

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 2/22/2018 3:37:42 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Jen,

B5

d

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



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To: Rotstein, David <David.Rotstein@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>
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Dr. Adin at NCSU emailed additional theories. She continues to see more cases. The Vet Cardiology Community is discussing this quite a bit.

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JJ-About Erucic acid- <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4593/full>; Based on this-looks like low likelihood of risk in dogs but poultry can show DCM lesions

B5

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



From: Jones, Jennifer L
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To: Rotstein, David <David.Rotstein@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>
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FYI: B5 Stay tuned for our test results.

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FYI-

JJ-Vet emailed-“ As additional information, one of our cardiologist colleagues in B6 posted a question about this association today on our list serve. She has seen 4 cases of DCM in dogs eating kangaroo and lentil (I assume B4 but not sure) in the last year - 2 were housemates but related.”

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Going to test the leftover food for Selenium based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for Se.

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BLUF: **Final Conclusion:** The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

Recommend NFA.

B5

B5

Final Conclusion: The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that [B5] taurine, or carnitine caused the dogs' illness.

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FYI-Taurine/carnitine still pending, but [B5] egative.

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We received the food and plan to test for [B5] The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?
2. She forwarded me an article about [B5]
 - a. I don't believe our labs or Covance can test for this. Eurofins can test for this.

Thoughts from the group?

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Ok, thanks, Dave. I'll check

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question,

B5

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This would highly unlikely, but wanted to put it out there.

David Rotstein, DVM, MPVM, Dipl.ACVP
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From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We could test for **B5** in food, what does the group think? Any additional testing? Is it worth testing the **B5**

Medical Record Review:

B6

Presenting complaint: **B6** dyspnea, cough of 3 week duration-wheezing type more frequent at night à rDVM, treated w/ prednisone and doxycycline for kennel cough à **B6** inappetance, vomiting à **B6** dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated à **B6** treated as outpatient, **B6** as syring feeding, dog regurgitated and had marked dyspnea à ER à refer to NCSU à **B6** put on mechanical ventilator à **B6** euthanized

B6

B6

tFAST **B6**: severe cardiomegaly with ventricular hypocontractility

Echc **B6** dcm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

Prior MHx: coffee brown urine including clumping after strenuous activity when it is hot outside and resolves with 24-36 hours; also Crystalluria

B6

Presented **B6** episodes of collapse, first occurred mid February, fall 6 seconds without losing consciousnessà immediately return to normal à2 weeks later again collapse, then on à 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February;à recheck 7/10, doing better, no collapsing episodes except a stumbling moment when excited, respiratory rate normal, diet changed to Hill's

B6

B6

Rads: left sided congestive heart failure

B6 -7/10: moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

Thoughts: **B5**

B5

Jennifer Jones, DVM
Veterinary Medical Officer



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Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
240-506-6763 (BB)



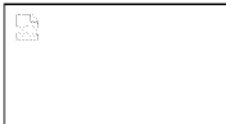
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Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to [B4] who said there was [B4] in this food... but that doesn't rule out treats.

[B5]

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for [B5]

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

From: Jones, Jennifer L
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Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHF à severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigs à plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodes à 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 2/22/2018 3:42:50 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed-I think this is going to be a

B5

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Jen,

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The dogs were not anemic, but I do wonder if a full iron panel could be done (TIBC, etc.).

As for the genetic defects in Golden—hopefully, this will continued to be pursued as it may be that this is not a good diet for animals with a pre-existing genetic issue.

d

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Ok, thanks, Dave. I'll check [B5]

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question, but not [B5]

[B5]

This would highly unlikely, but wanted to put it out there.

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

Date: July 13, 2017 at 2:44:24 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

Medical Record Review:

B6

Presenting complaint [B6]: dyspnea, cough of 3 week duration-wheezing type more frequent at night à rDVM, treated w/ prednisone and doxycycline for kennel cough à [B6] inappetance, vomiting à [B6] dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated à [B6] treated as outpatient, [B6] as syringe feeding, dog regurgitated and had marked dyspnea à ER à refer to NCSU à [B6] put on mechanical ventilator à [B6] euthanized

B6

B6

tFAST B6: severe cardiomegaly with ventricular hypocontractility

Echo B6: dcm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

Prior MHx: coffee brown urine including clumping after strenuous activity when it is hot outside and resolves with 24-36 hours; also Crystalluria

Presented **B6** episodes of collapse, first occurred mid February, fall 6 seconds without losing consciousness à immediately return to normal à 2 weeks later again collapse, then on à 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February; à recheck 7/10, doing better, no collapsing episodes except a stumbling moment when excited, respiratory rate normal, diet changed to Hill's

B6

Rads: left sided congestive heart failure

B6 -7/10: moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

Thoughts

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

o I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
 CVM Vet-LIRN Liaison
 CVM OSC/DC/CERT
 7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
240-506-6763 (BB)



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Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to **B4** who said there was **B4** in this food... but that doesn't rule out treats.

B5

Jennifer Jones, DVM
 Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for

B5

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

From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHF à severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigs à plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodes à 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 2/22/2018 3:44:16 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

That sounds like a plan

B5

B5 ???

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
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From: Jones, Jennifer L
Sent: Thursday, February 22, 2018 10:43 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed-I think this is going to be

B6

B6

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



From: Rotstein, David
Sent: Thursday, February 22, 2018 10:38 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Jen,

B5

The dogs were not anemic, but I do wonder if a full iron panel could be done (TIBC, etc.).

As for the genetic defects in Goldens—hopefully, this will continued to be pursued as it may be that this is not a good diet for animals with a pre-existing genetic issue.

d

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: Jones, Jennifer L
Sent: Thursday, February 22, 2018 10:33 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

B5

Dr. Adin at NCSU emailed additional theories. She continues to see more cases. The Vet Cardiology Community is discussing this quite a bit.

B5

B5

B5

B5

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



From: Jones, Jennifer L

Sent: Tuesday, January 23, 2018 2:00 PM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI
results.

B5

Stay tuned for our test

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



From: Jones, Jennifer L
Sent: Thursday, January 11, 2018 9:36 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

JJ-Vet emailed-“ As additional information, one of our cardiologist colleagues [B6] posted a question about this association today on our list serve. She has seen 4 cases of DCM in dogs eating kangaroo and lentil (I assume [B4] but not sure) in the last year - 2 were housemates but related.”

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



From: Jones, Jennifer L
Sent: Wednesday, January 03, 2018 2:32 PM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for Selenium based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for Se.

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



From: Rotstein, David
Sent: Tuesday, August 22, 2017 8:39 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 8:37 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **Final Conclusion:** The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

B5

Final Conclusion: The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine/carnitine still pending, but **B5** negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for **B5**. The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?
2. She forwarded me an article about **B5**.
 - a. I don't believe our labs or Covance can test for this. Eurofins can test for this.

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
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Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

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B5

This would highly unlikely, but wanted to put it out there.

David Rotstein, DVM, MPVM, Dipl.ACVP
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To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

Medical Record Review:

B6

Presenting complaint [B6]: dyspnea, cough of 3 week duration-wheezing type more frequent at night à rDVM, treated w/ prednisone and doxycycline for kennel cough à [B6] inappetance, vomiting à [B6] dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated à [B6] treated as outpatient, [B6] as syring feeding, dog regurgitated and had marked dyspnea à ER à refer to NCSU à [B6] put on mechanical ventilator à [B6] euthanized

B6

B6

tFAST **B6** severe cardiomegaly with ventricular hypocontractility

Echo **B6** dcm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

Prior MHx: coffee brown urine including clumping after strenuous activity when it is hot outside and resolves with 24-36 hours; also Crystalluria

B6

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B6

B6

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Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

Thoughts

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David

Sent: Tuesday, July 11, 2017 12:44 PM

To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)

240-506-6763 (BB)



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Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

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B5

Jennifer Jones, DVM
Veterinary Medical Officer



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To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for [B5]

B5

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

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Cc: Ceric, Olgica; Reimschuessel, Renate
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Vet will submit PFR online à

2 dogs-unrelated miniature schnauzers

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Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Darcy Adin'
Sent: 2/23/2018 6:29:27 PM
Subject: RE: Kangaroo & Lentil-Associated DCM
Attachments: 800.218-Results-sent to NCSU-2.23.2018.xlsx

Good afternoon Darcy,

I attached the food testing results. These include the 2 samples you recently sent and [B6] food sample. All products contained inadequate iron content, below the AAFCO claim. In people, low iron has been associated with idiopathic DCM (Marinescu and McCullough 2011). According to the article, anemia was found in 12 to 55% of patients in heart failure, and the anemia's severity correlated to the degree of heart failure. [B5]

B5

Have you looked at an Iron Blood panel in any of the dogs? I didn't have the full CBC results from your cases, but did you see any hemogram parameter changes (MCHC etc)?

We'd like to request a total iron panel on one of the dogs that ate the food you submitted, either the dog that ate the California Naturals Chicken Meal or Fromm Heartland food. We would reimburse NCSU directly for the testing. Please send me an estimate for the charges, and I can make a purchase request. I must make a request prior to any testing. After you complete the testing, please send me a copy of the results and an invoice. We can then call back with our VISA information.

Please respond if you're interested in the testing.
Thank you and take care,
Jen

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Thursday, February 22, 2018 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Fwd: Kangaroo & Lentil-Associated DCM

Hi Jennifer,

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B5 Maybe I will hear back but wondering if you have any leads there?

Thank you for your help as always!
Take care
Darcy

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To: dbadin@ncsu.edu

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B6

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Subject: Re: Kangaroo & Lentil-Associated DCM
To: **B6**
Cc: "Fries, Ryan C" <rfries@illinois.edu>, "Adin, Darcy" **B6**

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Please feel free to direct any questions to: B6 or Ryan Fries (rfries@illinois.edu)

Sincerely,

The Clinical Cardiology Service
University of Illinois
Department of Veterinary Clinical Medicine
1008 W Hazelwood Dr.
Urbana, IL 61801

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B6

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Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

DOCUMENT PRODUCED IN NATIVE

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 2/23/2018 8:08:16 PM
Subject: Re: Kangaroo & Lentil-Associated DCM
Attachments: iron def dcm with or wo anemia kids.pdf

Hi Jennifer,

Wow! That is interesting and awesome to have a lead! We have not looked at iron panels in any of the dogs. I just went through their CBCs (most but not all had them done). Only 2 of 23 were anemic and these were normocytic normochromic (although for one the MCH and MCHC were at the low end of the normal range). One anemia was mild (37) and the other was more severe and unexplained (5 yr Lab, 27%, this dog died after a week just recently). Thank you for the paper. I attached another one in kids.

We are definitely interested in looking this. My tech is currently looking at options. One issue is that we had a freezer failure about a month ago - devastating.... I refroze the samples but I am uncertain if these are still OK to test. She is calling the company because the dog that ate the California natural chicken food you sampled was one of them (B6). The dog that ate Fromm is no longer with us and his samples were not only thawed but older (company states they should be less than 28 days). And (B6) samples fall in that category as well.

If the company tells us that testing serum that has been thawed will not give us accurate results. we have saved serum from a few recent cases that were eating:

1. California Natural Salmon and peas (I also bought a bag of this off amazon when I heard they had discontinued the CN line) - this dog is clinically doing well but only 2 weeks out
2. Blue Buffalo grain free bison (this is the dog with the unexplained HCT of 27% and died after a week)
3. Zignature grain free lamb and peas (had been eating California natural kangaroo and lentil the year before) - this dog did not make it out of the hospital

I know this latter scenario

(B5)

(B5)

for (B6) - the owners brought in the food but from a different bag).

(B5)

We will be proactive about getting the actual food and doing some iron testing on our end if new cases come it.

Thank you for your thoughts!

On Fri, Feb 23, 2018 at 1:29 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

I attached the food testing results. These include the 2 samples you recently sent and (B6) food sample. All products contained inadequate iron content, below the AAFCO claim. In people, low iron has been associated with idiopathic DCM (Marinescu and McCullough 2011). According to the article, anemia was found in 12 to 55% of patients in heart failure, and the anemia's severity correlated to the degree of heart failure. It's

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From: Darcy Adin <dbadin@ncsu.edu>
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Sent: 2/26/2018 3:37:09 PM
Subject: Re: Kangaroo & Lentil-Associated DCM

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Darcy Adin'
Sent: 2/26/2018 4:02:40 PM
Subject: RE: Kangaroo & Lentil-Associated DCM

Thank you, Darcy, for the additional paper.

I'll make a purchase request for one of the dogs. After you ship, please send me an invoice for the testing and a copy of the results.

Take care,
Jen

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Veterinary Medical Officer
Tel: 240-402-5421



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We can send serum to **B4** to assess iron and TIBC for \$66. I think it would be best to send off serum that was not inadvertently thawed. Since it is not too expensive I was thinking I'd send off 2 samples **B6** our anemic dog that ate Blue buffalo and **B6** a dog that ate CN salmon) - I can cover the cost of the 2nd one.

Thanks!
Darcy

On Fri, Feb 23, 2018 at 1:29 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
Good afternoon Darcy,

I attached the food testing results. These include the 2 samples you recently sent and **B6** food sample. All products contained inadequate iron content, below the AAFCO claim. In people, low iron has been associated with idiopathic DCM (Marinescu and McCullough 2011). According to the article, anemia was found in 12 to 55% of patients in heart failure, and the anemia's severity correlated to the degree of heart failure. It's

B5

We'd like to request a total iron panel on one of the dogs that ate the food you submitted, either the dog that ate the California Naturals Chicken Meal or Fromm Heartland food. We would reimburse NCSU directly for the testing. Please send me an estimate for the charges, and I can make a purchase request. I must make a request prior to any testing. After you complete the testing, please send me a copy of the results and an invoice. We can

then call back with our VISA information.

Please respond if you're interested in the testing.

Thank you and take care,

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: [240-402-5421](tel:240-402-5421)



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Thursday, February 22, 2018 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: Fwd: Kangaroo & Lentil-Associated DCM

Hi Jennifer,

I hope you are doing well! Just thought I would forward this email chain to you as the growing concern about grain-free diets in the veterinary cardiology community continues to expand. Also, I wasn't sure if you were aware of the 5 DCM cases eating kangaroo and lentil diets that [redacted B6] had reported to the FDA last year so just wanted to be sure these were somehow linked with ours from NCSU as part of the same concern.

B5

2003. Maybe I will hear back but wondering if you have any leads there?

Thank you for your help as always!
Take care
Darcy

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

From: [redacted B6]
Date: Wed, Feb 21, 2018 at 5:42 PM
Subject: Fwd: Kangaroo & Lentil-Associated DCM
To: dbadin@ncsu.edu

Hi Darcy,

Tried to copy you on this, and the email that I have for you bounced. [redacted B6] gave me this one. Shall I change

your email in the Secretary records to this? I had the [B6] one listed below.

[B6]

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

From: [B6]
Date: Wed, Feb 21, 2018 at 5:34 PM
Subject: Re: Kangaroo & Lentil-Associated DCM
To: [B6]
Cc: "Fries, Ryan C" <rfries@illinois.edu>, "Adin, Darcy" [B6]

Hi [B6] and Ryan,

Before I put this out on the listserve, I did want to give you a little more information. Please feel free to contact me on my cell phone [B6] if you want to talk in person. We are definitely interested in pursuing this and would love to work together to make this a multicenter effort.

We have done further investigation on our cases here and have identified two more (total of 6 so far) going back in records from 2016 to the present on Kangaroo and Lentil diets. We do not have complete diet histories on all our cases, sadly, and still have some work here to pull hard copy charts from 2016. While we have on our intake history form a question regarding diet, this form has not been consistently scanned into the computer medical record and the diet is not always mentioned in the reports that are. Also, our ER service does not routinely ask diet history so cases that presented on ER and later transferred may not have a reported diet. I think it is possible that we will find more when we get the rest of the charts from 2016 reviewed, we have completed the reported diet histories for 2017. We have also found an interesting diet pattern, especially concerning some of Josh Stern's concerns about goldens on grain free diets. About 75% of our DCM cases with reported diet histories in 2017 were on grain free diets. We are going back through other records of cardiac patients that had other diseases to see what proportion of these other cases were on grain free diets (may be our clients just like to feed grain free?), but [B6] my resident, found a publication that reported about 19% prevalence of pets being fed grain free diets in 2016. It seems like our DCM population has a much higher exposure to grain free diets than we would expect.

[B6] did contact Darcy Adin at NC State, and she has already done a fair amount of work on Kangaroo and Lentil diets and DCM. They have about 10 cases out of a total of 47 cases with diet histories. (Not counting the one we found in 2016 thus far, we had 5/23 in 2017-18). We did complete FDA reports on our cases, but Darcy is way ahead of us and has been working with the FDA on looking for the culprit deficiency/toxicity. They investigated selenium and have ruled out selenium deficiency as playing a role. Darcy is presenting an abstract on her cases at ACVIM from what she has told [B6] with description of increased sphericity of the LV relative to other forms of DCM in these cases.

This may be a moot point for future patients to some degree as California Natural has discontinued their Kangaroo and Lentil diet. Four of our cases were on this, one on a non-specified Kangaroo and Lentil, and one was on Zignature brand Kangaroo and Lentil. The dog on the Zignature diet was a taurine deficient Cocker. Interestingly, another one of my patients on a Zignature diet (pork-based) was also taurine deficient. All ten of Darcy's cases were on California Natural. However, the fact that it is being discontinued does not negate the importance of identifying a nutritional role in the disease.

Maybe we can all get together so that we do not wind up with parallel studies (like Fox and Kittleson with taurine in dogs from way back). Our combined efforts as you mention will be much more meaningful than anything done separately. My resident (and me too!) is very interested in working with you, Darcy, and others to

get this information out there. I am also forwarding this to Darcy to get her input.

B6

On Wed, Feb 21, 2018 at 2:24 PM, **B6** wrote:

Hi **B6**

We would like to explore if there is interest in the cardiology community in studying the reported cases of kangaroo and lentil-associated DCM. It seems that many services have seen at least a handful of cases. Would you be willing to distribute the message below to the cardiology list-serves (both diplomates and residents)?

Thank you in advance!

B6

To All Cardiologists and Cardiology Residents,

We are contacting you out of a growing concern about an apparent connection between kangaroo and lentil (K&L) diets and acquired DCM. As has been reported by others, we have had several cases of DCM in atypical breeds on K&L diets. The ongoing discuss on the VIN cardiology list-serve reflects that this may be widespread issue and raises concerns that there are many more cases which are unreported or possibly unrecognized.

Like many of you, we feel this is an issue that warrants immediate attention, as it may represent a preventable condition. If there is a link, we would like to establish that as soon as possible in order to raise awareness for general practitioners and the public. At the University of Illinois, we have not seen enough cases on our own to evaluate the issue, but it seems that there are many more out there. To our knowledge, there is not currently an organized effort to compile information about these cases, although we know there is some discussion and effort regarding analysis of the diets in question.

To further evaluate the clinical picture of K&L diets and DCM, we are reaching out to all of you and hope to generate a discussion about reviewing cases of DCM and determining if there is a relationship with K&L diets. Even if your service has only seen a single case, in aggregate, there may be enough cases to develop a better clinical picture and elevate the discussion beyond anecdotal evidence. We realize that asking for a review of records can be a labor-intensive process and the capabilities of records systems varies widely. A good place to start may be simply reviewing resident case logs of DCM in the last 12 months to quickly identify cases of DCM and pull specific records.

If there is already an ongoing effort to gather case data, we are unaware and apologize for proposing a redundant study. If such an effort is already underway, we would like to volunteer our case data, and if not, we volunteer our service or assistance in compiling case data.

Our initial thoughts on approaching this would be starting with an initial survey to gauge how many cardiology services have seen K&L-associated DCM cases, and whether there is interest in sharing case information. We hope to eventually gather basic case information and would try to design the survey to require minimal time and effort. We welcome any thoughts, suggestions or any level of interest or participation in this. We also want to make sure that we are not duplicating or impinging on any other service's work, and will defer to any ongoing efforts regarding this issue.

We look forward to hearing all of your thoughts and working with anyone who is interested. Pending the response, we hope to follow up with an initial survey.

Please feel free to direct any questions to **B6** or Ryan Fries (rfries@illinois.edu)

Sincerely,

The Clinical Cardiology Service
University of Illinois
Department of Veterinary Clinical Medicine
1008 W Hazelwood Dr.

--
B6

--
B6

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 2/26/2018 4:34:28 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519
Attachments: Higgins et al-Fe CHF w DCM-2017.pdf

NCSU is going to test one dog that ate a grain free diet. I'm waiting to hear from the other vet about Fe testing. Dr. Adin also sent this paper.

BLUF: In this study involving children w/ DCM and Heart Failure-96.4% of patients had Fe deficiency, only 39.3% had anemia, and only 2/11 with anemia had a microcytic anemia

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



From: Rotstein, David
Sent: Thursday, February 22, 2018 10:44 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

That sounds like a plan

B5 ??

B5

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: Jones, Jennifer L
Sent: Thursday, February 22, 2018 10:43 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed-I think this is going to be: B5

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



From: Rotstein, David
Sent: Thursday, February 22, 2018 10:38 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Jen,

B5

d

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: Jones, Jennifer L
Sent: Thursday, February 22, 2018 10:33 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

Dr. Adin at NCSU emailed additional theories. She continues to see more cases. The Vet Cardiology Community is discussing this quite a bit.

B5

Jennifer Jones, DVM

FDA-CVM-FOIA-2019-1704-016869

Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Tuesday, January 23, 2018 2:00 PM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI- [redacted] **B5** Stay tuned for our test results.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Thursday, January 11, 2018 9:36 AM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

JJ-Vet emailed-“ As additional information, one of our cardiologist colleagues [redacted] **B6** posted a question about this association today on our list serve. She has seen 4 cases of DCM in dogs eating kangaroo and lentil (I assume [redacted] **B4** but not sure) in the last year - 2 were housemates but related.”

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421



From: Jones, Jennifer L

Sent: Wednesday, January 03, 2018 2:32 PM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; 'Reimschuessel, Renate (<Renate.Reimschuessel@fda.hhs.gov>)' <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for Selenium based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for Se.

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



From: Rotstein, David
Sent: Tuesday, August 22, 2017 8:39 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 8:37 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **Final Conclusion:** The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

B5

B5

Final Conclusion: The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine/carnitine still pending, but **B5** negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for

B5

The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?
2. She forwarded me an article about **B5**
 - a. I don't believe our labs or Covance can test for this. Eurofins can test for this.

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L

Sent: Tuesday, July 18, 2017 8:18 AM

To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David

Sent: Thursday, July 13, 2017 2:54 PM

To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question,

B5

B5

This would highly unlikely, but wanted to put it out there.

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

Date: July 13, 2017 at 2:44:24 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

Medical Record Review:

B4

Presenting complaint **B6**: dyspnea, cough of 3 week duration-wheezing type more frequent at night à rDVM, treated w/ prednisone and doxycycline for kennel cough à **B6** nappetance, vomiting à **B6** dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated à **B6** treated as outpatient, **B6** as syring feeding, dog regurgitated and had marked dyspnea à ER à refer to NCSU à **B6** put on mechanical ventilator à **B6** euthanized

B6

B6

tFAST **B6**: severe cardiomegaly with ventricular hypocontractility

Echo **B6**: dcm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

Prior MHx: coffee brown urine including clumping after strenuous activity when it is hot outside and resolves with 24-36 hours; also Crystalluria

B6

Presented **B6**: episodes of collapse, first occurred mid February, fall 6 seconds without losing consciousness → immediately return to normal → 2 weeks later again collapse, then on 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February; → recheck 7/10, doing better, no collapsing episodes except a stumbling moment when

excited, respiratory rate normal, diet changed to Hill's

B6

Rads: left sided congestive heart failure

B6 -7/10: moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

Thoughts: **B5**

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
240-506-6763 (BB)



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From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to **B4** who said there was **B4** in this food... but that doesn't rule out treats.

