. They describe how veterinarians help with our case investigations. I also attached an owner friendly version.
Sincerely,

Olgica Ceric, DVM, PhD
From: [Name]
To: Jones, Jennifer L
Sent: 5/18/2018 5:43:58 PM
Subject: Diet Breakdown by brand and breed
Attachments: Diet Breakdown by Brand.xlsx; Diet Breakdown by Breed.xlsx
Here you go! Please also share my slides with Martin. As I mentioned, for your presentation...

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

From: Palmer, Lee Anne
Sent: Friday, July 19, 2019 9:53 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: presentations!

Hi there – thanks for today’s meetings. I made edits and sliced a few and here’s the pre-clearance version of ours.

Thanks!

Lee Anne

Lee Anne M. Palmer, VMD, MPH
Acting Director, Division of Veterinary Product Safety

Center for Veterinary Medicine
Office of Surveillance and Compliance
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov
Hi Jen – were you expecting this one? Thx - LA

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Thursday, April 12, 2018 1:36 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ_PetFood_Report_Notification@fda.hhs.gov; HQ_PetFood_Report_Notification@fda.hhs.gov
Subject: Zignature Kangaroo Formula - EON-351031

A PFR Report has been received and PFR Event [EON-351031] has been created in the EON System.

A "PDF" report by name "2045676-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-351031
ICSR #: 2045676
EON Title: PFR Event created for Zignature Kangaroo Formula; 2045676

<table>
<thead>
<tr>
<th>AE Date</th>
<th>02/22/2018</th>
<th>Number Fed/Exposed</th>
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<td>Best By Date</td>
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<td>Number Reacted</td>
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<tr>
<td>Animal Species</td>
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<td>Outcome to Date</td>
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<tr>
<td>Breed</td>
<td>Retriever - Golden</td>
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<tr>
<td>Age</td>
<td>6 Years</td>
<td></td>
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<tr>
<td>District Involved</td>
<td>PFR</td>
<td>DO</td>
<td></td>
</tr>
</tbody>
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Product information

Individual Case Safety Report Number: 2045676
Product Group: Pet Food
Product Name: Zignature Kangaroo Formula
Description: Feb 23, 2018 Patient presented to the cardiology service 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.
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Treated With Product: 1
Number of Animals Reacted With Product: 1

<table>
<thead>
<tr>
<th>Product Name</th>
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<tbody>
<tr>
<td>Zignature Kangaroo Formula</td>
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Sender information

B6
USA

Owner information

B6
USA

To view this PFR Event, please click the link below:
https://eon.fda.gov/eon/browse/EON-351031

To view the PFR Event Report, please click the link below:
https://eon.fda.gov/eon/EventCustomDetailsAction/viewReport.jspa?decorator=none&e=0&issueType=12&issueId=367419

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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.
Thanks, Lee Anne. No, I wasn’t expecting it, but I can start with MRx!

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

Hi Jen – were you expecting this one? Thx - LA

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</table>
**Product information**

**Individual Case Safety Report Number:** 2045676  
**Product Group:** Pet Food  
**Product Name:** Zignature Kangaroo Formula  
**Description:** Feb 23, 2018 Patient presented to the cardiology service at [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.

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

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**Sender information**

[B6]  
USA

**Owner information**

[B6]  
USA

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https://eon.fda.gov/eon/browse/EON-351031

To view the PFR Event Report, please click the link below:  
https://eon.fda.gov/eon/EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueld=367419

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Good morning 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).

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