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for B5

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

From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHF à severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigs à plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodes à 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 2/26/2018 4:38:39 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks Jen

Looking forward to what they find and glad that they are running it. Will they be doing a full iron profile?

B5

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: Jones, Jennifer L
Sent: Monday, February 26, 2018 11:35 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

NCSU is going to test one dog that ate a grain free diet. I'm waiting to hear from the other vet about Fe testing. Dr. Adin also sent this paper.

BLUF: In this study involving children w/ DCM and Heart Failure-96.4% of patients had Fe deficiency, only 39.3% had anemia, and only 2/11 with anemia had a microcytic anemia

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



From: Rotstein, David
Sent: Thursday, February 22, 2018 10:44 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

That sounds like a plan.

B5

B5 ?

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
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From: Jones, Jennifer L
Sent: Thursday, February 22, 2018 10:43 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed-I think this is going to be:

B5

B5

B5

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



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Sent: Thursday, February 22, 2018 10:38 AM
To: Jones, Jennifer L <Jennifer.Jones@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>
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Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Jen,

B5

d

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
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From: Jones, Jennifer L

Sent: Thursday, February 22, 2018 10:33 AM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

Dr. Adin at NCSU emailed additional theories. She continues to see more cases. The Vet Cardiology Community is discussing this quite a bit.

B5

B5

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



From: Jones, Jennifer L

Sent: Tuesday, January 23, 2018 2:00 PM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI: **B5** Stay tuned for our test results.

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



From: Jones, Jennifer L

Sent: Thursday, January 11, 2018 9:36 AM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

JJ-Vet emailed-“ As additional information, one of our cardiologist colleagues B6 posted a question about this association today on our list serve. She has seen 4 cases of DCM in dogs eating kangaroo and lentil (I assume B4 but not sure) in the last year - 2 were housemates but related.”

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



From: Jones, Jennifer L

Sent: Wednesday, January 03, 2018 2:32 PM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>;

'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for Selenium based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for Se.

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



From: Rotstein, David

Sent: Tuesday, August 22, 2017 8:39 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 8:37 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **Final Conclusion:** The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

B5

Final Conclusion: The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine/carnitine still pending, but **B5** negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for **B5**. The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?
2. She forwarded me an article about **B5**.
 - a. I don't believe our labs or Covance can test for this. Eurofins can test for this.

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check **B5**

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question

B5

B5

This would highly unlikely, but wanted to put it out there.

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: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

Medical Record Review:

B6

Presenting complaint: B6 dyspnea, cough of 3 week duration-wheezing type more frequent at night à rDVM, treated w/ prednisone and doxycycline for kennel cough à B6 nappetance, vomiting à

B6 dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated à B6 treated as outpatient B6 as syring feeding, dog regurgitated and had marked dyspnea à ER à refer to NCSU à B6 put on mechanical ventilator à B6 euthanized

B6

B6

tFAST [B6]: severe cardiomegaly with ventricular hypocontractility

Echo [B6]: dcm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

Prior MHx: coffee brown urine including clumping after strenuous activity when it is hot outside and resolves with 24-36 hours; also Crystalluria

[B6]

Presented [B6]: episodes of collapse, first occurred mid February, fall 6 seconds without losing consciousness à immediately return to normal à 2 weeks later again collapse, then on à 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February; à recheck 7/10, doing better, no collapsing episodes except a stumbling moment when excited, respiratory rate normal, diet changed to Hill's

B6

B6

Rads: left sided congestive heart failure

B6 -7/10: moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

Thoughts

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
240-506-6763 (BB)



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From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to [B4] who said there was [B4] in this food... but that doesn't rule out treats.

B5

Jennifer Jones, DVM
 Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for [B5]

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

From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
 2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHFà severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigsà plasma, urine, serum, and myocardial tissue available


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Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 2/26/2018 4:43:36 PM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519
Attachments:  Autopsy.PDF

I requested a full iron panel.

There was one necropsy done. I believe there is heart left that we could test if we see abnormalities in the iron panels.

From the necropsy:

B6

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



From: Rotstein, David
Sent: Monday, February 26, 2018 11:39 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks Jen

Looking forward to what they find and glad that they are running it. Will they be doing a full iron profile?

B5

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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Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

NCSU is going to test one dog that ate a grain free diet. I'm waiting to hear from the other vet about Fe testing. Dr. Adin also sent this paper.
BLUF: In this study involving children w/ DCM and Heart Failure-96.4% of patients had Fe deficiency, only 39.3% had anemia, and only 2/11 with anemia had a microcytic anemia

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Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

That sounds like a plan.

B5 ?

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
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Sent: Thursday, February 22, 2018 10:43 AM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed-I think this is going to be

B5

B5

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



From: Rotstein, David

Sent: Thursday, February 22, 2018 10:38 AM

To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Jen,

B5

d

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: Jones, Jennifer L

Sent: Thursday, February 22, 2018 10:33 AM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

Dr. Adin at NCSU emailed additional theories. She continues to see more cases. The Vet Cardiology Community is discussing this quite a bit.

B5

B5

B5

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



From: Jones, Jennifer L
Sent: Tuesday, January 23, 2018 2:00 PM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI: B5 Stay tuned for our test results.

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



From: Jones, Jennifer L
Sent: Thursday, January 11, 2018 9:36 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

JJ-Vet emailed-“ As additional information, one of our cardiologist colleagues in B6 posted a question about this association today on our list serve. She has seen 4 cases of DCM in dogs eating kangaroo and lentil (I assume CN but not sure) in the last year - 2 were housemates but related.”

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



From: Jones, Jennifer L

Sent: Wednesday, January 03, 2018 2:32 PM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for Selenium based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for Se.

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



From: Rotstein, David

Sent: Tuesday, August 22, 2017 8:39 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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



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

From: Jones, Jennifer L

Sent: Tuesday, August 22, 2017 8:37 AM

To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **Final Conclusion:** The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

B5

B5

Final Conclusion: The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine/carnitine still pending, but **B5** negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for B5 The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?
2. She forwarded me an article about B5
 - a. I don't believe our labs or Covance can test for this. Eurofins can test for this.

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question, B5

B5

This would highly unlikely, but wanted to put it out there.

David Rotstein, DVM, MPVM, Dipl.ACVP
CVM Vet-LIRN Liaison

CVM OSC/DC/CERT
7519 Standish Place
240-506-6763 (BB)

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We could test: [redacted] B5
[redacted] B5

Medical Record Review:

[redacted] B6

Presenting complaint [redacted] B6: dyspnea, cough of 3 week duration-wheezing type more frequent at night à rDVM, treated w/ prednisone and doxycycline for kennel cough à [redacted] B6 inappetance, vomiting à [redacted] B6 dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated à [redacted] B6 treated as outpatient, [redacted] B6 as syring feeding, dog regurgitated and had marked dyspnea à ER à refer to NCSU à [redacted] B6 put on mechanical ventilator à [redacted] B6 euthanized

B6

B6

tFAST **B6** severe cardiomegaly with ventricular hypocontractility

Echo **B6** dcm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

Prior MHx: coffee brown urine including clumping after strenuous activity when it is hot outside and resolves with 24-36 hours; also Crystalluria

B6

Presented **B6** episodes of collapse, first occurred mid February, fall 6 seconds without losing consciousness à immediately return to normal à 2 weeks later again collapse, then on à 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February; à recheck 7/10, doing better, no collapsing episodes except a stumbling moment when excited, respiratory rate normal, diet changed to Hill's

B6

Rads: left sided congestive heart failure

B6 -7/10: moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
240-506-6763 (BB)



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From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to **B4** who said there was **B4** in this food... but that doesn't rule out treats.

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for **B5**

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

From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHF à severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigs à plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodes à 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421

fax: 301-210-4685

e-mail: jennifer.jones@fda.hhs.gov

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



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L
Sent: 2/27/2018 12:28:17 PM
Subject: Re: Question-Grain Free-DCM cases

I'd suggest individual cases.

Thanks

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: February 27, 2018 at 7:10:39 AM EST
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: Question-Grain Free-DCM cases

Dave,
The vet asked how folks should submit the reports. Your thoughts? I'd say individual reports for each, but wanted to confirm.

The talk of grain free related DCM is exploding on our list serve. One question people have is related to data collection and I thought I would get your input. Should we as a group:

B5

Thanks, Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Darcy Adin'
Sent: 2/27/2018 12:42:32 PM
Subject: RE: blr0004.1.pdf

Thank you, Darcy.

I recommend veterinarians submit individual reports about each patient and the pet food he or she consumed.

Then can submit the reports one of two ways:

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

Telephone: <https://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm>

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, February 26, 2018 10:37 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: blr0004.1.pdf

Hi Jennifer,

Here is an invoice for iron testing for one of the dogs. This dog was eating California Natural Salmon and peas.

The talk of grain free related DCM is exploding on our list serve. One question people have is related to data collection and I thought I would get your input. Should we as a group:

B5

Thanks for your thoughts!
Darcy

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Darcy Adin'
Sent: 3/5/2018 6:58:31 PM
Subject: RE: blr0004.1.pdf

Thank you for the update, Darcy. We can write a check and mail it. I'll just need NCSU's TaxID number.

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Saturday, March 03, 2018 7:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: blr0004.1.pdf

Hi Jennifer,

We received iron and TIBC results from the 2 dogs we analyzed and they are relatively normal.

1. **B6** - Iron **B6** (ref range 73-245 ug/dl), TIBC could not be determined because her total iron was a bit high so unsaturated binding was low - I talked to the clinical pathologist at the lab who felt this was not clinically significant and just a result of her slightly high iron)
2. **B6** - Iron **B6** (73-245), TIBC **B6** (270-530)

They are going to run ferritin levels on the blood too as an indication of total body scores - may or may not be helpful.

B5

I will keep you posted on the ferritin levels. Please let me know if there is anything else you think we could do?

I talked to our financial office and the easiest way for reimbursement would be if you could write a check out to NC State University - is this possible?

Thank you again and hope you have a great weekend!
Darcy

On Mon, Feb 26, 2018 at 10:36 PM, Darcy Adin <dbadin@ncsu.edu> wrote:
Hi Jennifer,

Here is an invoice for iron testing for one of the dogs. This dog was eating California Natural Salmon and peas.

The talk of grain free related DCM is exploding on our list serve. One question people have is related to data collection and I thought I would get your input. Should we as a group:

B5

Thanks for your thoughts!

Darcy

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 3/7/2018 4:11:00 AM
Subject: Re: blr0004.1.pdf

Hi Jennifer,

Our Tax id# is [REDACTED]

Thank you!

Darcy

On Mar 5, 2018, at 1:58 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you for the update, Darcy. We can write a check and mail it. I'll just need NCSU's TaxID number.

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



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Saturday, March 03, 2018 7:37 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: blr0004.1.pdf

Hi Jennifer,

We received iron and TIBC results from the 2 dogs we analyzed and they are relatively normal.

1. [REDACTED] - Iron [REDACTED] (ref range 73-245 ug/dl), TIBC could not be determined because her total iron was a bit high so unsaturated binding was low - I talked to the clinical pathologist at the lab who felt this was not clinically significant and just a result of her slightly high iron)
2. [REDACTED] Iron [REDACTED] (73-245), TIBC [REDACTED] (270-530)

They are going to run ferritin levels on the blood too as an indication of total body scores - may or may not be helpful.

B5

I will keep you posted on the ferritin levels. Please let me know if there is anything else you think we could do?

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Darcy

On Mon, Feb 26, 2018 at 10:36 PM, Darcy Adin <dbadin@ncsu.edu> wrote:
Hi Jennifer,

Here is an invoice for iron testing for one of the dogs. This dog was eating California Natural Salmon and peas.

The talk of grain free related DCM is exploding on our list serve. One question people have is related to data collection and I thought I would get your input. Should we as a group:

B5

Thanks for your thoughts!
Darcy

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Darcy Adin'
Sent: 3/13/2018 11:32:43 AM
Subject: RE: Kangaroo & Lentil-Associated DCM

Thank you, Darcy. Will you please send a copy of the lab report? I put the invoice through and our business team should be mailing the check.

The Phosphorous we tested for is elemental phosphorous. It would encompass the total phosphorous content (despite the source) in the food.

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Friday, March 09, 2018 9:28 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Kangaroo & Lentil-Associated DCM

Hi Jennifer,

We received the ferritin results back and they are approximately 3x the upper normal. I am meeting with one of our clinical pathologists next week to discuss what this might mean. B5

B5

Also, is the phosphorous that you tested for the same as B5

Thank you!
Darcy

On Fri, Feb 23, 2018 at 1:29 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
Good afternoon Darcy,

I attached the food testing results. These include the 2 samples you recently sent and B6 food sample. All products contained inadequate iron content, below the AAFCO claim. In people, low iron has been associated with idiopathic DCM (Marinescu and McCullough 2011). According to the article, anemia was found in 12 to 55% of patients in heart failure, and the anemia's severity correlated to the degree of heart failure. It's

B5

We'd like to request a total iron panel on one of the dogs that ate the food you submitted, either the dog that ate

the California Naturals Chicken Meal or Fromm Heartland food. We would reimburse NCSU directly for the testing. Please send me an estimate for the charges, and I can make a purchase request. I must make a request prior to any testing. After you complete the testing, please send me a copy of the results and an invoice. We can then call back with our VISA information.

Please respond if you're interested in the testing.

Thank you and take care,

Jen

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Thursday, February 22, 2018 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: Fwd: Kangaroo & Lentil-Associated DCM

Hi Jennifer,

I hope you are doing well! Just thought I would forward this email chain to you as the growing concern about grain-free diets in the veterinary cardiology community continues to expand. Also, I wasn't sure if you were aware of the 5 DCM cases eating kangaroo and lentil diets that B6 had reported to the FDA last year so just wanted to be sure these were somehow linked with ours from NCSU as part of the same concern.

B5

2003. Maybe I will hear back but wondering if you have any leads there?

Thank you for your help as always!
Take care
Darcy

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

From: B6
Date: Wed, Feb 21, 2018 at 5:42 PM
Subject: Fwd: Kangaroo & Lentil-Associated DCM
To: dbadin@ncsu.edu

Hi Darcy,

Tried to copy you on this, and the email that I have for you bounced. [B6] gave me this one. Shall I change your email in the Secretary records to this? I had the [B6] one listed below.

[B6]

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

From: [B6]
Date: Wed, Feb 21, 2018 at 5:34 PM
Subject: Re: Kangaroo & Lentil-Associated DCM
To: [B6]
Cc: "Fries, Ryan C" <rfries@illinois.edu>, "Adin, Darcy" <[B6]>

Hi [B6] and Ryan,

Before I put this out on the listserve, I did want to give you a little more information. Please feel free to contact me on my cell phone [B6] if you want to talk in person. We are definitely interested in pursuing this and would love to work together to make this a multicenter effort.

We have done further investigation on our cases here and have identified two more (total of 6 so far) going back in records from 2016 to the present on Kangaroo and Lentil diets. We do not have complete diet histories on all our cases, sadly, and still have some work here to pull hard copy charts from 2016. While we have on our intake history form a question regarding diet, this form has not been consistently scanned into the computer medical record and the diet is not always mentioned in the reports that are. Also, our ER service does not routinely ask diet history so cases that presented on ER and later transferred may not have a reported diet. I think it is possible that we will find more when we get the rest of the charts from 2016 reviewed, we have completed the reported diet histories for 2017. We have also found an interesting diet pattern, especially concerning some of Josh Stern's concerns about goldens on grain free diets. About 75% of our DCM cases with reported diet histories in 2017 were on grain free diets. We are going back through other records of cardiac patients that had other diseases to see what proportion of these other cases were on grain free diets (may be our clients just like to feed grain free?), but [B6] my resident, found a publication that reported about 19% prevalence of pets being fed grain free diets in 2016. It seems like our DCM population has a much higher exposure to grain free diets than we would expect.

[B6] did contact Darcy Adin at NC State, and she has already done a fair amount of work on Kangaroo and Lentil diets and DCM. They have about 10 cases out of a total of 47 cases with diet histories. (Not counting the one we found in 2016 thus far, we had 5/23 in 2017-18). We did complete FDA reports on our cases, but Darcy is way ahead of us and has been working with the FDA on looking for the culprit deficiency/toxicity. They investigated selenium and have ruled out selenium deficiency as playing a role. Darcy is presenting an abstract on her cases at ACVIM from what she has told [B6] with description of increased sphericity of the LV relative to other forms of DCM in these cases.

This may be a moot point for future patients to some degree as California Natural has discontinued their Kangaroo and Lentil diet. Four of our cases were on this, one on a non-specified Kangaroo and Lentil, and one was on Zignature brand Kangaroo and Lentil. The dog on the Zignature diet was a taurine deficient Cocker. Interestingly, another one of my patients on a Zignature diet (pork-based) was also taurine deficient. All ten of Darcy's cases were on California Natural. However, the fact that it is being discontinued does not negate the importance of identifying a nutritional role in the disease.

Maybe we can all get together so that we do not wind up with parallel studies (like Fox and Kittleson with taurine in dogs from way back). Our combined efforts as you mention will be much more meaningful than anything done separately. My resident (and me too!) is very interested in working with you, Darcy, and others to get this information out there. I am also forwarding this to Darcy to get her input.

B6

On Wed, Feb 21, 2018 at 2:24 PM, **B6** wrote:
Hi **B6**,

We would like to explore if there is interest in the cardiology community in studying the reported cases of kangaroo and lentil-associated DCM. It seems that many services have seen at least a handful of cases. Would you be willing to distribute the message below to the cardiology list-serves (both diplomates and residents)?

Thank you in advance!

B6

To All Cardiologists and Cardiology Residents,

We are contacting you out of a growing concern about an apparent connection between kangaroo and lentil (K&L) diets and acquired DCM. As has been reported by others, we have had several cases of DCM in atypical breeds on K&L diets. The ongoing discussion on the VIN cardiology list-serve reflects that this may be a widespread issue and raises concerns that there are many more cases which are unreported or possibly unrecognized.

Like many of you, we feel this is an issue that warrants immediate attention, as it may represent a preventable condition. If there is a link, we would like to establish that as soon as possible in order to raise awareness for general practitioners and the public. At the University of Illinois, we have not seen enough cases on our own to evaluate the issue, but it seems that there are many more out there. To our knowledge, there is not currently an organized effort to compile information about these cases, although we know there is some discussion and effort regarding analysis of the diets in question.

To further evaluate the clinical picture of K&L diets and DCM, we are reaching out to all of you and hope to generate a discussion about reviewing cases of DCM and determining if there is a relationship with K&L diets. Even if your service has only seen a single case, in aggregate, there may be enough cases to develop a better clinical picture and elevate the discussion beyond anecdotal evidence. We realize that asking for a review of records can be a labor-intensive process and the capabilities of records systems varies widely. A good place to start may be simply reviewing resident case logs of DCM in the last 12 months to quickly identify cases of DCM and pull specific records.

If there is already an ongoing effort to gather case data, we are unaware and apologize for proposing a redundant study. If such an effort is already underway, we would like to volunteer our case data, and if not, we volunteer our service or assistance in compiling case data.

Our initial thoughts on approaching this would be starting with an initial survey to gauge how many cardiology services have seen K&L-associated DCM cases, and whether there is interest in sharing case information. We hope to eventually gather basic case information and would try to design the survey to require minimal time and effort. We welcome any thoughts, suggestions or any level of interest or participation in this. We also want to make sure that we are not duplicating or impinging on any other service's work, and will defer to any ongoing efforts regarding this issue.

We look forward to hearing all of your thoughts and working with anyone who is interested. Pending the response, we hope to follow up with an initial survey.

Please feel free to direct any questions to **B6** or Ryan Fries (rfries@illinois.edu)

Sincerely,

The Clinical Cardiology Service
University of Illinois
Department of Veterinary Clinical Medicine
1008 W Hazelwood Dr.
Urbana, IL 61801

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B6

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B6

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 3/13/2018 11:45:44 AM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519
Attachments: 800.218-Iron Panel Results.pdf

The full iron panels for 2/3 dogs showed elevated Ferritin (3x the upper reference range per the vet). This is an acute phase protein.

B5

B6

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



From: Jones, Jennifer L
Sent: Monday, February 26, 2018 11:44 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I requested a full iron panel.

There was one necropsy done. I believe there is heart left that we could test if we see abnormalities in the iron panels.

From the necropsy:

B6

B6

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



From: Rotstein, David
Sent: Monday, February 26, 2018 11:39 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks Jen

Looking forward to what they find and glad that they are running it. Will they be doing a full iron profile?

B5

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: Jones, Jennifer L
Sent: Monday, February 26, 2018 11:35 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

NCSU is going to test one dog that ate a grain free diet. I'm waiting to hear from the other vet about Fe testing. Dr. Adin also sent this paper.
BLUF: In this study involving children w/ DCM and Heart Failure-96.4% of patients had Fe deficiency, only 39.3% had anemia, and only 2/11 with anemia had a microcytic anemia

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



From: Rotstein, David
Sent: Thursday, February 22, 2018 10:44 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

That sounds like a plan.

B5

B5

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: Jones, Jennifer L
Sent: Thursday, February 22, 2018 10:43 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed-I think this is going to be

B5

B5

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



From: Rotstein, David
Sent: Thursday, February 22, 2018 10:38 AM

To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Jen,

B5

d

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: Jones, Jennifer L
Sent: Thursday, February 22, 2018 10:33 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

B5

Dr. Adin at NCSU emailed additional theories. She continues to see more cases. The Vet Cardiology Community is discussing this quite a bit.

B5

B5

B5

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



From: Jones, Jennifer L
Sent: Tuesday, January 23, 2018 2:00 PM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI:
results

B5

Stay tuned for our test

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

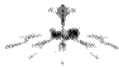


From: Jones, Jennifer L
Sent: Thursday, January 11, 2018 9:36 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

JJ-Vet emailed-“ As additional information, one of our cardiologist colleagues B6 posted a question about this association today on our list serve. She has seen 4 cases of DCM in dogs eating kangaroo and lentil (I assume B4 but not sure) in the last year - 2 were housemates but related.”

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



From: Jones, Jennifer L
Sent: Wednesday, January 03, 2018 2:32 PM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for Selenium based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for Se.

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



From: Rotstein, David
Sent: Tuesday, August 22, 2017 8:39 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 8:37 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **Final Conclusion:** The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

B5

B5

Final Conclusion: The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Monday, August 07, 2017 7:02 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine/carnitine still pending, but **B5** negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Thursday, July 27, 2017 7:25 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for **B5**. The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?
2. She forwarded me an article about **B5**.
 - a. I don't believe our labs or Covance can test for this. Eurofins can test for this.

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, July 18, 2017 8:18 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question,

B5

B5

This would highly unlikely, but wanted to put it out there.

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: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

B5

Medical Record Review:

B6

Presenting complaint **B6** dyspnea, cough of 3 week duration-wheezing type more frequent at night à rDVM, treated w/ prednisone and doxycycline for kennel cough à **B6** inappetance, vomiting à **B6** dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated à **B6** treated as outpatient, **B6** as syring feeding, dog regurgitated and had marked dyspnea à ER à refer to NCSU à **B6** put on mechanical ventilator à **B6** euthanized

B6

B6

tFAST **B6**: severe cardiomegaly with ventricular hypocontractility

Echo **B6**: dcm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

Prior MHx: coffee brown urine including clumping after strenuous activity when it is hot outside and resolves with 24-36 hours; also Crystalluria

B6

Presented **B6** episodes of collapse, first occurred mid February, fall 6 seconds without losing consciousnessà immediately return to normal à2 weeks later again collapse, then on à 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February;à recheck 7/10, doing better, no collapsing episodes except a stumbling moment when excited, respiratory rate normal, diet changed to Hill's

B6

B6

B6 Rads: left sided congestive heart failure

-7/10: moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

B6 Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP

CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
240-506-6763 (BB)



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From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to [B4] who said there was [B4] in this food... but that doesn't rule out treats.

[B5]

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen f [B5]

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

From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHFà severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigsà plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodesà 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica; Nemser, Sarah; Reimschuessel, Renate
Sent: 3/13/2018 11:53:14 AM
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks Jen.

I agree and wonder if

B5

dave

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: Jones, Jennifer L
Sent: Tuesday, March 13, 2018 7:46 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

The full iron panels for 2/3 dogs showed elevated Ferritin (3x the upper reference range per the vet). This is an acute phase protein.

B5

B6

B6

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



From: Jones, Jennifer L
Sent: Monday, February 26, 2018 11:44 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I requested a full iron panel.

There was one necropsy done. I believe there is heart left that we could test if we see abnormalities in the iron panels.

From the necropsy:

B6

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



From: Rotstein, David
Sent: Monday, February 26, 2018 11:39 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Thanks Jen

Looking forward to what they find and glad that they are running it. Will they be doing a full iron profile?

B5

B5

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: Jones, Jennifer L
Sent: Monday, February 26, 2018 11:35 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

NCSU is going to test one dog that ate a grain free diet. I'm waiting to hear from the other vet about Fe testing. Dr. Adin also sent this paper.
BLUF: In this study involving children w/ DCM and Heart Failure-96.4% of patients had Fe deficiency, only 39.3% had anemia, and only 2/11 with anemia had a microcytic anemia

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



From: Rotstein, David
Sent: Thursday, February 22, 2018 10:44 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

That sounds like a plan.

B5

B5

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: Jones, Jennifer L
Sent: Thursday, February 22, 2018 10:43 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed-I think this is going to be B5

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



From: Rotstein, David
Sent: Thursday, February 22, 2018 10:38 AM
To: Jones, Jennifer L <Jennifer.Jones@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Jen,

B5

d

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



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From: Jones, Jennifer L

Sent: Thursday, February 22, 2018 10:33 AM

To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

Dr. Adin at NCSU emailed additional theories. She continues to see more cases. The Vet Cardiology Community is discussing this quite a bit.

B5

B5

B5

B5

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



From: Jones, Jennifer L
Sent: Tuesday, January 23, 2018 2:00 PM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI- **B5** Stay tuned for our test results.

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



From: Jones, Jennifer L
Sent: Thursday, January 11, 2018 9:36 AM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-

JJ-Vet emailed-“ As additional information, one of our cardiologist colleagues in **B6** posted a question about this association today on our list serve. She has seen 4 cases of DCM in dogs eating kangaroo and lentil (I assume **B4** but not sure) in the last year - 2 were housemates but related.”

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



From: Jones, Jennifer L
Sent: Wednesday, January 03, 2018 2:32 PM
To: Rotstein, David <David.Rotstein@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: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; 'Reimschuessel, Renate (Renate.Reimschuessel@fda.hhs.gov)' <Renate.Reimschuessel@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Going to test the leftover food for Selenium based on our discussion during the PFO meeting today. I asked the vet if any dogs tested (blood/tissue) for Se.

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



From: Rotstein, David
Sent: Tuesday, August 22, 2017 8:39 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Agreed. Thanks Jen

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: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 8:37 AM
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

BLUF: **Final Conclusion:** The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

B5

Final Conclusion: The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L

Sent: Monday, August 07, 2017 7:02 AM

To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: 800.218-Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

FYI-Taurine/carnitine still pending, but [B5] negative.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L

Sent: Thursday, July 27, 2017 7:25 AM

To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We received the food and plan to test for [B5]. The vet also mentioned two items of interest:

1. She's treated 2 other dogs in last 2 weeks with DCM/CHF and being fed California Natural food. That brings us to 4 DCM dogs recently eating this food.
 - a. We can consider taurine and other types of testing?
2. She forwarded me an article about [B5].
 - a. I don't believe our labs or Covance can test for this. Eurofins can test for this.

Thoughts from the group?

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L

Sent: Tuesday, July 18, 2017 8:18 AM

To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check [B5].

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David

Sent: Thursday, July 13, 2017 2:54 PM

To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren

Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question, [B5].

B5

This would highly unlikely, but wanted to put it out there.

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: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

B5

Medical Record Review:

B6

Presenting complaint **B6**: dyspnea, cough of 3 week duration-wheezing type more frequent at nightà rDVM, treated w/ prednisone and doxycycline for kennel coughà **B6** inappetance, vomiting à **B6** dyspneic and recheck, hospitalized and treated for pneumonia, regurgitatedà **B6** treated as outpatient, **B6** as syring feeding, dog regurgitated and had marked dyspneaà ER à refer to NCSU à **B6** put on mechanical ventilatorà **B6** euthanized

B6

Labwork:

B6

B6

tFAST B6: severe cardiomegaly with ventricular hypocontractility

Echc B6: dcm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked

alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

Prior MHx: coffee brown urine including clumping after strenuous activity when it is hot outside and resolves with 24-36 hours; also Crystalluria

B6

Presented **B6** episodes of collapse, first occurred mid February, fall 6 seconds without losing consciousnessà immediately return to normal à2 weeks later again collapse, then on à 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February;à recheck 7/10, doing better, no collapsing episodes except a stumbling moment when excited, respiratory rate normal, diet changed to Hill's

B6

B6 Rads: left sided congestive heart failure

-7/10: moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

B6 Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left

ventricular systolic function, suspected DCM

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Tuesday, July 11, 2017 12:44 PM
To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
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From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to **B4** who said there was **B4** in this food... but that doesn't rule out treats.

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for **B5**

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

From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHF à severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigs à plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodes à 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM
Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine

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Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 3/14/2018 10:01:02 PM
Subject: Re: Kangaroo & Lentil-Associated DCM
Attachments: VH Send Out Labs - LABRADOR RETRIEVER - 2_26_2018 - [B6] - [B6] - IRON AND IRON BINDING CAPACITY.pdf

Hi Jennifer,

I've attached the report for [B6]

Thanks!
Darcy

On Tue, Mar 13, 2018 at 7:32 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy. Will you please send a copy of the lab report? I put the invoice through and our business team should be mailing the check.

The Phosphorous we tested for is elemental phosphorous. It would encompass the total phosphorous content (despite the source) in the food.

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Friday, March 09, 2018 9:28 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: Re: Kangaroo & Lentil-Associated DCM

Hi Jennifer,

We received the ferritin results back and they are approximately 3x the upper normal. I am meeting with one of our clinical pathologists next week to discuss what this might mean. [B5]

[B5]

Also, is the phosphorous that you tested for the same as B5

Thank you!

Darcy

On Fri, Feb 23, 2018 at 1:29 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

I attached the food testing results. These include the 2 samples you recently sent and B6 food sample. All products contained inadequate iron content, below the AAFCO claim. In people, low iron has been associated with idiopathic DCM (Marinescu and McCullough 2011). According to the article, anemia was found in 12 to 55% of patients in heart failure, and the anemia's severity correlated to the degree of heart failure. B5

B5

B5

We'd like to request a total iron panel on one of the dogs that ate the food you submitted, either the dog that ate the California Naturals Chicken Meal or Fromm Heartland food. We would reimburse NCSU directly for the testing. Please send me an estimate for the charges, and I can make a purchase request. I must make a request prior to any testing. After you complete the testing, please send me a copy of the results and an invoice. We can then call back with our VISA information.

Please respond if you're interested in the testing.

Thank you and take care,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: [240-402-5421](tel:240-402-5421)



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Thursday, February 22, 2018 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: Fwd: Kangaroo & Lentil-Associated DCM

Hi Jennifer,

I hope you are doing well! Just thought I would forward this email chain to you as the growing concern about grain-free diets in the veterinary cardiology community continues to expand. Also, I wasn't sure if you were aware of the 5 DCM cases eating kangaroo and lentil diets that [B6] had reported to the FDA last year so just wanted to be sure these were somehow linked with ours from NCSU as part of the same concern.

B5

2003. Maybe I will hear back but wondering if you have any leads there?

Thank you for your help as always!

Take care

Darcy

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

From: [B6] <[B6]>
Date: Wed, Feb 21, 2018 at 5:42 PM
Subject: Fwd: Kangaroo & Lentil-Associated DCM
To: dbadin@ncsu.edu

Hi Darcy,

Tried to copy you on this, and the email that I have for you bounced. [B6] gave me this one. Shall I change your email in the Secretary records to this? I had the [B6] one listed below.

B6

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

From: **B6** <**B6**>

Date: Wed, Feb 21, 2018 at 5:34 PM

Subject: Re: Kangaroo & Lentil-Associated DCM

To: **B6** <**B6**>

Cc: "Fries, Ryan C" <rfries@illinois.edu>, "Adin, Darcy" **B6**

Hi **B6** and Ryan,

Before I put this out on the listserv, I did want to give you a little more information. Please feel free to contact me on my cell phone **B6** if you want to talk in person. We are definitely interested in pursuing this and would love to work together to make this a multicenter effort.

We have done further investigation on our cases here and have identified two more (total of 6 so far) going back in records from 2016 to the present on Kangaroo and Lentil diets. We do not have complete diet histories on all our cases, sadly, and still have some work here to pull hard copy charts from 2016. While we have on our intake history form a question regarding diet, this form has not been consistently scanned into the computer medical record and the diet is not always mentioned in the reports that are. Also, our ER service does not routinely ask diet history so cases that presented on ER and later transferred may not have a reported diet. I think it is possible that we will find more when we get the rest of the charts from 2016 reviewed, we have completed the reported diet histories for 2017. We have also found an interesting diet pattern, especially concerning some of Josh Stern's concerns about goldens on grain free diets. About 75% of our DCM cases with reported diet histories in 2017 were on grain free diets. We are going back through other records of cardiac patients that had other diseases to see what proportion of these other cases were on grain free diets (may be our clients just like to feed grain free?), but **B6**, my resident, found a publication that reported about 19% prevalence of pets being fed grain free diets in 2016. It seems like our DCM population has a much higher exposure to grain free diets than we would expect.

B6 did contact Darcy Adin at NC State, and she has already done a fair amount of work on Kangaroo and Lentil diets and DCM. They have about 10 cases out of a total of 47 cases with diet histories. (Not counting the one we found in 2016 thus far, we had 5/23 in 2017-18). We did complete FDA reports on our cases, but Darcy is way ahead of us and has been working with the FDA on looking for the culprit deficiency/toxicity. They investigated selenium and have ruled out selenium deficiency as playing a role. Darcy is presenting an abstract on her cases at ACVIM from what she has told **B6** with description of increased sphericity of the LV relative to other forms of DCM in these cases.

This may be a moot point for future patients to some degree as California Natural has discontinued their Kangaroo and Lentil diet. Four of our cases were on this, one on a non-specified Kangaroo and Lentil, and one was on Zignature brand Kangaroo and Lentil. The dog on the Zignature diet was a taurine deficient Cocker. Interestingly, another one of may patients on a Zignature diet (pork-based) was also taurine deficient. All ten of

Darcy's cases were on California Natural. However, the fact that it is being discontinued does not negate the importance of identifying a nutritional role in the disease.

Maybe we can all get together so that we do not wind up with parallel studies (like Fox and Kittleson with taurine in dogs from way back). Our combined efforts as you mention will be much more meaningful than anything done separately. My resident (and me too!) is very interested in working with you, Darcy, and others to get this information out there. I am also forwarding this to Darcy to get her input.

B6

On Wed, Feb 21, 2018 at 2:24 PM, **B6** **B6** wrote:

Hi **B6**

We would like to explore if there is interest in the cardiology community in studying the reported cases of kangaroo and lentil-associated DCM. It seems that many services have seen at least a handful of cases. Would you be willing to distribute the message below to the cardiology list-serves (both diplomates and residents)?

Thank you in advance!

B6

To All Cardiologists and Cardiology Residents,

We are contacting you out of a growing concern about an apparent connection between kangaroo and lentil (K&L) diets and acquired DCM. As has been reported by others, we have had several cases of DCM in atypical breeds on K&L diets. The ongoing discussion on the VIN cardiology list-serve reflects that this may be a widespread issue and raises concerns that there are many more cases which are unreported or possibly unrecognized.

Like many of you, we feel this is an issue that warrants immediate attention, as it may represent a preventable condition. If there is a link, we would like to establish that as soon as possible in order to raise awareness for general practitioners and the public. At the University of Illinois, we have not seen enough cases on our own to evaluate the issue, but it seems that there are many more out there. To our knowledge, there is not currently an organized effort to compile information about these cases, although we know there is some discussion and effort regarding analysis of the diets in question.

To further evaluate the clinical picture of K&L diets and DCM, we are reaching out to all of you and hope to generate a discussion about reviewing cases of DCM and determining if there is a relationship with K&L diets. Even if your service has only seen a single case, in aggregate, there may be enough cases to develop a better clinical picture and elevate the discussion beyond anecdotal evidence. We realize that asking for a review of records can be a labor-intensive process and the capabilities of records systems varies widely. A good place to start may be simply reviewing resident case logs of DCM in the last 12 months to quickly identify cases of DCM and pull specific records.

If there is already an ongoing effort to gather case data, we are unaware and apologize for proposing a redundant study. If such an effort is already underway, we would like to volunteer our case data, and if not, we volunteer our service or assistance in compiling case data.

Our initial thoughts on approaching this would be starting with an initial survey to gauge how many cardiology services have seen K&L-associated DCM cases, and whether there is interest in sharing case information. We hope to eventually gather basic case information and would try to design the survey to require minimal time and effort. We welcome any thoughts, suggestions or any level of interest or participation in this. We also want to make sure that we are not duplicating or impinging on any other service's work, and will defer to any ongoing efforts regarding this issue.

We look forward to hearing all of your thoughts and working with anyone who is interested. Pending the response, we hope to follow up with an initial survey.

Please feel free to direct any questions to B6 or Ryan Fries (rfries@illinois.edu)

Sincerely,

The Clinical Cardiology Service

University of Illinois

Department of Veterinary Clinical Medicine

1008 W Hazelwood Dr.

Urbana, IL 61801

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B6

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B6

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

--

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Clinical Assistant Professor of Cardiology

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1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

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Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

Analytical Sciences Laboratory

University of Idaho

Holm Research Center
875 Perimeter Dr. MS 2203
Moscow, Idaho 83844-2203

Phone: (208) 885-7081 FAX: (208) 885-8937
email: asl@uidaho.edu http://www.agls.uidaho.edu/asl/

Certificate of Analysis

Prepared For: Jennnifer Jones
Vet-LIRN
8401 Muirkirk Road

Laurel, MD 20708

Case ID: VFEB18-028
Report Date: 16-Feb-18
Date Received: 07-Feb-18
Client Reference: 2018-2078
Owner: Jennifer Jones
Species: Dog

Report Status: Final Preliminary Addendum Corrected

Interpretation of Results:

The laboratory does *not* provide reference ranges for elements in feed/food samples. Interpretation of values is dependent on the type of material submitted, percent this material will comprise in the total diet, and species/age of animal receiving the material. Comparison to the product label or consultation with a nutritionist might be warranted.

[B6]

Veterinary Toxicologist

QC Review/Approval: [B6]

UI Analytical Sciences Laboratory Certificate of Analysis

Client Sample ID: 800.218-Sub 1-dog food

Sample Type: Feed - Dry
Weight

UIASL Sample ID: V1800390

Species: Dog

Preservation: Dried & Ground

Macro Element Screen

Method: ICP -- Nitric Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Calcium	13000	4.0	—
Magnesium	1300	2.0	—
Phosphorus	7400	20	—

Comment:

Trace Mineral Screen by ICP/MS

Method: ICP-MS -- Nitric Acid Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Iron	30	1.0	—
Cobalt	0.12	0.010	—
Copper	21	0.10	—
Zinc	240	0.10	—
Selenium	0.70	0.010	—

Comment:

Client Sample ID: 800.218-Sub 2-dog food

Sample Type: Feed - Dry
Weight

UIASL Sample ID: V1800391

Species: Dog

Preservation: Dried & Ground

Macro Element Screen

Method: ICP -- Nitric Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Calcium	10000	4.0	—
Magnesium	1400	2.0	—
Phosphorus	6700	20	—

Comment:

Trace Mineral Screen by ICP/MS

Method: ICP-MS -- Nitric Acid Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Iron	30	1.0	—
Cobalt	0.14	0.010	—
Copper	19	0.10	—
Zinc	280	0.10	—
Selenium	0.65	0.010	—

Comment:

ND = Not Detected NA = Not Applicable RL = Reporting Limit QNS = Quantity Not Sufficient

* = Outside Reference Range

16-Feb-18

UI Analytical Sciences Laboratory Certificate of Analysis

Case ID: VFEB18-028

Client Sample ID: 800.218-Sub 4-dog food

Sample Type: Feed - Dry
Weight

UIASL Sample ID: V1800392

Species: Dog

Preservation: Dried & Ground

Macro Element Screen

Method: ICP -- Nitric Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Calcium	12000	4.0	—
Magnesium	1400	2.0	—
Phosphorus	10000	20	—

Comment:

Trace Mineral Screen by ICP/MS

Method: ICP-MS -- Nitric Acid Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Iron	30	1.0	—
Cobalt	0.37	0.010	—
Copper	25	0.10	—
Zinc	170	0.10	—
Selenium	0.85	0.010	—

Comment:

Client Sample ID: 800.218-Sub 5-dog food

Sample Type: Feed - Dry
Weight

UIASL Sample ID: V1800393

Species: Dog

Preservation: Dried & Ground

Macro Element Screen

Method: ICP -- Nitric Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Calcium	18000	4.0	—
Magnesium	1400	2.0	—
Phosphorus	13000	20	—

Comment:

Trace Mineral Screen by ICP/MS

Method: ICP-MS -- Nitric Acid Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Iron	39	1.0	—
Cobalt	0.14	0.010	—
Copper	19	0.10	—
Zinc	330	0.10	—
Selenium	0.66	0.010	—

Comment:

ND = Not Detected NA = Not Applicable RL = Reporting Limit QNS = Quantity Not Sufficient

* = Outside Reference Range

**UI Analytical Sciences Laboratory
Certificate of Analysis**

Client Sample ID: 800.218-Sub 6-dog food

Sample Type: Feed - Dry
Weight

UIASL Sample ID: V1800394

Species: Dog

Preservation: Dried & Ground

Macro Element Screen

Method: ICP -- Nitric Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Calcium	9300	4.0	—
Magnesium	1500	2.0	—
Phosphorus	6800	20	—

Comment:

Trace Mineral Screen by ICP/MS

Method: ICP-MS -- Nitric Acid Digest

	Results (µg/g)	RL	Adult Approx. Ref. Range
Iron	31	1.0	—
Cobalt	0.14	0.010	—
Copper	16	0.10	—
Zinc	200	0.10	—
Selenium	0.68	0.010	—

Comment:

Note: Any included reference ranges are only guidelines and the analytical results need to be interpreted in conjunction with management and dietary factors, as well as with clinical and/or postmortem observations. Reference ranges can vary significantly between individuals or groups of animals from different ranges and habitats or on different diets.

Note: Serum concentrations of some elements (e.g., zinc, iron, phosphorus, magnesium) may be artificially elevated due to hemolysis or leaching from the red blood cells. Zinc can leach from some rubber blood collection tube stoppers. The sample should be spun and the serum separated from the clot prior to shipping. We recommend collecting blood in plastic vials or royal blue top vacutainer tubes without heparin (for trace element analysis) for submission of samples to be analyzed for zinc.

Samples will be discarded one month after date of final report unless otherwise requested.

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Darcy Adin'
Sent: 4/27/2018 12:56:49 PM
Subject: RE: Kangaroo & Lentil-Associated DCM

Good morning Darcy,
We conducted iodine screening for the California Naturals Chicken product and Fromm products you sent us. The products contained 3.19 ppm and 1.58 ppm iodine, respectively. Both product iodine levels are within the AAFCO minimum and maximum range (1 ppm to 11 ppm). Based on this, it is unlikely an exogenous thyroid hormone in the food could be causing the DCM.
Take care and enjoy your weekend,
Jen

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Wednesday, March 28, 2018 2:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Kangaroo & Lentil-Associated DCM

Thank you! A nutritionist that I spoke to brought up the question of whether typical iron analysis
B5 thank you for checking! **B5**

Take care
Darcy

On Wed, Mar 28, 2018 at 2:45 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
Good afternoon Darcy,
I believe the screen measured total iron content. I will check with the lab, but it should include all iron species.
I'll let you know if I hear anything different.
Thank you and take care,
Jen

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, March 27, 2018 11:53 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Kangaroo & Lentil-Associated DCM

Hi Jennifer,

Do you you if the analysis of iron in the diet tested for

B5

Thank you!

Darcy

On Fri, Feb 23, 2018 at 1:29 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
Good afternoon Darcy,

I attached the food testing results. These include the 2 samples you recently sent and [REDACTED] B6 [REDACTED] food sample. All products contained inadequate iron content, below the AAFCO claim. In people, low iron has been associated with idiopathic DCM (Marinescu and McCullough 2011). According to the article, anemia was found in 12 to 55% of patients in heart failure, and the anemia's severity correlated to the degree of heart failure. It's

[REDACTED] B5 [REDACTED]

We'd like to request a total iron panel on one of the dogs that ate the food you submitted, either the dog that ate the California Naturals Chicken Meal or Fromm Heartland food. We would reimburse NCSU directly for the testing. Please send me an estimate for the charges, and I can make a purchase request prior to any testing. After you complete the testing, please send me a copy of the results and an invoice. We can then call back with our VISA information.

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



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Sent: Thursday, February 22, 2018 9:23 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: Fwd: Kangaroo & Lentil-Associated DCM

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B5

Thank you for your help as always!
Take care
Darcy

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

From: [REDACTED] **B6**
Date: Wed, Feb 21, 2018 at 5:42 PM
Subject: Fwd: Kangaroo & Lentil-Associated DCM
To: dbadin@ncsu.edu

Hi Darcy,

Tried to copy you on this, and the email that I have for you bounced. [REDACTED] **B6** gave me this one. Shall I change your email in the Secretary records to this? I had the [REDACTED] **B6** one listed below.

[REDACTED] **B6**

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

From: [REDACTED] **B6**
Date: Wed, Feb 21, 2018 at 5:34 PM
Subject: Re: Kangaroo & Lentil-Associated DCM
To: [REDACTED] **B6**
Cc: "Fries, Ryan C" <rfries@illinois.edu>, "Adin, Darcy" [REDACTED] **B6**

Hi [REDACTED] **B6** and Ryan,

Before I put this out on the listserve, I did want to give you a little more information. Please feel free to contact me on my cell phone [REDACTED] **B6** if you want to talk in person. We are definitely interested in pursuing this and would love to work together to make this a multicenter effort.

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[B6]

On Wed, Feb 21, 2018 at 2:24 PM, [B6] wrote:

Hi [B6]

We would like to explore if there is interest in the cardiology community in studying the reported cases of kangaroo and lentil-associated DCM. It seems that many services have seen at least a handful of cases. Would you be willing to distribute the message below to the cardiology list-serves (both diplomates and residents)?

Thank you in advance!

[B6]

To All Cardiologists and Cardiology Residents,

We are contacting you out of a growing concern about an apparent connection between kangaroo and lentil (K&L) diets and acquired DCM. As has been reported by others, we have had several cases of DCM in atypical breeds on K&L diets. The ongoing discussion on the VIN cardiology list-serve reflects that this may be a widespread issue and raises concerns that there are many more cases which are unreported or possibly unrecognized.

Like many of you, we feel this is an issue that warrants immediate attention, as it may represent a preventable condition. If there is a link, we would like to establish that as soon as possible in order to raise awareness for general practitioners and the public. At the University of Illinois, we have not seen enough cases on our own to evaluate the issue, but it seems that there are many more out there. To our knowledge, there is not currently an organized effort to compile information about these cases, although we know there is some discussion and effort regarding analysis of the diets in question.

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Our initial thoughts on approaching this would be starting with an initial survey to gauge how many cardiology services have seen K&L-associated DCM cases, and whether there is interest in sharing case information. We hope to eventually gather basic case information and would try to design the survey to require minimal time and effort. We welcome any thoughts, suggestions or any level of interest or participation in this. We also want to make sure that we are not duplicating or impinging on any other service's work, and will defer to any ongoing efforts regarding this issue.

We look forward to hearing all of your thoughts and working with anyone who is interested. Pending the response, we hope to follow up with an initial survey.

Please feel free to direct any questions to: B6 or Ryan Fries (rfries@illinois.edu)

Sincerely,

The Clinical Cardiology Service
University of Illinois
Department of Veterinary Clinical Medicine
1008 W Hazelwood Dr.
Urbana, IL 61801

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B6

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B6

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607

919-513-6032

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Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
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--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'Darcy Adin'
Sent: 4/27/2018 1:02:30 PM
Subject: RE: Kangaroo & Lentil-Associated DCM

You're welcome. Thank you again for inviting so many different experts.

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



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Friday, April 27, 2018 8:59 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Kangaroo & Lentil-Associated DCM

Thank you Jennifer! Great to know.
I thought last week's discussion was great - thank you for initiating that.
Take care
Darcy

On Apr 27, 2018, at 8:56 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Darcy,
We conducted iodine screening for the California Naturals Chicken product and Fromm products you sent us. The products contained 3.19 ppm and 1.58 ppm iodine, respectively. Both product iodine levels are within the AAFCO minimum and maximum range (1 ppm to 11 ppm). Based on this, it is unlikely an exogenous thyroid hormone in the food could be causing the DCM.
Take care and enjoy your weekend,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
<image001.png> <image004.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Wednesday, March 28, 2018 2:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Kangaroo & Lentil-Associated DCM

Thank you! A nutritionist that I spoke to brought up the question

B5

B5 - thank you for checking!

Take care
Darcy

On Wed, Mar 28, 2018 at 2:45 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,
I believe the screen measured

B5

I'll let you know if I hear anything different.

Thank you and take care,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421
<image001.png> <image005.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, March 27, 2018 11:53 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: Kangaroo & Lentil-Associated DCM

Hi Jennifer,

Do you you if the

B5

Thank you!
Darcy

On Fri, Feb 23, 2018 at 1:29 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
Good afternoon Darcy,

I attached the food testing results. These include the 2 samples you recently sent and [redacted] food sample. All products contained inadequate iron content, below the AAFCO claim. In people, low iron has been associated with idiopathic DCM (Marinescu and McCullough 2011). According to the article, anemia was found in 12 to 55% of patients in heart failure, and the anemia's severity correlated to the degree of heart failure. It's

B5

We'd like to request a total iron panel on one of the dogs that ate the food you submitted, either the dog that ate the California Naturals Chicken Meal or Fromm Heartland food. We would reimburse NCSU directly for the testing. Please send me an estimate for the charges, and I can make a purchase request. I must make a request prior to any testing. After you complete the testing, please send me a copy of the results and an invoice. We can then call back with our VISA information.

Please respond if you're interested in the testing.

Thank you and take care,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

Tel: 240-402-5421

<image001.png> <image006.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Thursday, February 22, 2018 9:23 AM

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

Subject: Fwd: Kangaroo & Lentil-Associated DCM

Hi Jennifer,

I hope you are doing well! Just thought I would forward this email chain to you as the growing concern about grain-free diets in the veterinary cardiology community continues to expand. Also, I wasn't sure if you were aware of the 5 DCM cases eating kangaroo and lentil diets that [B6] had reported to the FDA last year so just wanted to be sure these were somehow linked with ours from NCSU as part of the same concern.

B5

2003. Maybe I will hear back but wondering if you have any leads there?

Thank you for your help as always!

Take care

Darcy

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

From: [B6]

Date: Wed, Feb 21, 2018 at 5:42 PM

Subject: Fwd: Kangaroo & Lentil-Associated DCM

To: dbadin@ncsu.edu

Hi Darcy,

Tried to copy you on this, and the email that I have for you bounced. [B6] gave me this one. Shall I change your email in the Secretary records to this? I had the [B6] one listed below.

[B6]

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

From: [B6]

Date: Wed, Feb 21, 2018 at 5:34 PM

Subject: Re: Kangaroo & Lentil-Associated DCM

To: [B6]

Cc: "Fries, Ryan C" <rfries@illinois.edu>, "Adin, Darcy" [B6]

Hi [B6] and Ryan,

Before I put this out on the listserve, I did want to give you a little more information. Please feel free to contact me on my cell phone [B6] if you want to talk in person. We are definitely interested in pursuing this and would love to work together to make this a multicenter effort.

We have done further investigation on our cases here and have identified two more (total of 6 so far) going back in records from 2016 to the present on Kangaroo and Lentil diets. We do not have complete diet histories on all our cases, sadly, and still have some work here to pull hard copy charts from 2016. While we have on our intake history form a question regarding diet, this form has not been consistently scanned into the computer medical record and the diet is not always mentioned in the reports that are. Also, our ER service does not routinely ask diet history so cases that presented on ER and later transferred may not have a reported diet. I think it is possible that we will find more when we get the rest of the charts from 2016 reviewed, we have completed the reported diet histories for 2017. We have also found an interesting diet pattern, especially concerning some of Josh Stern's concerns about goldens on grain free diets. About 75% of our DCM cases with reported diet histories in 2017 were on grain free diets. We are going back through other records of cardiac patients that had other diseases to see what proportion of these other cases were on grain free diets (may be our clients just like to feed grain free?), but [B6] my resident, found a publication that reported about 19% prevalence of pets being fed grain free diets in 2016. It seems like our DCM population has a much higher exposure to grain free diets than we would expect.

[B6] did contact Darcy Adin at NC State, and she has already done a fair amount of work on Kangaroo and Lentil diets and DCM. They have about 10 cases out of a total of 47 cases with diet histories. (Not counting the one we found in 2016 thus far, we had 5/23 in 2017-18). We did complete FDA reports on our cases, but Darcy is way ahead of us and has been working with the FDA on looking for the culprit deficiency/toxicity. They investigated selenium and have ruled out selenium deficiency as playing a role. Darcy is presenting an abstract on her cases at ACVIM from what she has told [B6] with description of increased sphericity of the LV relative to other forms of DCM in these cases.

This may be a moot point for future patients to some degree as California Natural has discontinued their Kangaroo and Lentil diet. Four of our cases were on this, one on a non-specified Kangaroo and Lentil, and one was on Zignature brand Kangaroo and Lentil. The dog on the Zignature diet was a taurine deficient Cocker. Interestingly, another one of my patients on a Zignature diet (pork-based) was also taurine deficient. All ten of Darcy's cases were on California Natural. However, the fact that it is being discontinued does not negate the importance of identifying a nutritional role in the disease.

Maybe we can all get together so that we do not wind up with parallel studies (like Fox and Kittleson with taurine in dogs from way back). Our combined efforts as you mention will be much more meaningful than anything done separately. My resident (and me too!) is very interested in working with you, Darcy, and others to get this information out there. I am also forwarding this to Darcy to get her input.

[B6]

On Wed, Feb 21, 2018 at 2:24 PM, [B6] wrote:

Hi [B6]

We would like to explore if there is interest in the cardiology community in studying the reported cases of kangaroo and lentil-associated DCM. It seems that many services have seen at least a handful of cases. Would you be willing to distribute the message below to the cardiology list-serves (both diplomates and residents)?

Thank you in advance!

B6

To All Cardiologists and Cardiology Residents,

We are contacting you out of a growing concern about an apparent connection between kangaroo and lentil (K&L) diets and acquired DCM. As has been reported by others, we have had several cases of DCM in atypical breeds on K&L diets. The ongoing discuss on the VIN cardiology list-serve reflects that this may be widespread issue and raises concerns that there are many more cases which are unreported or possibly unrecognized.

Like many of you, we feel this is an issue that warrants immediate attention, as it may represent a preventable condition. If there is a link, we would like to establish that as soon as possible in order to raise awareness for general practitioners and the public. At the University of Illinois, we have not seen enough cases on our own to evaluate the issue, but it seems that there are many more out there. To our knowledge, there is not currently an organized effort to compile information about these cases, although we know there is some discussion and effort regarding analysis of the diets in question.

To further evaluate the clinical picture of K&L diets and DCM, we are reaching out to all of you and hope to generate a discussion about reviewing cases of DCM and determining if there is a relationship with K&L diets. Even if your service has only seen a single case, in aggregate, there may be enough cases to develop a better clinical picture and elevate the discussion beyond anecdotal evidence. We realize that asking for a review of records can be a labor-intensive process and the capabilities of records systems varies widely. A good place to start may be simply reviewing resident case logs of DCM in the last 12 months to quickly identify cases of DCM and pull specific records.

If there is already an ongoing effort to gather case data, we are unaware and apologize for proposing a redundant study. If such an effort is already underway, we would like to volunteer our case data, and if not, we volunteer our service or assistance in compiling case data.

Our initial thoughts on approaching this would be starting with an initial survey to gauge how many cardiology services have seen K&L-associated DCM cases, and whether there is interest in sharing case information. We hope to eventually gather basic case information and would try to design the survey to require minimal time and effort. We welcome any thoughts, suggestions or any level of interest or participation in this. We also want to make sure that we are not duplicating or impinging on any other service's work, and will defer to any ongoing efforts regarding this issue.

We look forward to hearing all of your thoughts and working with anyone who is interested. Pending the response, we hope to follow up with an initial survey.

Please feel free to direct any questions to: B6 or Ryan Fries (rfries@illinois.edu)

Sincerely,

The Clinical Cardiology Service
University of Illinois
Department of Veterinary Clinical Medicine
1008 W Hazelwood Dr.
Urbana, IL 61801

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B6

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B6

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

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NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Rotstein, David </O=FDA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAVID.ROTSTEIN>
To: Queen, Jackie L; Jones, Jennifer L; Reimschuessel, Renate; Ceric, Olgica; Palmer, Lee Anne; Carey, Lauren
Sent: 7/11/2017 9:17:05 PM
Subject: Fwd: Alternated between: --California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils and Kangaroo & Red Lentils Recipe: Darcy Adin - EON-323515
Attachments: 2023228-report.pdf

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 <pfpreventcreation@fda.hhs.gov>
Date: July 11, 2017 at 5:16:15 PM EDT
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>, HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>, [REDACTED] B6
[REDACTED] B6
Subject: Alternated between: --California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils and Kangaroo & Red Lentils Recipe: Darcy Adin - EON-323515

A PFR Report has been received and PFR Event [EON-323515] has been created in the EON System.

A "PDF" report by name "2023228-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-323515

ICSR #: 2023228

EON Title: PFR Event created for Alternated between: -California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils and Kangaroo & Red Lentils Recipe; 2023228

AE Date	B6	Number Fed/Exposed	2
Best By Date		Number Reacted	2
Animal Species	Dog	Outcome to Date	Died Euthanized
Breed	Schnauzer - Miniature		
Age	2.5 Years		
District Involved	PFR-New York DO		

Product information

Individual Case Safety Report Number: 2023228

Product Group: Pet Food

Product Name: Alternated between: -California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils and Kangaroo & Red Lentils Recipe

Description: Please note: Dr. Jennifer Jones was consulted prior to submission of this report. She would like to be involved in the case review 3 week history of cough treated unsuccessfully with B6 3 day history of inappetence and vomiting prior to presentation to B6 emergency service for dyspnea. Radiographs showed severe pulmonary edema and echocardiogram showed severe Dilated Cardiomyopathy. There was an initial response to diuretic therapy however, he declined and was placed on the ventilator for respiratory support and continued CHF treatment. Attempts to wean off the ventilator were unsuccessful and aquaphoresis was performed. He continued to decline despite aggressive therapy and was euthanized. Infectious disease testing was negative and taurine and carnitine analysis showed adequate levels. Necropsy initially did not reveal a cause for DCM and supported alveolar injury (possibly ventilator related); B6

B6

B6

B6

B6

had been

fed California Naturals Adult - both kangaroo with lentils and venison with lentils along with Milo's kitchen treats. We have samples of these foods from 6/17 but not the original bags from when he was presented 2/17. These samples were provided at the time his housemate, B6 (unrelated, older miniature schnauzer) also presented with severe DCM and CHF. I will enter this dog as a separate affected patient. Both dogs had extensive infectious disease testing which was negative and nutritional amino acid deficiencies were ruled out. Because of this, their unrelated lineages (although the same breed, they were from different lines), different ages but similar time of presentation (B6 had clinical signs at the time B6 was treated, but didn't present with CHF for several months), we are considering common environmental factors which could precipitate DCM, including food contamination or toxin exposure.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 2

Product Name	Lot Number or ID	Best By Date
Alternated between: -California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils and Kangaroo & Red Lentils Recipe		

Sender information

Darcy Adin
1060 William Moore Dr
Raleigh, NY 27607
USA

Owner information

B6

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

<https://eon.fda.gov/eon//browse/EON-323515>

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=338847>

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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.

From: Jones, Jennifer L </o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Jennifer.Jonesaa8>
To: 'Darcy Adin'
CC: Ceric, Olgica
Sent: 7/12/2017 11:02:55 AM
Subject: RE: Pet food concern

Thank you, Darcy.
We received the complaints on our end, and will be in touch about next steps.
Kind regards,
Jennifer

Jennifer Jones, DVM
Veterinary Medical Officer



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, July 11, 2017 5:44 PM
To: Jones, Jennifer L
Subject: Re: Pet food concern

Hi Jennifer,

I've submitted the reports through the portal - one for each dog. The numbers are:

2023230 (I) for **B6**
2023228 (I) for **B6**

I've also attached the visit summaries for **B6** (2) and **B6** (1) as well as **B6** necropsy report. I have the biological samples stored at -80 and also have food samples.

Thank you so much for your help and I'll look forward to hearing from you or someone on your team!

Take care

Darcy

On Tue, Jul 11, 2017 at 7:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I can chat today from 11-1pm or or 2-3pm.

Jen

Jennifer Jones, DVM
Veterinary Medical Officer



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, July 10, 2017 6:47 PM
To: Jones, Jennifer L
Cc: Reimschuessel, Renate; **B6**

Subject: Re: Pet food concern

Thank you Dr. Jones! I'm sorry I am just reading email now so I have missed you! I'd love to chat with you about the cases. I am on clinics this week but can try to call you if you have another block of time tomorrow (or later this week). My number is [B6] or I can be paged from [B6]

Thank you!

Darcy

On Jul 10, 2017, at 1:05 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hello Dr. Adin,

Please let me know if you'd like to chat about the case this afternoon. I'll be in the office from 1-3pm (tel: [240-402-5421](tel:240-402-5421)).

If you suspect an animal's illness may be due to the food, you can submit a report at www.safetyreporting.hhs.gov

Please mention Vet-LIRN encouraged you to submit a report. Please email me the ICSR number (similar to a confirmation number), so I can find the report on my end.

Thank you,

Jennifer

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image004.png](#)>

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

Sent: Monday, July 10, 2017 11:31 AM

To: [B6]

Cc: Jones, Jennifer L; Reimschuessel, Renate

Subject: Re: Pet food concern

Thank you! I will work on this submission later today. I appreciate your help!

On Mon, Jul 10, 2017 at 10:49 AM, [B6] wrote:
Hi Dr. Adin,

As we discussed this morning, one avenue to explore your concern about pet food contamination (toxin or infectious disease) is the FDA program. Here is a website that highlights how you can report a complaint.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

[B6]

[B6]

B6

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
919-513-6032

From: Jones, Jennifer L </o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Jennifer.Jonesaa8>
To: Rotstein, David; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
CC: Ceric, Olgica
Sent: 7/18/2017 12:17:39 PM
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

Ok, thanks, Dave. I'll check with the vet if seafood fed and will plan to test [B5]

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David
Sent: Thursday, July 13, 2017 2:54 PM
To: Jones, Jennifer L; Palmer, Lee Anne; Reimschuessel, Renate; Queen, Jackie L; Carey, Lauren
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

I think testing is worth pursuing. Oddball question, [B5]

I was thinking of the [B5] [B5]

This would highly unlikely, but wanted to put it out there.

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: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: July 13, 2017 at 2:44:24 PM EDT
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers-EON-323515-323519

We could test for [B5] in food, what does the group think? Any additional testing? Is it worth

testing the [B5]?

Medical Record Review:

[B6]

Presenting complaint: [B6]: dyspnea, cough of 3 week duration-wheezing type more frequent at night rDVM, treated w/ [B6] for kennel cough 1/30 inappetance, vomiting à [B6] dyspneic and recheck, hospitalized and treated for pneumonia, regurgitated à [B6] treated as outpatient, [B6] as syring feeding, dog regurgitated and had marked dyspnea ER à refer to NCSU à [B6] put on mechanical ventilator à [B6] euthanized

PE [B6] P 160 bpm, R 64 rpm, pale pink mm, Gr [B6] left apical systolic murmur, femoral pulse hypokinetic but synchronous, jugular venous distention

B6

B6

tFAST **B6** severe cardiomegaly with ventricular hypocontractility

Echo **B6** dcm vs. myocarditis vs pacing induce vs. other (severely dilated & hypocontractile left & right ventricles, severely dilated left and right atria)

Necropsy: Lung-severe diffuse alveolar injury with marked fibrin deposition (hyaline) and marked alveolar histiocytosis and multifocal type II pneumocyte hyperplasia; mod to marked diffuse pulmonary edema; mild cardiomegaly with mild mitral valve endocardiosis and mild left ventricular hypertrophy and left atrial dilation; thorax with mild pleural effusion; Suspect primary non-cardiogenic etiology but if clinical cardiac dysfunction then functional cardiac abnormalities cannot be ruled out

Prior MHx: coffee brown urine including clumping after strenuous activity when it is hot outside and resolves with 24-36 hours; also Crystalluria

B6

Presented **B6**: episodes of collapse, first occurred mid February, fall 6 seconds without losing consciousnessà immediately return to normal à2 weeks later again collapse, then on à 6/3 post 2 hour hike collapsed again; panting more than usual; good appetite for treats but reluctant to eat food since February;à recheck 7/10, doing better, no collapsing episodes except a stumbling moment when excited, respiratory rate normal, diet changed to Hill's

B6

B6

B6 Rads: left sided congestive heart failure

-7/10: moderate left sided cardiomegaly without heart failure, moderate hepatomegaly

B6 Echo: mitral valve endocardiosis with left atrial enlargement and heart failure, decreased left ventricular systolic function, suspected DCM

Thoughts: possible **B5**

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Rotstein, David

Sent: Tuesday, July 11, 2017 12:44 PM

To: Jones, Jennifer L; Reimschuessel, Renate; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L

Cc: Ceric, Olgica

Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Jen,

B5

so I don't think that could be ruled out.

I do like the exploration of other causes.

d.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place, RM 120
240-402-5613 (Office) (NEW NUMBER)
240-506-6763 (BB)



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From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 12:41 PM
To: Reimschuessel, Renate; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Yes, and also, vet talked to [B4] who said there was [B4] in this food... but that doesn't rule out treats.

[B5]
[B5]
[B5]

Jennifer Jones, DVM
Veterinary Medical Officer



From: Reimschuessel, Renate
Sent: Tuesday, July 11, 2017 11:51 AM
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica
Subject: RE: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Davis may be able to screen for [B5]

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

From: Jones, Jennifer L
Sent: Tuesday, July 11, 2017 11:38 AM
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L
Cc: Ceric, Olgica; Reimschuessel, Renate
Subject: Head's up-potential DCM case-Dr. Adin-NCSU-2 Schnauzers

Vet will submit PFR online à
2 dogs-unrelated miniature schnauzers

Dog 1: 2 yr à presented 2/2017 with fulminant CHFà severe DCM on echo, taurine/carnitine normal, infectious disease testing negative, died on the ventilator, necropsy done-myocardial changes were subtle but could be similar to moldy corn toxicity in pigsà plasma, urine, serum, and myocardial tissue available

Dog 2: 7 yr, had a syncopal episode ~2/2017 but presented to vet for progressive frequency of syncopal episodesà 6/2017 for CHF, diagnosed with DCM similar to housemate, nearly same image on Echo, taurine/carnitine normal, infectious disease testing negative, they have changed the diet (Hill's) and dog is responding to treatment; plasma, urine, and serum available

Dogs were eating California Naturals (different bag than from 2/2017) and treats (Milo's Kitchen); Vet has samples of food and treats

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
Laurel, Maryland 20708
new tel: 240-402-5421
fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



From: Jones, Jennifer L </o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Jennifer.Jonesaa8>
To: [B6]
CC: Ceric, Olgica
Sent: 7/18/2017 12:39:11 PM
Subject: Vet-LIRN request for open product [B5] testing (800.218)
Attachments: 800.218-Medical Record Review.doc; EON-323515 [B6] Calif Naturals-dog 1.pdf; EON-323519 [B6] Calif Naturals-dog 2.pdf

Good morning [B6]

Vet-LIRN received a report about two genetically unrelated Miniature Schnauzer dogs in the same household that may have developed Dilated cardiomyopathy after eating a dog food. The complaints and a medical record summary are attached.

We'd like to request open dog food testing for [B5]

Please let me know if you're able to do the testing.

Please also plan to bill the Vet-LIRN infrastructure grant for the testing.

Thank you kindly,
Jen

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
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fax: 301-210-4685
e-mail: jennifer.jones@fda.hhs.gov
Web: <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>



Report Details - EON-323515

ICSR: 2023228
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2017-07-11 17:06:59 EDT

Reported Problem:
Problem Description: Please note: Dr. Jennifer Jones was consulted prior to submission of this report. She would like to be involved in the case review. 3 week history of cough treated unsuccessfully with B6. 3 day history of inappetence and vomiting prior to presentation to B6 emergency service for dyspnea. Radiographs showed severe pulmonary edema and echocardiogram showed severe Dilated Cardiomyopathy. There was an initial response to B6 therapy however, he declined and was placed on the ventilator for respiratory support and continued CHF treatment. Attempts to wean off the ventilator were unsuccessful and aquaphoresis was performed. He continued to decline despite aggressive therapy and was euthanized. Infectious disease testing was negative and taurine and carnitine analysis showed adequate levels. Necropsy initially did not reveal a cause for DCM and supported alveolar injury (possibly ventilator related). A re-

B6

B6 had been fed California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils and Kangaroo & Red Lentils Recipe along with Milo's kitchen treats. We have samples of these foods from 6/17 but not the original bags from when he was presented 2/17. These samples were provided at the time his housemate B6 (unrelated, older miniature schnauzer) also presented with severe DCM and CHF. I will enter this dog as a separate affected patient. Both dogs had extensive infectious disease testing which was negative and nutritional amino acid deficiencies were ruled out. Because of this, their unrelated lineages (although the same breed, they were from different lines), different ages but similar time of presentation, B6 had clinical signs at the time B6 was treated, but didn't present with CHF for several months), we are considering common environmental factors which could precipitate DCM, including food contamination or toxin exposure.

Date Problem Started: B6
Concurrent Medical Problem: No
Outcome to Date: Died Euthanized
Date of Death: B6

Product Information:
Product Name: Alternated between: -California Natural Adult Limited Ingredient Grain Free Venison & Green Lentils and Kangaroo & Red Lentils Recipe
Product Type: Pet Food
Lot Number:
UPC: not available
Package Type: BAG
Package Size: 26 Pound
Purchase Date: 06/01/2017
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: In a cabinet, in the original bag
Product Use Information:
Description: twice daily feeding The sample we have is from 6/17, however, we do not have food samples from 2/17 when both dogs started with clinical signs.
Time Interval between Product: 2 Years

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

Manufacturer /Distributor Information:	
Purchase Location Information:	Address: United States

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Schnauzer - Miniature
Gender:	Male
Reproductive Status:	Neutered
Weight:	8.2 Kilogram
Age:	B6 years
Assessment of Prior Health:	Excellent
Number of Animals Given the Product:	2
Number of Animals Reacted:	2
Owner Information:	Owner Information provided: Yes
Contact:	Name: B6 Phone: B6 Email: B6
Address:	B6 United States

Healthcare Professional Information:	Practice Name:	North Carolina State University, College of Veterinary Medicine
	Contact:	Name: Darcy Adin Phone: (919) 513-6694 Other Phone: B6 Email: dbadin@ncsu.edu
	Address:	1060 William Moore Dr Raleigh New York 27607 United States
	Practice Name:	North Carolina State University College of Veterinary Medici
	Contact:	Name: B6 Phone: 9195136694

		Other Phone:	B6
	Practice Name:	North Carolina state University, College of Veterinary Medic	
	Contact:	Name:	B6
		Phone:	
		Other Phone:	

Sender Information:	Name:	Darcy Adin	
	Address:	1060 William Moore Dr Raleigh New York 27607 United States	
	Contact:	Phone:	9195136694
		Other Phone:	B6
		Email:	dbadin@ncsu.edu
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email		
Reported to Other Parties:	Manufacturer		

Additional Documents:

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 7/18/2017 1:10:06 PM
Subject: Re: Pet food concern (800.218)
Attachments: [B5] toxicity dcm.pdf

Dear Dr. Jones,

Thank you for your follow up! I will contact the owner about potential seafood ingestion. We have a sample of the food in a plastic container in the refrigerator. It weighs 340 g and is 6.5" x 3" x 5".

Also, I don't know if it would be possible to test the food (or our biological samples) for [B5] - I've attached a paper showing its association with DCM in mice through oral ingestion. [B5]

[B5]

Thank you!
Darcy

On Tue, Jul 18, 2017 at 8:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Dr. Adin,

After reviewing the complaint and medical records, we'd like to request the following:

· Please check with the owner/confirm that no anchovies/sardines/seafood were fed (either in February 2017 or consistently) [B5]

· Collect open bag of California Naturals food to test for [B5]

- o Please email me the size/weight of the food.
- o We will send you an empty box with a prepaid shipping label to send the product back to our lab.
- o After we test the product, we'll send you the results to share with the owner.

After I get the size/weight of the food, I'll send the box.

Thank you for helping with the case.

Jennifer

Jennifer Jones, DVM

Veterinary Medical Officer



From: Darcy Adin [mailto:dbadin@ncsu.edu]

Sent: Tuesday, July 11, 2017 5:44 PM
To: Jones, Jennifer L
Subject: Re: Pet food concern

Hi Jennifer,

I've submitted the reports through the portal - one for each dog. The numbers are:

2023230 (I) for [B6]
2023228 (I) for [B6]

I've also attached the visit summaries for [B6] (2) and [B6] (1) as well as [B6] necropsy report. I have the biological samples stored at -80 and also have food samples.

Thank you so much for your help and I'll look forward to hearing from you or someone on your team!

Take care

Darcy

On Tue, Jul 11, 2017 at 7:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I can chat today from 11-1pm or or 2-3pm.

Jen

Jennifer Jones, DVM

Veterinary Medical Officer



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Monday, July 10, 2017 6:47 PM
To: Jones, Jennifer L

Cc: Reimschuessel, Renate

B6

Subject: Re: Pet food concern

Thank you Dr. Jones! I'm sorry I am just reading email now so I have missed you! I'd love to chat with you about the cases. I am on clinics this week but can try to call you if you have another block of time tomorrow (or later this week). My number is **B6** or I can be paged from **B6**

Thank you!

Darcy

On Jul 10, 2017, at 1:05 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hello Dr. Adin,

Please let me know if you'd like to chat about the case this afternoon. I'll be in the office from 1-3pm (tel: [240-402-5421](tel:240-402-5421)).

If you suspect an animal's illness may be due to the food, you can submit a report at www.safetyreporting.hhs.gov

Please mention Vet-LIRN encouraged you to submit a report. Please email me the ICSR number (similar to a confirmation number), so I can find the report on my end.

Thank you,

Jennifer

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image004.png](#)>

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

Sent: Monday, July 10, 2017 11:31 AM

To: **B6**

Cc: Jones, Jennifer L; Reimschuessel, Renate

Subject: Re: Pet food concern

Thank you! I will work on this submission later today. I appreciate your help!

On Mon, Jul 10, 2017 at 10:49 AM, **B6** wrote:

Hi Dr. Adin,

As we discussed this morning, one avenue to explore your concern about pet food contamination (toxin or infectious disease) is the FDA program. Here is a website that highlights how you can report a complaint.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

B6

B6

--

Darcy B. Adin, DVM, DACVIM (Cardiology)

Clinical Assistant Professor of Cardiology

North Carolina State University

NC State Veterinary Hospital

1060 William Moore Drive

Raleigh, NC 27607

919-513-6032

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North Carolina State University

NC State Veterinary Hospital

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Raleigh, NC 27607

919-513-6032

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 8/18/2017 2:37:43 PM
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

I'm not sure what timeline to expect so forgive me if this premature, but I wanted to check in to see if you have any information about the cases yet?

Thanks!
Darcy Adin

On Jul 28, 2017, at 9:18 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

This is great information to add to the case. Thank you, Darcy.

Jennifer Jones, DVM
Veterinary Medical Officer



From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, July 26, 2017 9:39 PM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Jennifer,

I don't know if there is anything to this but I have treated 2 other dogs in the last 2 weeks with DCM and CHF that are being fed California natural food (one kangaroo and lentil, and we are trying to find out about the other one which is in our ER now). One is mixed breed and we'll recommend testing for taurine deficiency. The other was a golden and taurine was a bit low but not super low so although we supplemented, I wasn't totally convinced it was the cause. Unfortunately she died a week later.

I don't have a sense for how widely fed this diet is but I don't see it on the top selling lists I can find by google, so seeing 4 DCM dogs recently eating this particular food is interesting to say the least. I thought this might be of interest to you as you start to look at the California natural food sample from the B6 dogs.

Thank you!
Darcy

On Jul 26, 2017, at 8:08 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy. One way I've seen veterinarians handle the reimbursement for other cases is posting the amount to the patient's chart, leaving a balance of the shipping charges. In those cases, our accountant then called and paid the shipping charge balance on the account.

Jennifer Jones, DVM
Veterinary Medical Officer

<image001.png> <image002.png>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, July 26, 2017 7:42 AM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones

We included the invoice in the package. There was a fair bit of discussion here because I don't think there will be an easy way to reimburse - so probably don't worry about it!

Thank you!

Darcy

On Jul 26, 2017, at 6:32 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Excellent. Thank you, Darcy. Please email or fax an invoice so we can reimburse you for the shipping.

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image003.png>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, July 25, 2017 10:36 PM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Thank you Dr. Jones!

It went out tonight by FedEx tonight. I'll look forward to hearing from you soon.

Take care

Darcy

On Tue, Jul 25, 2017 at 10:48 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I spoke with my colleague. If you can, please return ship the box using FedEx or your preferred carrier. You'll ship the box for overnight delivery on a Monday-Wednesday. Please ship to:

Attention: Jennifer Jones
8401 Muirkirk Rd
Laurel, MD 20708

After you return ship the box, please email or fax ([301-210-4685](tel:301-210-4685)) an invoice for the shipping charges. We can then call NCSU and reimburse with our VISA information.

Please let me know if you have questions.

Thank you again for your patience,

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image005.png>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, July 25, 2017 10:30 AM

To: Jones, Jennifer L

Cc: Ceric, Olgica

Subject: Re: Pet food concern (800.218)

thanks!

On Tue, Jul 25, 2017 at 8:45 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I'm sorry for the trouble getting the label. I'm going to reach out to my colleague to get one made for you. I'll send it via email. If that doesn't work, then we can go with FedEx.

Thank you for the update, and sorry for the trouble with the label,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image008.png](#)>

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

Sent: Monday, July 24, 2017 3:31 PM

To: Jones, Jennifer L

Subject: Re: Pet food concern (800.218)

Hi Jen,

The shipping box arrived this afternoon, however, we don't see a return shipping label. Our shipping and receiving staff suggested that FedEx might be better since with UPS pick up, we can't control how much time the package may be sitting in the heat. I'm happy to send however you would recommend though!

Thank you!

Darcy

On Fri, Jul 21, 2017 at 12:47 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

The package will ship today and arrive Monday. UPS said they will give you a return shipping label. For some reason, we were unable to put it in the shipping box we sent to you. UPS, however, has assured us they will give you the label Monday. Please let me know if you do not get that label, because I'll need to get you one.

Thank you,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image009.png](#)>

From: Jones, Jennifer L

Sent: Wednesday, July 19, 2017 1:04 PM

To: 'Darcy Adin'

Cc: Ceric, Olgica

Subject: RE: Pet food concern (800.218)

Excellent. Thank you, Darcy. We'll ship the kit to your office to collect the food. It will contain the return shipping label for use with the box.

The box should arrive for you by close of business Tuesday (7/25).

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image008.png](#)>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, July 18, 2017 9:59 PM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

The owner confirmed that neither dog has received anchovies, sardines or seafood in February or chronically.
Thank you!
Darcy

On Jul 18, 2017, at 8:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Dr. Adin,
After reviewing the complaint and medical records, we'd like to request the following:

- Please check with the owner/confirm that no anchovies/sardines/seafood were fed (either in February 2017 or consistently) [B5]
- Collect open bag of California Naturals food to test for [B5]
 - o Please email me the size/weight of the food.
 - o We will send you an empty box with a prepaid shipping label to send the product back to our lab.
 - o After we test the product, we'll send you the results to share with the owner.

After I get the size/weight of the food, I'll send the box.
Thank you for helping with the case,
Jennifer

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image003.png>

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Sent: Tuesday, July 11, 2017 5:44 PM
To: Jones, Jennifer L
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Hi Jennifer,

I've submitted the reports through the portal - one for each dog. The numbers are:
2023230 (I) for [B6]
2023228 (I) for [B6]

I've also attached the visit summaries for [B6] (2) and [B6] (1) as well as [B6] necropsy report. I have the biological samples stored at -80 and also have food samples.

Thank you so much for your help and I'll look forward to hearing from you or someone on your team!
Take care
Darcy

On Tue, Jul 11, 2017 at 7:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,
I can chat today from 11-1pm or or 2-3pm.
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image010.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, July 10, 2017 6:47 PM
To: Jones, Jennifer L
Cc: Reimschuessel, Renate; [B6]

Subject: Re: Pet food concern

Thank you Dr. Jones! I'm sorry I am just reading email now so I have missed you! I'd love to chat with you about the cases. I am on clinics this week but can try to call you if you have another block of time tomorrow (or later this week). My number is [B6] or I can be paged from [B6]
Thank you!
Darcy

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Hello Dr. Adin,
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Please mention Vet-LIRN encouraged you to submit a report. Please email me the ICSR number (similar to a confirmation number), so I can find the report on my end.
Thank you,
Jennifer

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image004.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, July 10, 2017 11:31 AM
To: [B6]
Cc: Jones, Jennifer L; Reimschuessel, Renate
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We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

B6

B6

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From: Jones, Jennifer L </o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Jennifer.Jonesaa8>
To: 'Darcy Adin'
CC: Ceric, Olgica
Sent: 8/22/2017 11:37:29 AM
Subject: RE: Pet food concern (800.218)
Attachments: 800.218-TAMU [B5] neg.pdf

Good morning Dr. Adin,
We received results of the product testing for [B5] those were negative. Please see the attached. The results for the [B5] and taurine are in progress. I'll forward along as soon as possible.
Thank you for your patience,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Friday, August 18, 2017 10:38 AM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

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Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image002.png](#)>

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<[image001.png](#)> <[image003.png](#)>

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Veterinary Medical Officer
<[image001.png](#)> <[image005.png](#)>

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

Sent: Tuesday, July 25, 2017 10:30 AM

To: Jones, Jennifer L

Cc: Ceric, Olgica

Subject: Re: Pet food concern (800.218)

thanks!

On Tue, Jul 25, 2017 at 8:45 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I'm sorry for the trouble getting the label. I'm going to reach out to my colleague to get one made for you. I'll send it via email. If that doesn't work, then we can go with FedEx.

Thank you for the update, and sorry for the trouble with the label,

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image008.png](#)>

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

Sent: Monday, July 24, 2017 3:31 PM

To: Jones, Jennifer L

Subject: Re: Pet food concern (800.218)

Hi Jen,

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Jennifer Jones, DVM
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<image001.png> <image009.png>

From: Jones, Jennifer L
Sent: Wednesday, July 19, 2017 1:04 PM
To: 'Darcy Adin'
Cc: Ceric, Olgica
Subject: RE: Pet food concern (800.218)

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The box should arrive for you by close of business Tuesday (7/25).

Jen

Jennifer Jones, DVM
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From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, July 18, 2017 9:59 PM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

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The owner confirmed that neither dog has received anchovies, sardines or seafood in February or chronically.
Thank you!
Darcy

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Good morning Dr. Adin,
After reviewing the complaint and medical records, we'd like to request the following:

- Please check with the owner/confirm that no anchovies/sardines/seafood were fed (either in February 2017 or consistently). B5
injury.
- Collect open bag of California Naturals food to test for B5
 - Please email me the size/weight of the food.
 - We will send you an empty box with a prepaid shipping label to send the product back to our lab.
 - After we test the product, we'll send you the results to share with the owner.

After I get the size/weight of the food, I'll send the box.
Thank you for helping with the case,
Jennifer

Jennifer Jones, DVM
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<image001.png> <image003.png>

From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, July 11, 2017 5:44 PM
To: Jones, Jennifer L
Subject: Re: Pet food concern

Hi Jennifer,

I've submitted the reports through the portal - one for each dog. The numbers are:
2023230 (I) for [B6]
2023228 (I) for [B6]

I've also attached the visit summaries for [B6] (2) and [B6] (1) as well as [B6] necropsy report. I have the biological samples stored at -80 and also have food samples.

Thank you so much for your help and I'll look forward to hearing from you or someone on your team!
Take care
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On Tue, Jul 11, 2017 at 7:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:
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I can chat today from 11-1pm or or 2-3pm.
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From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Monday, July 10, 2017 6:47 PM
To: Jones, Jennifer L
Cc: Reimschuessel, Renate; [B6]

Subject: Re: Pet food concern

Thank you Dr. Jones! I'm sorry I am just reading email now so I have missed you! I'd love to chat with you about the cases. I am on clinics this week but can try to call you if you have another block of time tomorrow (or later this week). My number is [B6] or I can be paged from [B6]
Thank you!
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Please let me know if you'd like to chat about the case this afternoon. I'll be in the office from 1-3pm (tel: [240-402-5421](tel:240-402-5421)).

If you suspect an animal's illness may be due to the food, you can submit a report at www.safetyreporting.hhs.gov

Please mention Vet-LIRN encouraged you to submit a report. Please email me the ICSR number (similar to a

confirmation number), so I can find the report on my end.

Thank you,
Jennifer

Jennifer Jones, DVM
Veterinary Medical Officer
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From: Darcy Adin [mailto:dbadin@ncsu.edu]
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To: [REDACTED]
Cc: Jones, Jennifer L; Reimschuessel, Renate
Subject: Re: Pet food concern

Thank you! I will work on this submission later today. I appreciate your help!

On Mon, Jul 10, 2017 at 10:49 AM, [REDACTED] wrote:
Hi Dr. Adin,

As we discussed this morning, one avenue to explore your concern about pet food contamination (toxin or infectious disease) is the FDA program. Here is a website that highlights how you can report a complaint.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

[REDACTED]

[REDACTED]

--
Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
Raleigh, NC 27607
[919-513-6032](tel:919-513-6032)

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Texas A&M Veterinary Medical Diagnostic Laboratory
 483 Agronomy Road
 College Station TX 77840
 Phone: (979) 845-3414 Fax: (979) 845-1794

Report Date: 8/4/2017

Final Report

Date Received: 8/4/2017

Case Coordinator: **B6**

Accession No: **B6**

JENNIFER JONES, DVM
 8401 MUIRKIRK RD.
 LAUREL MD 20708

Phone: (240) 402-5421
 Fax: (301) 210-4685
 Email: jennifer.jones@fda.hhs.gov

Associated Parties

Vet Practice	TAMU Veterinary Pathobiology	Account #:	B6	Attn:	B6
				TAMU, TX Brazos 77843-4467 (979) 845-5941	
	Jennifer Jones, DVM			8401 Muirkirk Rd. Laurel, MD 20708 (240) 402-5421	

Customer Requests

Specimens Submitted: 1 bag,
 Customer Test Request: Please test dog food product for **B5**

History

Please see previous email.

Lab Findings

Toxicology

Specimen	Test Name	Method	Basis	Toxicology Result	Units
Dog food - 800.218 - 1	B6	ELISA	As received basis	None Detected, < 5	ppm
B6 was not detected in this sample at the detection limit of 5 ppm. -- B6					
DABT, Veterinary Toxicologist: B6					

Client Report History

Report Type	Delivery Method	Sent To	Date Sent
Final	Email	jennifer.jones@fda.hhs.gov	8/4/2017 3:59 PM

Accession Number **B6**

Final (8/4/2017)

Page 1 of 1

From: Darcy Adin <dbadin@ncsu.edu>
To: Jones, Jennifer L
Sent: 8/22/2017 12:16:50 PM
Subject: Re: Pet food concern (800.218)

Hi Jennifer

It was kangaroo. That's great about the [B5] We'll wait for the taurine and [B5] however I guess I'd be surprised if this was the answer since blood amino acid levels were adequate. Is there any other testing that can be done (e.g. [B5])

Thanks so much!

Darcy

On Aug 22, 2017, at 7:54 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

My apologies for the second email.

Which dry food (Kangaroo or Venison) was sent to us for the testing?

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image002.png](#)>

From: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 7:37 AM
To: 'Darcy Adin'
Cc: Ceric, Olgica
Subject: RE: Pet food concern (800.218)

Good morning Dr. Adin,

We received results of the product testing for [B5] those were negative. Please see the attached. The results for the [B5] and taurine are in progress. I'll forward along as soon as possible.

Thank you for your patience,

Jen

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<[image001.png](#)> <[image003.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Friday, August 18, 2017 10:38 AM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

I'm not sure what timeline to expect so forgive me if this premature, but I wanted to check in to see if you have any information about the cases yet?

Thanks!

Darcy Adin

On Jul 28, 2017, at 9:18 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

This is great information to add to the case. Thank you, Darcy.

Jennifer Jones, DVM
Veterinary Medical Officer
<image001.png> <image004.png>

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To: Jones, Jennifer L
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I don't have a sense for how widely fed this diet is but I don't see it on the top selling lists I can find by google, so seeing 4 DCM dogs recently eating this particular food is interesting to say the least. I thought this might be of interest to you as you start to look at the California natural food sample from the B6 dogs.

Thank you!
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Thank you, Darcy. One way I've seen veterinarians handle the reimbursement for other cases is posting the amount to the patient's chart, leaving a balance of the shipping charges. In those cases, our accountant then called and paid the shipping charge balance on the account.

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Veterinary Medical Officer
<image001.png> <image002.png>

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Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones

We included the invoice in the package. There was a fair bit of discussion here because I don't think there will be an easy way to reimburse - so probably don't worry about it!

Thank you!
Darcy

On Jul 26, 2017, at 6:32 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Excellent. Thank you, Darcy. Please email or fax an invoice so we can reimburse you for the shipping.

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Take care
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Hi Darcy,

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Attention: Jennifer Jones
8401 Muirkirk Rd
Laurel, MD 20708

After you return ship the box, please email or fax ([301-210-4685](tel:301-210-4685)) an invoice for the shipping charges. We can then call NCSU and reimburse with our VISA information.
Please let me know if you have questions.
Thank you again for your patience,
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B6

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1060 William Moore Drive
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From: Jones, Jennifer L </o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Jennifer.Jonesaa8>
To: 'Darcy Adin'
CC: Ceric, Olgica
Sent: 8/22/2017 12:20:21 PM
Subject: RE: Pet food concern (800.218)

Thank you for the quick response.

There aren't any test

B5

B5

Jennifer Jones, DVM
Veterinary Medical Officer



From: Darcy Adin [mailto:dbadin@ncsu.edu]
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Veterinary Medical Officer
<[image001.png](#)> <[image005.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, July 25, 2017 10:30 AM

To: Jones, Jennifer L

Cc: Ceric, Olgica

Subject: Re: Pet food concern (800.218)

thanks!

On Tue, Jul 25, 2017 at 8:45 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I'm sorry for the trouble getting the label. I'm going to reach out to my colleague to get one made for you. I'll send it via email. If that doesn't work, then we can go with FedEx.

Thank you for the update, and sorry for the trouble with the label,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image008.png](#)>

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

Sent: Monday, July 24, 2017 3:31 PM

To: Jones, Jennifer L

Subject: Re: Pet food concern (800.218)

Hi Jen,

The shipping box arrived this afternoon, however, we don't see a return shipping label. Our shipping and receiving staff suggested that FedEx might be better since with UPS pick up, we can't control how much time the package may be sitting in the heat. I'm happy to send however you would recommend though!

Thank you!

Darcy

On Fri, Jul 21, 2017 at 12:47 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good afternoon Darcy,

The package will ship today and arrive Monday. UPS said they will give you a return shipping label. For some reason, we were unable to put it in the shipping box we sent to you. UPS, however, has assured us they will give you the label Monday. Please let me know if you do not get that label, because I'll need to get you one.

Thank you,

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image009.png](#)>

From: Jones, Jennifer L

Sent: Wednesday, July 19, 2017 1:04 PM

To: 'Darcy Adin'

Cc: Ceric, Olgica

Subject: RE: Pet food concern (800.218)

Excellent. Thank you, Darcy. We'll ship the kit to your office to collect the food. It will contain the return shipping label for use with the box.

The box should arrive for you by close of business Tuesday (7/25).

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image008.png](#)>

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

Sent: Tuesday, July 18, 2017 9:59 PM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

The owner confirmed that neither dog has received anchovies, sardines or seafood in February or chronically.

Thank you!

Darcy

On Jul 18, 2017, at 8:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Good morning Dr. Adin,

After reviewing the complaint and medical records, we'd like to request the following:

· Please check with the owner/confirm that no anchovies/sardines/seafood were fed (either in February 2017 or consistently). [B5]

[B5]

· Collect open bag of California Naturals food to test for [B5]

- Please email me the size/weight of the food.
- We will send you an empty box with a prepaid shipping label to send the product back to our lab.
- After we test the product, we'll send you the results to share with the owner.

After I get the size/weight of the food, I'll send the box.

Thank you for helping with the case,

Jennifer

Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image003.png](#)>

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

Sent: Tuesday, July 11, 2017 5:44 PM

To: Jones, Jennifer L

Subject: Re: Pet food concern

Hi Jennifer,

I've submitted the reports through the portal - one for each dog. The numbers are:

2023230 (I) for [B6]
2023228 (I) for [B6]

I've also attached the visit summaries for [B6] (2) and [B6] (1) as well as [B6] necropsy report. I have the biological samples stored at -80 and also have food samples.

Thank you so much for your help and I'll look forward to hearing from you or someone on your team!

Take care

Darcy

On Tue, Jul 11, 2017 at 7:33 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I can chat today from 11-1pm or or 2-3pm.

Jen

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image010.png](#)>

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

Sent: Monday, July 10, 2017 6:47 PM

To: Jones, Jennifer L

Cc: Reimschuessel, Renate; B6

Subject: Re: Pet food concern

Thank you Dr. Jones! I'm sorry I am just reading email now so I have missed you! I'd love to chat with you about the cases. I am on clinics this week but can try to call you if you have another block of time tomorrow (or later this week). My number is: B6 or I can be paged from B6

Thank you!

Darcy

On Jul 10, 2017, at 1:05 PM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hello Dr. Adin,

Please let me know if you'd like to chat about the case this afternoon. I'll be in the office from 1-3pm (tel: [240-402-5421](tel:240-402-5421)).

If you suspect an animal's illness may be due to the food, you can submit a report at www.safetyreporting.hhs.gov

Please mention Vet-LIRN encouraged you to submit a report. Please email me the ICSR number (similar to a confirmation number), so I can find the report on my end.

Thank you,

Jennifer

Jennifer Jones, DVM

Veterinary Medical Officer

<[image001.png](#)> <[image004.png](#)>

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

Sent: Monday, July 10, 2017 11:31 AM

To: B6

Cc: Jones, Jennifer L; Reimschuessel, Renate

Subject: Re: Pet food concern

Thank you! I will work on this submission later today. I appreciate your help!

On Mon, Jul 10, 2017 at 10:49 AM, B6 wrote:

Hi Dr. Adin,

As we discussed this morning, one avenue to explore your concern about pet food contamination (toxin or infectious disease) is the FDA program. Here is a website that highlights how you can report a complaint.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>

We work with the FDA Vet-LIRN program on diagnostics from the pet side, but they agree to include the case in the program and would coordinate with us (or another laboratory). I have copied Dr. Jones and Dr. Reimschuessel here - they can help let us know the process to see if these cases are eligible.

Regards,

B6

B6

--

Darcy B. Adin, DVM, DACVIM (Cardiology)
Clinical Assistant Professor of Cardiology
North Carolina State University
NC State Veterinary Hospital
1060 William Moore Drive
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1060 William Moore Drive
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919-513-6032

From: Jones, Jennifer L </o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Jennifer.Jonesaa8>
To: 'Darcy Adin'
CC: Ceric, Olgica
Sent: 8/22/2017 12:45:53 PM
Subject: RE: Pet food concern (800.218)
Attachments: 800.218-Covance-Taurine-Carnitine.pdf

We evaluated the taurine/carnitine results based on the "Kangaroo" protein variety. The results are attached. In short, the taurine was 0.26% (on DMB calculated using label moisture max) and the carnitine was 0.0077% (on DMB calculated using label moisture max). There are no AAFCO minimums for taurine and carnitine. However, there is an AAFCO minimum for taurine only in cats: 0.1% for extruded foods.

The cause of the two dogs' DCM is unclear. The bloodwork for these dogs showed normal taurine and carnitine levels. Based on the dogs' blood taurine/carnitine levels and the dry dog food test results, it is unlikely that **B5** taurine, or carnitine caused the dogs' illness.

At this time we will not request any further testing. Thank you very much for all your help with the case. Please let me know if you have any additional questions or any future animal food related illness concerns.

Jen

Jennifer Jones, DVM
Veterinary Medical Officer



From: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 8:20 AM
To: 'Darcy Adin'
Cc: Ceric, Olgica
Subject: RE: Pet food concern (800.218)

Thank you for the quick response.

There aren't any tests for: **B5**

Jennifer Jones, DVM
Veterinary Medical Officer



From: Darcy Adin [mailto:dbadin@ncsu.edu]
Sent: Tuesday, August 22, 2017 8:17 AM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Jennifer

It was kangaroo. That's great about the [B5] We'll wait for the taurine and [B5] however I guess I'd be surprised if this was the answer since blood amino acid levels were adequate. Is there any other testing that can be done (e.g. [B5]?)

Thanks so much!

Darcy

On Aug 22, 2017, at 7:54 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

My apologies for the second email.

Which dry food (Kangaroo or Venison) was sent to us for the testing?

Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image002.png](#)>

From: Jones, Jennifer L
Sent: Tuesday, August 22, 2017 7:37 AM
To: 'Darcy Adin'
Cc: Ceric, Olgica
Subject: RE: Pet food concern (800.218)

Good morning Dr. Adin,
We received results of the product testing for [B5] those were negative. Please see the attached. The results for the [B5] and taurine are in progress. I'll forward along as soon as possible.
Thank you for your patience,
Jen

Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image003.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Friday, August 18, 2017 10:38 AM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones,

I'm not sure what timeline to expect so forgive me if this premature, but I wanted to check in to see if you have any information about the cases yet?

Thanks!
Darcy Adin

On Jul 28, 2017, at 9:18 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

This is great information to add to the case. Thank you, Darcy.

Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image004.png](#)>

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

Sent: Wednesday, July 26, 2017 9:39 PM
To: Jones, Jennifer L
Subject: Re: Pet food concern (800.218)

Hi Jennifer,

I don't know if there is anything to this but I have treated 2 other dogs in the last 2 weeks with DCM and CHF that are being fed California natural food (one kangaroo and lentil, and we are trying to find out about the other one which is in our ER now). One is mixed breed and we'll recommend testing for taurine deficiency. The other was a golden and taurine was a bit low but not super low so although we supplemented, I wasn't totally convinced it was the cause. Unfortunately she died a week later.

I don't have a sense for how widely fed this diet is but I don't see it on the top selling lists I can find by google, so seeing 4 DCM dogs recently eating this particular food is interesting to say the least. I thought this might be of interest to you as you start to look at the California natural food sample from the B6 dogs.

Thank you!
Darcy

On Jul 26, 2017, at 8:08 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Thank you, Darcy. One way I've seen veterinarians handle the reimbursement for other cases is posting the amount to the patient's chart, leaving a balance of the shipping charges. In those cases, our accountant then called and paid the shipping charge balance on the account.

Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image002.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Wednesday, July 26, 2017 7:42 AM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Hi Dr. Jones

We included the invoice in the package. There was a fair bit of discussion here because I don't think there will be an easy way to reimburse - so probably don't worry about it!

Thank you!
Darcy

On Jul 26, 2017, at 6:32 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Excellent. Thank you, Darcy. Please email or fax an invoice so we can reimburse you for the shipping.

Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image003.png](#)>

From: Darcy Adin [<mailto:dbadin@ncsu.edu>]
Sent: Tuesday, July 25, 2017 10:36 PM
To: Jones, Jennifer L
Cc: Ceric, Olgica
Subject: Re: Pet food concern (800.218)

Thank you Dr. Jones!

It went out tonight by FedEx tonight. I'll look forward to hearing from you soon.

Take care

Darcy

On Tue, Jul 25, 2017 at 10:48 AM, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov> wrote:

Hi Darcy,

I spoke with my colleague. If you can, please return ship the box using FedEx or your preferred carrier. You'll ship the box for overnight delivery on a Monday-Wednesday. Please ship to:

Attention: Jennifer Jones
8401 Muirkirk Rd
Laurel, MD 20708

After you return ship the box, please email or fax ([301-210-4685](tel:301-210-4685)) an invoice for the shipping charges. We can then call NCSU and reimburse with our VISA information.

Please let me know if you have questions.

Thank you again for your patience,

Jen

Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image005.png](#)>

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

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To: Jones, Jennifer L

Cc: Ceric, Olgica

Subject: Re: Pet food concern (800.218)

thanks!

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Hi Darcy,

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Thank you for the update, and sorry for the trouble with the label,

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Jennifer Jones, DVM
Veterinary Medical Officer
<[image001.png](#)> <[image008.png](#)>

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Sent: Monday, July 24, 2017 3:31 PM

To: Jones, Jennifer L

Subject: Re: Pet food concern (800.218)

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The shipping box arrived this afternoon, however, we don't see a return shipping label. Our shipping and receiving staff suggested that FedEx might be better since with UPS pick up, we can't control how much time the package may be sitting in the heat. I'm happy to send however you would recommend though!

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Veterinary Medical Officer

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Cc: Ceric, Olgica

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Thank you!

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Good morning Dr. Adin,

After reviewing the complaint and medical records, we'd like to request the following:

· Please check with the owner/confirm that no anchovies/sardines/seafood were fed (either in February 2017 or consistently) B5

B5

· Collect open bag of California Naturals food to test for B5

○ Please email me the size/weight of the food.

○ We will send you an empty box with a prepaid shipping label to send the product back to our

lab.

- After we test the product, we'll send you the results to share with the owner.

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Regards,

B6

B6

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1060 William Moore Drive
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919-513-6032

Certificate of Analysis

Food and Drug Administration - CVM - Invoice Denise Durham

8401 Muirkirk Rd.
Laurel Maryland 20708 United States

Sample Name:	800.218	Covance Sample:	6406524
Project ID	FDA_CVM-20170804-0007	Receipt Date	04-Aug-2017
PO Number	HHSF223201610005I/HHSF22301002T	Receipt Condition	Ambient temperature
Sample Serving Size	100 g	Login Date	04-Aug-2017
		Online Order	20

Analysis	Result
L-Carnitine *	
L-Carnitine	69900 ppb
Taurine	
Taurine	231 mg/Serving Size

Method References	Testing Location
-------------------	------------------

L-Carnitine (CARNITNE_S) Covance Laboratories - Madison
 STAREY ET AL.: JOURNAL OF AOAC INTERNATIONAL VOL. 91, NO.1, 2008. (Modified).

Taurine (TAUR_LC_S) Covance Laboratories - Madison
 R. Schuster, "Determination of Amino Acids in Biological, Pharmaceutical, Plant and Food Samples by Automated Precolumn Derivatization and HPLC", Journal of Chromatography., 1988, 431, 271-284, Henderson, J.W., Ricker, R.D. Bidlingmeyer, B.A., Woodward, C., "Rapid, Accurate, Sensitive, and Reproducible HPLC Analysis of Amino Acids, Amino Acid Analysis Using Zorbax Eclipse-AAA columns and the Agilent 1100 HPLC," Agilent Publication, 2000, and Barkholt and Jensen, , "Amino Acid Analysis: Determination of Cysteine plus Half-Cystine in Proteins after Hydrochloric Acid Hydrolysis with a Disulfide Compound as Additive," Analytical Biochemistry, 177, 318-322 (1989).

Testing Location(s)	Released on Behalf of Covance by
---------------------	----------------------------------

Covance Laboratories - Madison

Edward Ladwig - Director

Covance Laboratories Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375



2918.01

These results apply only to the items tested. This certificate of analysis shall not be reproduced, except in its entirety, without the written approval of Covance.

* This analysis is not ISO accredited.

B6

B6



FAU Institutional Repository

<http://purl.fcla.edu/fau/fair>

This paper was submitted by the faculty of FAU's Harbor Branch Oceanographic Institute

Notice: This article was published by the European Association for Aquatic Mammals <http://www.aquaticmammalsjournal.org/> and may be cited as Bossart, Gregory D. , George Hensley, Juli D. Goldstein, Kenny Kroell, Charles A. Manire, R. H. Defran, and John S. Reif (2007) Cardiomyopathy and Myocardial Degeneration in Stranded Pygmy (*Kogia breviceps*) and Dwarf (*Kogia sima*) Sperm Whales, *Aquatic Mammals* 33(2) 214-222, DOI: 10.1578/AM.33.2.2007.214

Cardiomyopathy and Myocardial Degeneration in Stranded Pygmy (*Kogia breviceps*) and Dwarf (*Kogia sima*) Sperm Whales

Gregory D. Bossart,¹ George Hensley,¹ Juli D. Goldstein,¹ Kenny Kroell,¹ Charles A. Manire,² R. H. Defran,¹ and John S. Reif^{1,3}

¹Center for Coastal Research, Marine Mammal Research and Conservation Program, Harbor Branch Oceanographic Institution, 5600 U.S. 1 North, Fort Pierce, FL 34946, USA; E-mail: GBossart@hboi.edu

²Mote Marine Laboratory and Aquarium, 1600 Ken Thompson Parkway, Sarasota, FL 34236, USA

³Department of Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, CO 80523, USA

Abstract

Cardiomyopathy (CMP) has been documented as a disease associated with stranded pygmy (*Kogia breviceps*) and dwarf (*Kogia sima*) sperm whales in the United States and Asia. In this study, hearts from 27 pygmy and two dwarf sperm whales stranded in the coastal U.S. Atlantic Ocean and Gulf of Mexico from 1999 to 2006 were analyzed. Gross and microscopic examinations were conducted according to a standardized protocol designed to ensure systematic examination of tissue and data recording. Hearts were weighed and specific measurements made for selected tissues. Fourteen (48.3%) pygmy sperm whales had a microscopic diagnosis of CMP, 12 (41.4%) showed evidence of mild myocardial degeneration (MCD), one (3.4%) had moderate myocarditis and two (6.9%) had no pathological lesions. One dwarf sperm whale had CMP, and the other had mild MCD. The majority of stranded *Kogia* spp. with cardiac lesions came from the southeast Atlantic region (19/27, 70.3%). Cardiomyopathy and MCD lesions were found predominantly among adult whales. An excess of males was found for CMP and MCD (approximately 75% of both groups). The predominant histological lesions found in both disorders were anisokaryosis with karyomegaly and nuclear rowing, followed in frequency by interstitial edema. Cardiac weight, ventricular wall thickness, and valve circumference were compared between pygmy sperm whales with CMP and those with MCD. The largest differences were found for heart weight and intraventricular septum wall thickness, but none of the differences were statistically significant. Further adjustment for sex and body length did not alter the results. In the aggregate, these findings suggest that CMP in *Kogia* spp. is a chronic, progressive condition that represents a continuum from MCD to the more severe forms of the disorder. The etiology of this complex disorder remains unknown.

Key Words: pygmy sperm whale, *Kogia breviceps*, dwarf sperm whale, *Kogia sima*, cardiomyopathy, myocardial degeneration, stranding, U.S. Atlantic Ocean and Gulf of Mexico

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B4

B4

B4

B4

and Megan K. Stolen and Wendy Noke Durden (Hubbs-Sea World Research Institute, Orlando, Florida, USA) for heart acquisition. Special thanks go to Dr. Dan Odell for natural history information and Dr. Ruth Ewing for initial assistance in the heart dissection technique. Additionally, we gratefully acknowledge the volunteer members of the Southeastern Marine Mammal Stranding Network and Harbor Branch marine mammal volunteers for their tireless efforts in advancing the science of marine mammal medicine and pathology.

Liu, S-K., Dolensik, E. P., & Herron, A. J. (1982). Myopathy in a nyala. *Journal of the American Veterinary Medical Association*, *181*, 1232-1236.

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

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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.

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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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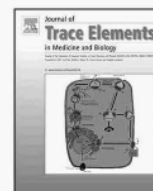
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Pathobiochemistry

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



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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 histo-pathology. 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.

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This paper was submitted by the faculty of FAU's Harbor Branch Oceanographic Institute

Notice: This article was published by the European Association for Aquatic Mammals <http://www.aquaticmammalsjournal.org/> and may be cited as Bossart, Gregory D. , George Hensley, Juli D. Goldstein, Kenny Kroell, Charles A. Manire, R. H. Defran, and John S. Reif (2007) Cardiomyopathy and Myocardial Degeneration in Stranded Pygmy (*Kogia breviceps*) and Dwarf (*Kogia sima*) Sperm Whales, *Aquatic Mammals* 33(2) 214-222, DOI: 10.1578/AM.33.2.2007.214

Cardiomyopathy and Myocardial Degeneration in Stranded Pygmy (*Kogia breviceps*) and Dwarf (*Kogia sima*) Sperm Whales

Gregory D. Bossart,¹ George Hensley,¹ Juli D. Goldstein,¹ Kenny Kroell,¹ Charles A. Manire,² R. H. Defran,¹ and John S. Reif^{1,3}

¹Center for Coastal Research, Marine Mammal Research and Conservation Program, Harbor Branch Oceanographic Institution, 5600 U.S. 1 North, Fort Pierce, FL 34946, USA; E-mail: GBossart@hboi.edu

²Mote Marine Laboratory and Aquarium, 1600 Ken Thompson Parkway, Sarasota, FL 34236, USA

³Department of Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, CO 80523, USA

Abstract

Cardiomyopathy (CMP) has been documented as a disease associated with stranded pygmy (*Kogia breviceps*) and dwarf (*Kogia sima*) sperm whales in the United States and Asia. In this study, hearts from 27 pygmy and two dwarf sperm whales stranded in the coastal U.S. Atlantic Ocean and Gulf of Mexico from 1999 to 2006 were analyzed. Gross and microscopic examinations were conducted according to a standardized protocol designed to ensure systematic examination of tissue and data recording. Hearts were weighed and specific measurements made for selected tissues. Fourteen (48.3%) pygmy sperm whales had a microscopic diagnosis of CMP, 12 (41.4%) showed evidence of mild myocardial degeneration (MCD), one (3.4%) had moderate myocarditis and two (6.9%) had no pathological lesions. One dwarf sperm whale had CMP, and the other had mild MCD. The majority of stranded *Kogia* spp. with cardiac lesions came from the southeast Atlantic region (19/27, 70.3%). Cardiomyopathy and MCD lesions were found predominantly among adult whales. An excess of males was found for CMP and MCD (approximately 75% of both groups). The predominant histological lesions found in both disorders were anisokaryosis with karyomegaly and nuclear rowing, followed in frequency by interstitial edema. Cardiac weight, ventricular wall thickness, and valve circumference were compared between pygmy sperm whales with CMP and those with MCD. The largest differences were found for heart weight and intraventricular septum wall thickness, but none of the differences were statistically significant. Further adjustment for sex and body length did not alter the results. In the aggregate, these findings suggest that CMP in *Kogia* spp. is a chronic, progressive condition that represents a continuum from MCD to the more severe forms of the disorder. The etiology of this complex disorder remains unknown.

Key Words: pygmy sperm whale, *Kogia breviceps*, dwarf sperm whale, *Kogia sima*, cardiomyopathy, myocardial degeneration, stranding, U.S. Atlantic Ocean and Gulf of Mexico

B4

B4

B4

B4

B4

B4

B4

B4

B4

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED]@eurofinsUS.com
CC: Ceric, Olgica
Sent: 9/27/2018 11:56:29 AM
Subject: RE: Heads up: FDA (Vet-LIRN) shipped sample to Eurofins

My apologies. Instead of converting the values, please confirm that the % for those values represents g/100g on an "As Is" basis?

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



From: Jones, Jennifer L
Sent: Thursday, September 27, 2018 7:54 AM
To: [REDACTED]@eurofinsUS.com
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: Heads up: FDA (Vet-LIRN) shipped sample to Eurofins

Thank you, [REDACTED] Would you please ask the lab to report the results for Starch, Soluble Fiber, Insoluble Fiber, Fat, Resistant Starch, Total Dietary Fiber, Protein, and Crude fiber on a g/100g basis? I need to convert the values for each of those analytes to a dry matter basis for each sample.

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



From: [REDACTED]@eurofinsUS.com
Sent: Wednesday, September 26, 2018 6:11 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Cc: Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>
Subject: RE: Heads up: FDA (Vet-LIRN) shipped sample to Eurofins

Hi Jen,
Thanks for the feedback and my apologies for the missing data. I have escalated this to see why those tests were missed. I am checking if we can get the data from the testing that was complete.

[REDACTED]

[REDACTED]

Eurofins
3301 Kinsman Blvd., Madison, WI 53704 USA

From: Jones, Jennifer L [Jennifer.Jones@fda.hhs.gov]
Sent: Wednesday, September 26, 2018 2:39 PM
To: [REDACTED]
Cc: Ceric, Olgica

Subject: RE: Heads up: FDA (Vet-LIRN) shipped sample to Eurofins

EXTERNAL EMAIL*

Hi **B6**

I hope you're well and thank you for sending the recent results. Were there any tests still pending on the samples? I noticed several samples were missing tests.

1. All 18 samples were missing Total Digestible Fiber

2. Samples 7650646 through 7650656 were missing Total Taurine, Total Cystine, and Total Methionine.

I assumed the amino acids listed in the results were free amino acids based on the quantities.

Thank you in advance,

Jen

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



From: Guag, Jake

Sent: Wednesday, September 05, 2018 12:36 PM

To: **B6** <@eurofinsUS.com> **B6** <@eurofinsUS.com>

Subject: Heads up: FDA (Vet-LIRN) shipped sample to Eurofins

Hi **B6**

We shipped a package with kibble samples to you today. The package is expected to arrive tomorrow (Sep 6, 2018), and its tracking number is 1ZA4420T0191543305 with UPS.

Thanks
Jake

Jake Guag, MPH, CPH
Biologist (FDA/CVM/OR/Vet-LIRN)
8401 Muirkirk Road
Laurel, Maryland 20708
Email: jake.guag@fda.hhs.gov
Tel: 240-402-0917

Notify us [here](#) to report this email as spam.

* WARNING - EXTERNAL: This email originated from outside of Eurofins. Do not click any links or open any attachments unless you trust the sender and know that the content is safe!

B6

B6

B6

192 pounds. Neutered Male
Canine / Great Dane

s Mr. brought, recently started coughing/gagging, like he's trying to clear his throat, not related to meals. Often when just laying down.

o: He would not enter building beyond reception room, so we did the work there
barn. T 103 (nervous), mm pink, Pulse Ox 98%. Heart tachycardic, irregular. Fem. pulses do not match the HR and are irregular.

4dx neg

s/o cbc/chem

EKG stat s/o

could not coax into xray today

a: no cardiomyopathy, VPC's, etc.

p: hold on meds, pending results.

EKG: A fib. likely Dil. Cardiomyopathy. recc: chest rads. US, cardiologist, so recc TUFTS; Mr. says will not take today; warned he may have congestive heart failure, leading to death, so evaluation and treatment are URGENT. (but his wife is away...)

2/17/2018	B6	Note
B6	DVM	B6 - Closed - 2/19/2018

2/17/2018

Page 1 of 1

B6 (1139)

6000/1000

VH 8/28/12-2/17/18

Patient History Report

Client: B6
 Phone: B6
 Address: B6
 Patient: B6 (1139)
 Species: Canine
 Age: 5 Yrs. 9 Mos.
 Color: Black
 Breed: Great Dane
 Sex: Neutered Male

Date Type Staff History

2/17/2018 L 1 Chemistry results from IDEXX Reference Laboratory Requisition

Test	Result	Posted	Final	Reference Range
ALB				2.7 - 3.9
ALKP				5 - 160
ALT				18 - 121
AMYL				337 - 1469
ANION GAP				11 - 26
AST				16 - 55
BICARB				13 - 27
BUN/UREA				9 - 31
Ca				8.4 - 11.8
Chloride				108 - 119
CHOL				131 - 345
CREA				0.5 - 1.5
DBIL				0.0 - 0.1
GGT				0 - 13
GLU				63 - 114
IBIL				0.0 - 0.2
LIPA				138 - 755
PROS				2.5 - 6.1
Potassium				4.0 - 5.4
TRIL				0.0 - 0.3
TP				5.5 - 7.5
Sodium				142 - 152
A/G Ratio				0.7 - 1.5
B/C Ratio				
Na/K Ratio				
GLOB				28 - 37
CK				2.4 - 4.0
SDMA				10 - 200
				0 - 14

B6

Asc: B6
 RE: 281 HEMOLYSIS INDEX 1+
 Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
 RE: 282 LIPEMIA INDEX N
 Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
 BOTH SDMA AND CREATININE ARE WITHIN THE REFERENCE INTERVAL which indicates kidney function is likely good. Evaluate a complete urinalysis and confirm there is no other evidence of kidney disease.

2/17/2018 L 1 Endocrinology results from IDEXX Reference Laboratory Requisition ID: B6

Test Result Reference Range Final

B6

Patient History Report

Client:
Phone:
Address:

B6

Patient: **B6** (1139)
Species: Canine
Age: 5 Yrs, 9 Mos.
Color: Black

Breed: Great Dane
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

B6

6000/C000

VH KI 12-1 0102/12/20

Patient History Report

Client:
Phone:
Address:

B6

Patient: **B6** (1139)
Species: Canine
Age: 5 Yrs. 9 Mos.
Color: Black

Breed: Great Dane
Sex: Neutered Male

Date	Type	Staff	History
------	------	-------	---------

B6

B6

0000370008

02/21/2018 1:57 PM FAX

Patient History Report

Client:
Phone:
Address:

B6

Patient: **B6** (1139)
Species: Canine
Age: 5 Yrs. 9 Mos.
Color: Black

Breed: Great Dane
Sex: Neutered Male

Date Type Staff History

B6

6000/9000

02/21/2018 1:57 PM FAX

Patient History Report

Client:
Phone:
Address:

B6

Patient: B6 (1139)
Species: Canine
Age: 5 Yrs. 9 Mos.
Color: Black

Breed: Great Dane
Sex: Neutered Male

Date Type Staff History

B6

0007/0009

02/21/2018 1:58 PM FAX

0000/0000 00/00

B6

LIAISON

PAGE 01/02

B6

0000/0000

02/21/2018 1:58 PM FAX

B6

LIAISON

02

B6

B6

Page 2 of 2

6000/6000

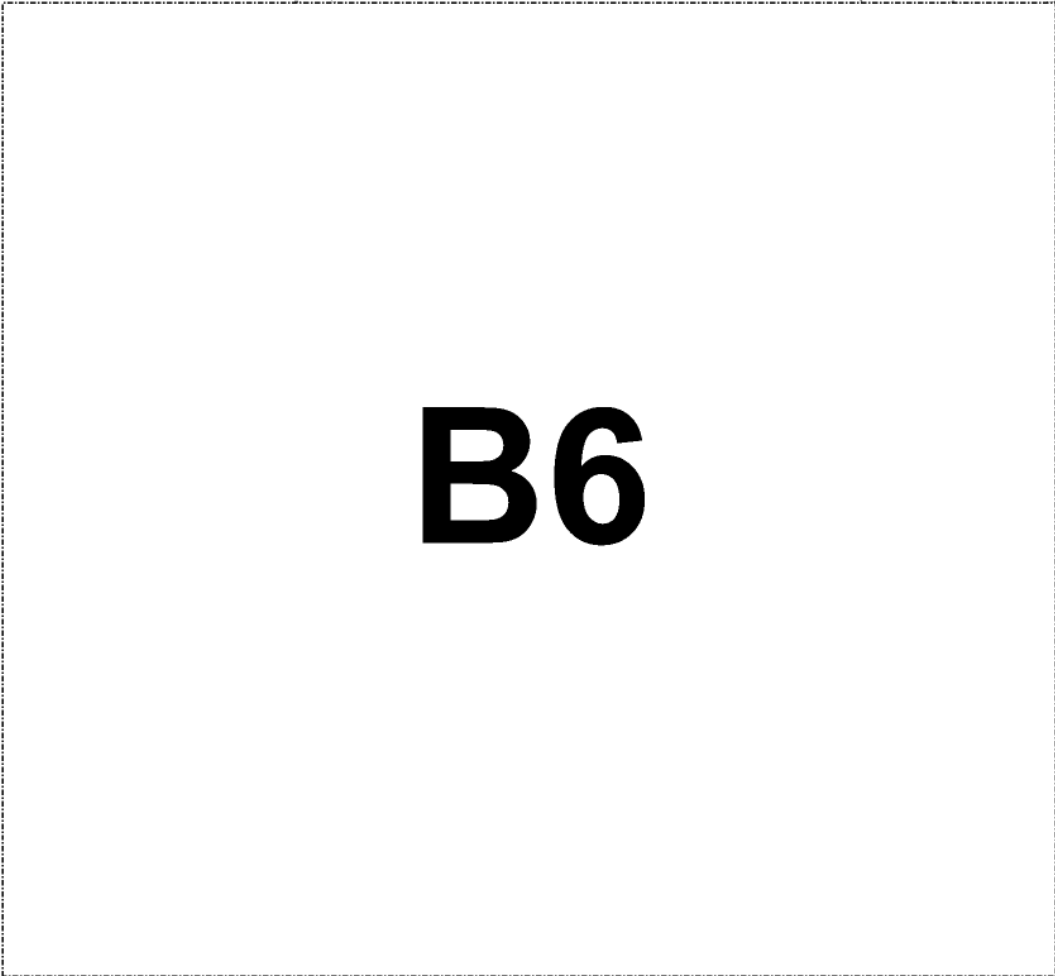
02/23/2018 1:58 PM FAX

REDACTED

B6

LIAISON

PAGE 82/82



B6
Page 2 of 2

8000/8000

02/21/2018 1:58 PM FAX

By: **B6**
Subjective

NEW VISIT (ER)

Doctor: **B6**
Student: **B6** V'18

Presenting complaint: Tachycardia, Afib

Referral visit? Yes

Diagnostics completed prior to visit: CBC/Chem, ECG (2/17)

HISTORY:

Signalment: 5 yo MN Great Dane

Current history: Coughing and gagging started on Thursday and has been persistent. Brought to vet on Saturday and recc'd coming to Tufts. Sounds like he is trying to clear his throat. Worse when lays down. Has never experienced this before. No collapse or exercise intolerance. Today seemed a little more out of breath. Coughed up white phelgm once. Diarrhea 3 weeks ago. Eating and drinking normally.

Prior medical history: Dx with **B6** (hasn't gotten any worse)

Current medications: Salmon oil supplements

Diet: Rachael Ray Nutrish Chicken

Vaccination status/flea & tick preventative use: Due for rabies, chewable for heatworm, seresto collar

Travel history: None

EXAM:

B6

C/V: Tachycardic, irregular rhythm with pulse deficits.

B6

ASSESSMENT:

A1: Tachycardia r/o tachyarrhythmia secondary to DCM vs stress vs hypovolemia

A2: Cough, gagging r/o CHF vs pneumonia vs lung pathology

A3: Irregular heart rhythm r/o atrial fibrillation secondary to DCM

A4: **B6**

PLAN:

B6

Diagnostics completed:

2/17/18 @ rDVM

-CBC:

B6

-Chem:

- ECG (read by IDEXX): Atrial fibrillation

2/20/18 @ Tufts

-NOVA:

B6

-PCV/TS:

B6

-CXR: Marked generalized cardiomegaly with LAE, interstitial infiltrates consistent with cardiogenic pulmonary edema. Pleural fissure lines.

-Cardio consult: LV walls are thin with markedly reduced contractile function. LV cavity is dilated. LA is moderately dilated. RV and RA are dilated. PA is the same size as the aorta. Trace pleural effusion. No pericardial effusion. No ascites.

-UA: USG 1.040; pH 7.5

Diagnostics pending:

2/20/18

-NT-pro BNP

Client communication:

Discussed with owners that Afib can be due to structural changes in the heart (like DCM) or idiopathic. His prognosis will depend on his underlying cause and his response to treatment. We will take some chest rads and have a cardio consult. We will have him on ECG constantly and start treating his Afib as soon as cardiology sees him. Another doctor will call you tomorrow between 10 am-12 pm.

Deposit & estimate status:

B6

Resuscitation code (if admitting to ICU):

B6

SOAP approved (DVM to sign):

B6

DVM

B6

Subjective

EXAM, GENERAL

Subjective (S) [B6] is a 5 yr old MN great dane, who has a history of coughing and gagging which started on Thursday and has been persistent. Brought to vet on Saturday and recc'd coming to Tufts. Has never experienced this before. No collapse or exercise intolerance. Had diarrhea 3 weeks ago. Today is panting with some mild effort, and drinking.

Prior medical history: Dx with [B6] (hasn't gotten any worse)

Current medications: Salmon oil supplements

Objective (O)

B6

H/L: 2/6 left systolic murmur, irregularly irregular heart rhythm, tachycardic, femoral pulses weak but synchronous, lungs normal bronchovesicular sounds, no crackles or wheezes appreciated. Jugular pulse 1/3 up neck.

B6

Assessment (A)

A1: Irregularly irregular heart beat rule out atrial fibrillation vs ventricular tachycardia vs other

A2: Tachycardia rule out atrial fibrillation vs ventricular tachycardia vs other

Plan (P)

B6

SOAP completed by: [B6] V18

SOAP reviewed by: [B6]

B6

Subjective

EXAM, GENERAL: Subjective (S) B6 is a 5 yr old MN great dane, who has a history of coughing and gagging which started on Thursday and has been persistent. Brought to vet on Saturday and rec'd coming to Tufts. Has never experienced this before. No collapse or exercise intolerance. Had diarrhea 3 weeks ago. Today is breathing with some mild effort, drinking, and eating.

Prior medical history: Dx with B6 (hasn't gotten any worse)

Current medications: Salmon oil supplements

Subjective (S) BAR, mentally appropriate

Objective (O)

B6

H/L: heart irregularly irregular heart rhythm, jugular pulses lower 1/3 of neck, femoral pulses weak but synchronous. Lungs normal bronchovesicular sounds bilaterally, no crackles or wheezes appreciated.

B6

Assessment (A)

A1: Irregularly irregular heart beat rule out atrial fibrillation vs ventricular tachycardia vs other

A2: Tachycardia rule out atrial fibrillation vs ventricular tachycardia vs other

Plan (P)

B6

SOAP completed by: B6 V18

SOAP reviewed by: B6

Soap Text Created By - Veterinarian: [B6] - Updated on: 9/10/2018 2:15:33 PM By: [B6]

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L
Sent: 8/8/2018 6:18:49 PM
Subject: RE: 800.267-EON-361371- [B6] Acana Pork and Squash

As a side note

[B5]

[B5]

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: Jones, Jennifer L
Sent: Wednesday, August 08, 2018 2:16 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Peloquin, Sarah <Sarah.Peloquin@fda.hhs.gov>
Subject: RE: 800.267-EON-361371- [B6] Acana Pork and Squash

MRx pending + Interview, no food

FYI-Joshua Stern encouraged her to submit the report to FDA. I'm assuming that's also why we've gotten more golden retrievers.

2 dogs in this home-both low Tau

[B6]-born w/ [B6] but apparently L-sided DCM

2nd dog-low Tau, no ECHO done

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



From: PFR Event [<mailto:pfpreventcreation@fda.hhs.gov>]
Sent: Saturday, August 04, 2018 9:32 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [B6]

Subject: Acana Pork and Squash: [B6] EON-361371

A PFR Report has been received and PFR Event [EON-361371] has been created in the EON System.

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

Below is the summary of the report:

EON Key: EON-361371

ICSR #: 2053236

EON Title: PFR Event created for Acana Pork and Squash; 2053236

AE Date	04/12/2016	Number Fed/Exposed	2
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Unknown
Breed	Retriever - Golden		
Age	4 Years		
District Involved	PFE [B6] DO		

Product information

Individual Case Safety Report Number: 2053236

Product Group: Pet Food

Product Name: Acana Pork and Squash

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana Pork and Squash		

Sender information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-361371>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=378105>

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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.

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David
Sent: 8/8/2018 7:04:55 PM
Subject: RE: 800.267-EON-361371 [B6] Acana Pork and Squash

I was told from the owner that Joshua Stern says Golden's may have their own higher reference range for Normal, meaning low end of normal may still be deficient.

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



From: Jones, Jennifer L
Sent: Wednesday, August 08, 2018 2:20 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: 800.267-EON-361371 [B6] Acana Pork and Squash

J

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



From: Rotstein, David
Sent: Wednesday, August 08, 2018 2:19 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: 800.267-EON-361371 [B6] Acana Pork and Squash

As a side note, [B6]

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: Jones, Jennifer L

Sent: Wednesday, August 08, 2018 2:16 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>

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

Subject: RE: 800.267-EON-361371 [REDACTED] Acana Pork and Squash

MRx pending + Interview, no food

FYI-Joshua Stern encouraged her to submit the report to FDA. I'm assuming that's also why we've gotten more golden retrievers.

2 dogs in this home-both low Tau

[REDACTED] born w/ [REDACTED] but apparently L-sided DCM
2nd dog-low Tau, no ECHO done

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



From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]

Sent: Saturday, August 04, 2018 9:32 PM

To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [REDACTED]

Subject: Acana Pork and Squash: [REDACTED] - EON-361371

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Animal Species	Dog	Outcome to Date	Unknown
Breed	Retriever - Golden		
Age	4 Years		
District Involved	PFF [REDACTED] DO		

Product information

Individual Case Safety Report Number: 2053236

Product Group: Pet Food

Product Name: Acana Pork and Squash

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

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Acana Pork and Squash		

Sender information

[B6]

USA

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

<https://eon.fda.gov/eon//browse/EON-361371>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspa?decorator=none&e=0&issueType=12&issueId=378105>

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: [REDACTED] B6
Sent: 8/22/2018 6:21:32 PM
Subject: 800.267-FDA Case Investigation for [REDACTED] B6 (EON-361371)
Attachments: 02-Vet-LIRN-NetworkProceduresVets-12.22.2015.pdf; Re: 800.267-FDA Case Investigation for [REDACTED] B6 (EON-361371)

Good afternoon [REDACTED] B6

We received permission from [REDACTED] B6 to request medical records for both [REDACTED] B6. A copy of the email is attached.

We received a consumer complaint from [REDACTED] B6 about her dogs' potential illness after consuming a storebought dog food.

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

- **Full Medical Records**

- o Please email (preferred) or fax (301-210-4685) a copy of both dogs' **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 owners help with our case investigations.

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

Thank you kindly,

Dr. Jones

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
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>





Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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.



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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.



Network Procedures for Veterinary Laboratory Investigation and Response Network Case Investigations

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.

From: [REDACTED] B6
To: Jones, Jennifer L
Sent: 8/9/2018 1:05:20 PM
Subject: Re: 800.267-FDA Case Investigation for [REDACTED] B6 (EON-361371)
Attachments: Taurine [REDACTED] B6 .pdf; [REDACTED] B6 2018-04-23 [REDACTED] B6 Taurine Report.pdf

Hi Dr. Jones

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

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

[REDACTED] B6

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

[REDACTED] B6
Phone [REDACTED] B6

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

Thanks again

[REDACTED] B6

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

From: Jones, Jennifer L
Date: 8/7/2018 4:20:07 PM
To: [REDACTED] B6
Subject: 800.267-FDA Case Investigation for [REDACTED] B6 (EON-361371)

Good afternoon [REDACTED] B6

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

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

- **Full Medical Records**
 - Please contact your veterinarian (primary veterinarian and cardiologist/specialist) and

ask them to email (preferred) or
fax (301-210-4685) a copy of [B6] entire medical history (not just this event).

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

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

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

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

Thank you kindly,

Dr. Jones

Jennifer L. A. Jones, DVM

Veterinary Medical Officer
U.S. Food & Drug Administration
Center for Veterinary Medicine
Office of Research
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
8401 Muirkirk Road, G704
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>



Soap Text Created By - Veterinarian: **B6** - Updated on: 5/28/2018 7:09:58 PM By: **B6**

Subjective

NEW VISIT (ER)

Doctor: **B6**
Student: **B6**

Presenting complaint: respiratory distress

Referral visit? yes (referred from **B6** for coughing workup - was going to make appointment)

Diagnostics completed prior to visit: at **B6** radiographs were heart disease vs. lung disease

HISTORY:

Signalment: 6yo **B6** Caucasian Shepherd Dog

Current history: Owners noticed increased respiratory rate (60/min) and short, shallow breaths this afternoon. Patient was in a cool house and resting at the time. He has been coughing for the past 2 weeks, with sometimes coughing up phlegm. The owner reports that he has a few of these coughing episodes a day. **B6** coughs a few times and then hacks once, then he recovers smoothly. He has a history of heart disease found at a veterinarian in **B6** in 2012 or 2013, where they noticed a "hole in his heart", the owner is unsure about what specific condition he has but says the vet told him that some of the blood in his heart goes backward and not forward.

Prior medical history: **B6**

Current medications: none

Vaccination status/flea & tick preventative use: UTD

Travel history: none recently

EXAM:

B6

C/V: No obvious murmur, but difficult to auscult due to patient size/coat and panting. NSA, FPSS.

B6

ASSESSMENT:

A1: Increased respiratory effort: r/o cardiac disease (DCM (suspected) vs. structural defect vs CHF) vs. lung

disease (pneumonia vs. bronchitis vs. allergy)

PLAN:

B6

Diagnostics completed:

AFAST: No evidence of free fluid.

TFAST: Decreased LV contractility. La:Ao WNL. No pleural or pericardial effusion.

Diagnostics pending:

CBC, chemistry

Client communication: Confirmed history and discussed initial diagnostic plan with owner. Discussed findings of TFAST with owner, and briefly discussed DCM. Recommended repeating CXR, owner would like to hold if possible to help conserve finances. I advised the owner that we would treat **B6** supportively overnight and get full cardiology evaluation tomorrow who would make additional treatment and diagnostic recommendations. Owner is happy with estimate. Advised owner that the new doctor will call tomorrow morning between 10-noon with update and plan for the day.

Deposit & estimate status: **B6**

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

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

B6

Subjective

Exam, cardiology

(S) T: 100.8

HR: 124

RR: panting

Mentation: BAR

Hydration: euhydrated

Overall impression since arrival or since last exam: Cardiovascularly stable overnight with progressively decreased HR other than with stimulation. Respiratory rate progressively decreased with continued mild effort. B6 given at 10pm and 2am. Panting this morning, may be related to temperature in ICU.

Appetite: Ate chicken well overnight. Ate remaining Proplan in bowl this morning when hand fed.

Diet Hx: Fed 4Health Grain Free Large Breed Dog food

(O)

B6

Heart: Difficult to auscult due to heavy haircoat. Normal sinus rhythm, femoral pulses fair- weak bilaterally.
Lungs: Mildly increased RR/RE with abdominal component to breathing. Normal bronchovesicular sounds, no crackles or wheezes.

B6

Assessments

A1: Increased respiratory rate/effort: r/o cardiac disease (suspect DCM vs. congenital defect vs. CHF) vs pulmonary disease (aspiration pneumonia vs. infectoius pneumonia vs. bronchitis)

A2: Occasional VPCs: 2* to DCM vs other myocardial disease

Plan

B6

Diagnostics:

NOVA: Lac 2.4 (0-2)

PCV/TS: 44/7.5

CBC: WNL

Chem: ALP 8 (12-48)

CXR: Moderate left-sided cardiomegaly w LA enlargement, venous distension and cardiogenic pulmonary edema consistent with left-sided heart failure.

Telemetry O/N: Single incidence of R on T couplet with intermittent isolated VPCs

SOAP completed by:

B6

SOAP reviewed by:

B6

Subjective

Exam, cardiology

(S) T: 101.4

HR: 144

RR: panting

Mentation: BAR

Hydration: euhydrated

Overall impression since arrival or since last exam: Cardiovascularly stable overnight. Heart rate varied overnight from 80-100 when quiet or resting to 130-170 when worked up and barking. Respiratory rate difficult to ascertain overnight as the patient was often panting, whining or barking. Respiratory effort and rate remained at or below 40 the few times it was able to be determined. The patient **B6** since the previous SOAP (10:30am, 1:30pm, 7:20pm, 4:00 am).

Appetite: Ate well overnight whenever food was offered. Telemetry showed intermittent single intercalated ventricular beats.

Diet Hx: Fed 4Health Grain Free Large Breed Dog food

(O)

BCS(1-9): 5/9

B6

Heart: Difficult to auscult due to size and heavy haircoat. Normal sinus rhythm, femoral pulses fair bilaterally.

Lungs: Panting constantly when awake. No crackles or wheezes ausculted.

B6

Assessments

A1: Increased respiratory rate/effort: DCM + CHF

A2: Occasional VPCs: 2* to DCM

B6

A4: Muscle wasting: 2* to cardiac disease vs. 2* to other systemic disease process

Plan

B6

B6

Diagnostics:

5/28

B6

5/29

CXR: Moderate left-sided cardiomegaly w LA enlargement, venous distension and cardiogenic pulmonary edema consistent with left-sided heart failure.

NOVA

PCV/T

B6

5/30

NOVA

PCV/TS

B6

SOAP completed by

SOAP reviewed by

B6

Soap Text Created By - Veterinarian:

B6

Updated on: 6/12/2018 12:05:03 PM

By:

B6

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Ceric, Olgica; Nemser, Sarah; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
Sent: 7/9/2018 1:13:49 PM
Subject: another dcm-FW: Taste of the Wild grain free lamb dry: Lisa Freeman - EON-358523
Attachments: 2051558-report.pdf

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



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From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Monday, July 09, 2018 9:08 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [B6]
Subject: Taste of the Wild grain free lamb dry: Lisa Freeman - EON-358523

A PFR Report has been received and PFR Event [EON-358523] has been created in the EON System.

A "PDF" report by name "2051558-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-358523

ICSR #: 2051558

EON Title: PFR Event created for Taste of the Wild grain free lamb dry; 2051558

AE Date	07/03/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable

Breed	Retriever - Labrador		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2051558

Product Group: Pet Food

Product Name: Taste of the Wild grain free lamb dry

Description: DCM and CHF

Submission Type: Initial

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

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

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild grain free lamb dry		

Sender information

Lisa Freeman
 200 Westboro Rd
 North Grafton, MA 01536
 USA

Owner information

B6 USA

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

<https://eon.fda.gov/eon//browse/EON-358523>

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=375147>

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

Report Details - EON-358523

ICSR: 2051558
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-07-09 08:56:52 EDT

Reported Problem:
Problem Description: DCM and CHF
Date Problem Started: 07/03/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Taste of the Wild grain free lamb dry
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Retriever - Labrador
Gender: Male
Reproductive Status: Neutered
Weight: 50.8 Kilogram
Age: B6 Years
Assessment of Prior Health: Good
Number of Animals Reacted: 1

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

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

Sender Information:	Name:	Lisa Freeman		
	Address:	200 Westboro Rd North Grafton Massachusetts 01536 United States		
	Contact:	Phone:	5088874523	
		Email:	lisa.freeman@tufts.edu	
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Reported to Other Parties:	None			

Additional Documents:

Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY

Cardiology Liaison: 508-887-4696

B6

Patient ID:

Canine

Years Old Male (Neutered) Labrador
Retriever Cross
Chocolate

Cardiology Appointment Report

Date: 7/11/2018

Attending Cardiologist:

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

B6

Cardiology Resident:

Cardiology Technician:

Student:

Presenting Complaint: Redcheck CHF with MVD, DCM, and supraventricular and ventricular arrhythmia

Concurrent Diseases:

None

General Medical History:

Was getting better until the last few days, eating well, etc; last few days has been more lethargic, not eating well. Started taurine on Sunday and decrease in appetite state Sunday evening. No v/d. Still breathing well. Resp rates at home 28-35 at rest.

Diet and Supplements:

Hill's Adult large breed lamb and rice dry
Hill's SD Chicken, carrots, and spinach canned
GNC Taurine supplement, 1000mg SID
No fish oil yet, introducing new diet aspects gradually
Cosequin

Cardiovascular History:

Prior CHF diagnosis? Y

Prior ATE? N

Prior arrhythmia? Y

Cough? Y, none since discharge 7/4

Shortness of breath or difficulty breathing? Y, none since 7/4

Syncope or collapse? N

Sudden onset lameness? N

Exercise intolerance? Y

Prior heart murmur? Y

Current Medications Pertinent to CV System:

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

V/VI

VI/VI

B6

Jugular vein:

- Bottom 1/3 of neck
- Middle 1/3 of neck

- Top 2/3rd of neck

Arterial pulses:

- Weak
- Fair
- Good
- Strong

- Bounding
- Pulse deficits
- Pulsus paradoxus
- Other:

Arrhythmia:

- None
- Sinus arrhythmia
- Premature beats

- Bradycardia
- Tachycardia

Gallop:

- Yes
- No
- Intermittent

- Pronounced
- Other:

Pulmonary assessments:

- Eupneic
- Mild dyspnea
- Marked dyspnea
- Normal BV sounds

- Pulmonary crackles
- Wheezes
- Upper airway stridor

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension

- Mild ascites
- Marked ascites

Problems:

CHF from DCM and MV disease - improving with medications

Lethargy and decreased appetite - initially improved and then returned, r/o secondary to taurine supplement on food v secondary to DCM/MVD v other

Arrhythmia - likely from DCM

Differential Diagnoses:

DCM - r/o primary vs nutritional

MVD

Arrhythmia - r/o secondary to DCM vs hypokalemia (no evidence) vs abdominal mass vs anemia (no evidence) vs other

Diagnostic plan:

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

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

ECG findings:

B6

Assessment and recommendations:

Patient has been breathing well at home with no coughing, but for the past few days has not been eating well. Subjectively there is less ventricular arrhythmia today than at hospitalization, but there are still occasional R on T ventricular couplets. 24 hour Holter monitor was considered, but declined due to logistics at this time. Recommend at home. Consider ing PO SID if liver values are normal. could be added, but owner cannot easily give TID medications; they would consider this if absolutely necessary. Recheck ECG via alivecor in 10-14 days after increasing . Recheck echo in 3-4 months, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance.

Owner believes that the decreased appetite is related to taurine administration; this is uncommon, but if there are no blood work changes to explain inappetence then consider either reducing the dose or switching to a different brand of taurine. Whole blood taurine levels were normal and the diet has been changed, so discontinuing taurine could also be considered if necessary.

Final Diagnosis:

DCM with component of MV disease, CHF
Ventricular and atrial arrhythmia
History of grain free diet (taste of the wild lamb)

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM Classification:

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

Client: **B6**
Patient: **B6**
Species: CANINE
Breed: MIXED_BREED_CAN
Gender: MALE NEUTERED
Age: 9Y

Date: 07/03/2018
Requisition #: [B6]
Accession #: [B6]
Ordered by: RUSH

IDEXX VetConnect 1-888-433-9987
TUFTS UNIVERSITY
200 WESTBORO RD
NORTH GRAFTON, Massachusetts 01536-1828
508-839-5395
Account #: [B6]

CARDIOPEP proBNP - CANINE

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

Comments:

1

B6

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

Discharge Instructions

Patient

Name: B6

Species: Canine

Chocolate Male (Neutered) Labrador

Retriever Cross

Birthdate: B6

Owner

Name: B6

B6

Patient ID: B6

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Student: B6

Cardiology Technician:

B6

Appointment Date: 7/11/2018 3:30 PM

Diagnoses:

Dilated cardiomyopathy (DCM) and mitral valve disease with improved congestive heart failure

Arrhythmia (ventricular and atrial)

Clinical Findings:

Thank you for bringing B6 to Tufts for recheck of his congestive heart failure secondary to dilated cardiomyopathy and mitral valve disease and recheck of his arrhythmia. You report that he has been doing well at home and was improving very well for the first few days after discharge from the hospital but that he has had decreased energy and appetite for the past couple of days. Physical examination today was normal except for a slight heart murmur and continued arrhythmia.

On ECG today we observed the continued arrhythmia, though it is improved since B6 hospital stay with the B6 treatment. There were still some instances of concerning ventricular arrhythmia (originating from the bottom chambers of the heart) today however. There are a few options at this point for monitoring and deciding on further treatment of B6 arrhythmia. The first is a Holter monitor, which is an ECG recording device that is worn at home and records the heart rhythm through a 24 hour period. This option is quite thorough and requires you to bring him back in to have it removed or to remove it at home and mail it back to us for reading. The other option is the B6 which can be used intermittently at home to record ECGs and the results can be emailed to us for evaluation. This is a little less thorough because it only records snapshots but could still be a very valuable diagnostic tool.

Adjusting B6 antiarrhythmic medications at this time without information about his heart rhythm at home is tricky because using and correctly dosing anti-arrhythmic drugs is somewhat complicated and these drugs are not entirely benign. At this time the arrhythmia that B6 has is not negatively affecting his quality of life but does put him at an increased risk of

sudden onset of a life-threatening arrhythmia. The adjustments to medication that are possible at this time include increasing the [B6] adding [B6] however needs to be dosed every 8 hours which is difficult for many people.

The other medication adjustments that we may make are to the [B6] which we will decide when the results of his bloodwork come back in the next couple of days. If he is getting a little bit too much diuresis from the [B6] this could cause his decreased appetite and energy levels. If his bloodwork comes back normal and he does not need less lasix then we may recommend stopping the torazine or changing brands and seeing if this improves his appetite.

You have expressed concerns about his quality of life at this point, but when we get dogs with CHF and DOM on the correct medications and doses they generally feel much better and return to their previous selves. It can take some time to arrive at the correct medication combination and doses and we believe that he will continue to feel better as we make these adjustments.

Monitoring at Home:

Please continue to monitor [B6] breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort. In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled. *An increase in breathing rate or effort will usually mean that you should give an extra dose of [B6]*. If difficulty breathing is not improved by within 30-60 minutes after giving extra [B6] then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic. There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).

We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination. If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Additionally, we talked last time about the at-home ECG monitoring device. This is not absolutely necessary, but can be a good monitoring tool at home.

Diet Suggestions:

[B6] can continue on the two foods that you have recently changed to and that you have found that he likes.

Medications:

B6

B6

Recheck Visits: We will be in contact as you monitor B6 at home with the AliveCore app and connect via email to discuss the results and plan for his next recheck. A recheck echocardiogram is recommended in ~4 months as long as B6 is doing well.

Thank you for entrusting us with B6 care. He is such a sweet boy! Please contact our Cardiology liaison, B6 at (508)-887-4696 or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case: B6

Owner: B6

Discharge Instructions

Client:
 Veterinarian:
 Patient ID:
 Visit ID:

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

Lab Results Report

Chemistry 21 (Cobas)		7/11/2018 4:25:20 PM	Accession ID: <input type="text" value="B6"/>
Test	Results	Reference Range	Units
GLUCOSE		67 - 135	
UREA		8 - 30	
CREATININE		0.6 - 2	
PHOSPHORUS		2.6 - 7.2	
CALCIUM2		9.4 - 11.3	
T. PROTEIN		5.5 - 7.8	
ALBUMIN		2.8 - 4	
GLOBULINS		2.3 - 4.2	
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	
CHLORIDE	B6	106 - 116	B6
POTASSIUM		3.7 - 5.4	
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	
D.BILIRUBIN		0 - 0.1	
I BILIRUBIN		0 - 0.2	
ALK PHOS		12 - 127	
ALT		14 - 86	
AST		9 - 54	
CHOLESTEROL		82 - 355	
OSMOLALITY (CALCULATED)		291 - 315	

B6

Sample Submission Form

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

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

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

Vet/Tech Contact: **B6**

Company Name: 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: _____
Email: **B6** Tel: **B6**

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

Sample Type: Plasma Whole Blood Urine Food Other: _____
Test Items: **B6** Complete Amino Acid Other: _____

Taurine Results (nmol/ml)

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

Reference Ranges (nmol/ml)

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

B6

B6

B6

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Rotstein, David; Palmer, Lee Anne; Queen, Jackie L; Carey, Lauren
CC: Peloquin, Sarah
Sent: 11/13/2018 7:43:03 PM
Subject: RE: 800.267-EON-35852; [B6] Taste of the Wild grain free lamb dry
Attachments: MRx.zip

Interview pending

[B6] 9 yr MC Lab X

[B6] eval at [B6] rough-worse at pm, over last weekend; at [B6] tachyarrhythm w/ murmur; recent lethargy, dyspnea, slow-possibly old some inapp after boarding in April 2018; UTD interceptor & vx; eats TOW and Cosequin

PE: 144 bpm, mild mm loss-hind end, Gr II-III/VI left basilar sys, weak aa pulse w/ deficits, premature beats, gallop, mild dyspnea

Echo: LV-marked dil w/ dec contractility, LA sev enl, MV slt thick, PA slt > Aorta; RH dil, +3 MR, +1 TR

ECG: sinus tachy, VPCs, ventricular bigeminy, APCs

proBNP [B6] (0-900)

Tau: WB [B6]

Tx: [B6] 1 g BID

7/11 recheck: diet changed, improved but last few days inc lethargy, hyporexia after starting Tau, giving 1g Tau SID

PE: good pulse, premature beats

ECG: sinus w/ isolated freq VPCs, occ V bigeminy, rare V couplets w/ R on T morph;

Labs: ALP [B6] (12-127), Chol [B6] (82-355)

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



From: Rotstein, David
Sent: Monday, July 09, 2018 9:14 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@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>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: another dcm-FW: Taste of the Wild grain free lamb dry: Lisa Freeman - EON-358523

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



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From: PFR Event [<mailto:pfpreventcreation@fda.hhs.gov>]
Sent: Monday, July 09, 2018 9:08 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [B6]
Subject: Taste of the Wild grain free lamb dry: Lisa Freeman - EON-358523

A PFR Report has been received and PFR Event [EON-358523] has been created in the EON System.

A "PDF" report by name "2051558-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-358523
ICSR #: 2051558
EON Title: PFR Event created for Taste of the Wild grain free lamb dry; 2051558

AE Date	07/03/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Retriever - Labrador		
Age	[B6] Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2051558
Product Group: Pet Food
Product Name: Taste of the Wild grain free lamb dry
Description: DCM and CHF
Submission Type: Initial
Report Type: Adverse Event (a symptom, reaction or disease associated with the product)
Outcome of reaction/event at the time of last observation: Stable
Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild grain free lamb dry		

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6
USA

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

<https://eon.fda.gov/eon//browse/EON-358523>

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=375147>

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.

B6

Patient ID: B6

B6 Canine

B6 Years Old Male (Neutered) Lab/x
Chocolate

Cardiology Appointment Report

Date: 7/3/2018

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student: B6

Presenting Complaint: Cough, tachyarrhythmia, heart murmur

Concurrent Diseases: None

General Medical History: Recently lethargic, appetite and P/U OK. Some inappetence after boarding in april 2018. UTD on interceptor and vaccines.

Diet and Supplements: Taste of the Wild Adult Grain-free Lamb, Cosequin

Cardiovascular History:

Prior CHF diagnosis? No

Prior ATE? No

Prior arrhythmia? Yes, tachyarrhythmia

Cough? Yes, sounded like dry heaving to O, especially bad this weekend, worse at night

Shortness of breath or difficulty breathing? A bit labored, even at rest as per O, over last week or two

Syncope or collapse? No

Sudden onset lameness? No

Exercise intolerance? Slow, O thinks just getting old

Prior heart murmur? Yes, see referring form, left systolic reportedly

Current Medications Pertinent to CV System:

None

Cardiac Physical Examination:

B6

Muscle condition:

- Normal
- Mild muscle loss, hind end
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

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

B6

Jugular vein:

- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of neck

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:

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

Abdominal exam:

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

Problems: Cough, tachyarrhythmia, heart murmur

Differential Diagnoses: Tachyarrhythmia r/o DCM, ARVC, SSS, Heart Block, Myocarditis; Heart Murmur r/o: DVD (mitral), stenosis
Cough - CHF vs laryngeal disease, pneumonia, neoplasia

Diagnostic plan:

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

Echocardiogram Findings:

General/2-D findings:

Abbreviated echo due to dyspnea and anxiety when restrained in lateral.

Dilated LV cavity with reduced contractile function, although septal motion is better than typical dog with isolated DCML. The LV cavity is markedly dilated. The LA is severely enlarged (more typical of a significant component of DMVD). The MV is slightly thickened with no obvious prolapse. The PA is slightly larger than the aorta.

The RH is also dilated. No pleural or pericardial effusion. No obvious cardiac masses visualized.

Echo was not completed as dog became short of breath and restless. A more complete exam would be desired once the dog is breathing better. B lines were noted in multiple lung lobes.

Doppler findings:

3+ MR

1+ TR

ECG findings:

B6

Assessment and recommendations:

Echocardiogram reveals DCM with markedly enlarged LA. The patient also had a significant amount of ventricular arrhythmia during the procedure. Based on the clinical signs and echocardiogram and the presence of B lines, the patient is believed to be in active CHF although chest radiographs would be necessary to confirm the presumptive diagnosis. The patient is eating a grain free diet with lamb as a meat protein and DCM secondary to taurine deficiency is a possibility (but the dog has features that indicate a significant component of mitral valve disease as well). level should be submitted and taurine supplementation should be started as well. Ideally the diet would be changed to a main stream brand, standard protein, non-grain free option. Recommend therapy with 12.5mg PO BID, 75 mg PO BID and 0 mg PO SID and then increase to BID or even higher dose.

Discussed outpatient vs inpatient care - owner eventually elected inpatient care. During ECG monitoring the dog had enough arrhythmia to trigger a decision to start

Addendum 7/4/18: Patient RR normalized overnight with no coughing. There is still significant arrhythmia, but subjective decrease in overall heart rate and frequency of arrhythmia. Recheck renal values are still normal. Recommend recheck ECG and renal values in 1-2 weeks. Recheck echo in 3-4 months, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance.

Final Diagnosis:

DCM with component of MV disease, CHF
Ventricular and atrial arrhythmia
Grain free diet (taste of the wild lamb)

Heart Failure Classification Score:

ISACHC Classification:

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

ACVIM Classification:

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

M-Mode

IVSd	om
LVIDd	om
LVPWd	om
IVSs	om
LVIDs	om
LVPWs	om
%FS	%
Ao Diam	om
LA Diam	om
LA/Ao	
Max LA	om

M-Mode Normalized

IVSdN	(0.29 - 0.52)
LVIDdN	(1.35 - 1.73) !
LVPWdN	(0.33 - 0.53)
IVSsN	(0.43 - 0.71) !
LVIDsN	(0.79 - 1.14) !
LVPWsN	(0.53 - 0.78) !
Ao Diam N	(0.68 - 0.89) !
LA Diam N	(0.64 - 0.90) !

2D

SA LA	om
Ao Diam	om
SA LA / Ao Diam	
IVSd	om
LVIDd	om
LVPWd	om
EDV(Teich)	ml
IVSs	om
LVIDs	om
LVPWs	om



ESV(Teich)
EF(Teich)
%FS
SV(Teich)

B6

ml
%
%
ml

Client: **B6**
Patient:
Species: CANINE
Breed: MIXED_BREED_CAN
Gender: MALE NEUTERED
Age: 9Y

Date: 07/03/2018
Requisition:
Accession: **B6**
Ordered by: RUSH

IDEXX VetConnect 1-888-433-9987
TUFTS UNIVERSITY
200 WES TEBORO RD
NORTH GRAFTON, Massachusetts 01536-1828
508-839-5395
Account: **B6**

CARDIOPEP T proBNP - CANINE

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

Comments:

B6

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

B6

Sample Submission Form

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

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

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

Vet/Tech Contact: **B6**

Company Name: 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:
 Email: **B6** Tel: 508-**B6**

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

B6

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

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

Reference Ranges (nmol/ml)

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

B6

S206388 Canine
 7/3/2018 4:14 PM
 TAURINE (WHOLE BLOOD)
 Lithium Heparin

Client: **B6**
 Veterinarian: **B6**
 Patient ID: **B6**
 Visit ID: 2485151

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

Lab Results Report

Chemistry 21 (Cobas)		7/11/2018 4:25:20 PM	Accession ID: B6
Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
NA/K		29 - 40	
T BILIRUBIN		0.1 - 0.3	mg/dL
D.BILIRUBIN		0 - 0.1	mg/dL
I BILIRUBIN		0 - 0.2	mg/dL
ALK PHOS		12 - 127	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CHOLESTEROL		82 - 355	mg/dL
OSMOLALITY (CALCULATED)	291 - 315	mmol/L	

Discharge Instructions

Patient

Name: B6

Species: Canine

Chocolate Male (Neutered) Lab/x

Birthdate: B6

Owner

Name: B6

Address: B6

Patient ID: B6

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Student: B6

Cardiology Technician:

B6

Admit Date: B6 1:09:58 PM

Discharge Date: B6

Diagnoses:

Dilated cardiomyopathy (DCM) and mitral valve disease with congestive heart failure

Arrhythmia (ventricular and atrial)

Case summary:

B6 was evaluated at VCA for a recent new cough that was worse at night and noticeable over last weekend. At VCA, a tachyarrhythmia (fast, incoordinated heart beat) and a murmur (abnormal heart sound) was discovered. When brought to Tufts, an echocardiogram and ECG was performed, and B6 was diagnosed with dilated cardiomyopathy (DCM) and congestive heart failure (CHF). On echocardiogram B6's heart was enlarged and he had some signs of pulmonary edema (fluid in lungs). He also has a leak at his mitral valve, and his ECG showed a worrisome arrhythmia.

DCM 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. Like B6 many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. B6 also had signs of significant mitral valve regurgitation, or a leak at one of his heart valves. The heart enlargement has now progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs. Unfortunately this is a progressive disease and we most likely cannot reverse the changes to the heart muscle, however we can use cardiac medications and some changes to the diet to make your dog comfortable and have him breathing easier.

We performed bloodwork which to help us monitor B6 kidney values and electrolytes which were normal at admission. We also discussed changing B6 Grain-free diet to one that includes taurine, supplemented or otherwise. If this diet is

changed, there is a chance [B6] heart disease could improve, so we have opted to check [B6] taurine levels and supplement chewable [B6] tablets during his stay.

We recommended that [B6] be hospitalized for further monitoring after giving a dose of [B6] [B6] to help with fluid overload, detailed below. An EKG was used to monitor [B6] arrhythmia overnight. [B6] breathing improved overnight, with less effort and a slower rate (less than 30 breaths per minute) and his heart rate had decreased. He still has frequent arrhythmias, but they have lessened since admission.

Monitoring at home:

- We would like you to monitor your dog's breathing rate and effort at home, ideally during sleep or at a time of rest. The doses of drugs will be adjusted based on the breathing rate and effort.
- In general, most dogs with heart failure that is well controlled have a breathing rate at rest of less than 35 to 40 breaths per minute. In addition, the breathing effort, noted by the amount of belly wall motion used for each breath, is fairly minimal if heart failure is controlled.
- *An increase in breathing rate or effort will usually mean that you should give an extra dose of [B6].* If difficulty breathing is not improved by within 30-60 minutes after giving extra [B6], then we recommend that a recheck exam be scheduled and/or that your dog be evaluated by an emergency clinic.
- There are instructions for monitoring breathing, and a form to help keep track of breathing rate and drug doses, on the Tufts HeartSmart web site (<http://vet.tufts.edu/heartsmart/at-home-monitoring/>).
- We also want you to watch for weakness or collapse, a reduction in appetite, worsening cough, or distention of the belly as these findings indicate that we should do a recheck examination.
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Medications:

B6

5. Taurine supplementation: Give 1000 mg by mouth twice a day

This is a dietary supplement in case there has been some deficiency [B6] diet. You can get this from human supplement stores.

We recommend using *Twinkl, Swanson, NOW, or GNC brands.*

Diet suggestions:

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

There is recent anecdotal evidence that suggest grain free foods may contribute to the development of dilated cardiomyopathy (DCM). If [B6] seems to do better on a grain free food, we recommend switching to a main stream brand grain free food and supplementing taurine.

Grain-free options would include Hill's Science Diet Adult Grain Free, Hill's Natural Balance Grain Free, Purina Beyond Grain Free, Purina One Grain Free, or any other grain free food from a large pet food company.

Additional information on supplements such as fish oil or other supplements that you might have questions about may be found on the Tufts HeartSmart web site: (<http://vet.tufts.edu/heartsmart/diet/>).

Fish Oil

Dogs with DCM and arrhythmias may benefit from the addition of omega-3 fatty acids (fish oil) to the diet. Diets such as the Royal Canin Boer or Early Cardiac diet, or Hill's j/d have ample fish oil and may not require much (or any) additional supplementation. If you would like to stick with a grain free diet, you can supplement omega-3s (see attached handout).

Exercise Recommendations:

For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that [B6] is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:

A recheck visit is recommended in 1-2 weeks after any medication adjustments are made. We have scheduled you an appointment for Wednesday July 11th at 3:30 PM. At this visit we will check your dog's breathing effort and heart function, do a blood test to recheck kidney values, and probably recheck a blood pressure. A recheck echocardiogram is recommended in 3-4 months.

Thank you for entrusting us with [B6] care. Please contact our Cardiology liaison: [B6] or email us at cardiovet@tufts.edu for scheduling and non-emergent questions or concerns.

Please visit our HeartSmart website for more information

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

Clinical Trials:

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

Case: [B6]

Owner: [B6]

Discharge Instructions

B6

Sample Submission Form

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

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

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

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

Email: B6
 Tel: 508-887-4669 Fax: 508-839-7936

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

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

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

Taurine Results (nmol/ml)

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

Reference Ranges (nmol/ml)

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

B6

B6

3206380 Canine
 7/3/2018 4:14 PM
 TAURINE (WHOLE BLOOD)
 Lithium Heparin

B6

Patient ID:

Canine

Years Old Male (Neutered) Lab/x
Chocolate

Cardiology Appointment Report

Date: 7/3/2018

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Cardiology Technician:

B6

Student:

Presenting Complaint: Cough, tachyarrhythmia, heart murmur

Concurrent Diseases: None

General Medical History: Recently lethargic, appetite and P/U OK. Some inappetence after boarding in april 2018. UTD on interceptor and vaccines.

Diet and Supplements: Taste of the Wild Adult Grain-free Lamb, Cosequin

Cardiovascular History:

Prior CHF diagnosis? No

Prior ATE? No

Prior arrhythmia? Yes, tachyarrhythmia

Cough? Yes, sounded like dry heaving to O, especially bad this weekend, worse at night

Shortness of breath or difficulty breathing? A bit labored, even at rest as per O, over last week or two

Syncope or collapse? No

Sudden onset lameness? No

Exercise intolerance? Slow, O thinks just getting old

Prior heart murmur? Yes, see referring form, left systolic reportedly

Current Medications Pertinent to CV System:

None

Cardiac Physical Examination:

B6

Muscle condition:

- Normal
- Mild muscle loss, hind end
- Moderate cachexia
- Marked cachexia

Cardiovascular Physical Exam:

Murmur Grade:

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

Murmur location/description: Left systolic, basilar

Jugular vein:

- Bottom 1/3 of neck
- Middle 1/3 of neck
- Top 2/3rd of neck

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:

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

Abdominal exam:

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

Problems: Cough, tachyarrhythmia, heart murmur

Differential Diagnoses: Tachyarrhythmia r/o DCM, ARVC, SSS, Heart Block, Myocarditis; Heart Murmur r/o: DVD (mitral), stenosis
Cough - CHF vs laryngeal disease, pneumonia, neoplasia

Diagnostic plan:

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

Echocardiogram Findings:

General/2-D findings:

Abbreviated echo due to dyspnea and anxiety when restrained in lateral.

Dilated LV cavity with reduced contractile function, although septal motion is better than typical dog with isolated DCM. The LV cavity is markedly dilated. The LA is severely enlarged (more typical of a significant component of DMVD). The MV is slightly thickened with no obvious prolapse. The PA is slightly larger than the aorta.

The RH is also dilated. No pleural or pericardial effusion. No obvious cardiac masses visualized.

Echo was not completed as dog became short of breath and restless. A more complete exam would be desired once the dog is breathing better. B lines were noted in multiple lung lobes.

Doppler findings:

3+ MR

1+ TR

B6

Assessment and recommendations:

Echocardiogram reveals DCM with markedly enlarged LA. The patient also had a significant amount of ventricular arrhythmia during the procedure. Based on the clinical signs and echocardiogram and the presence of B lines, the patient is believed to be in active CHF although chest radiographs would be necessary to confirm the presumptive diagnosis. The patient is eating a grain free diet with lamb as a meat protein and DCM secondary to taurine deficiency is a possibility (but the dog has features that indicate a significant component of mitral valve disease as well). Taurine level should be submitted and taurine supplementation should be started as well. Ideally the diet would be changed to a main stream brand, standard protein, non-grain free option. Recommend therapy with 2.5mg PO BID, 75 mg PO BID and 10 mg PO SID and then increase to BID or even higher dose.

Discussed outpatient vs inpatient care - owner eventually elected inpatient care. During ECG monitoring the dog had enough arrhythmia to trigger a decision to start

Addendum 7/4/18: Patient RR normalized overnight with no coughing. There is still significant arrhythmia, but subjective decrease in overall heart rate and frequency of arrhythmia. Recheck renal values are still normal. Recommend recheck ECG and renal values in 1-2 weeks. Recheck echo in 3-4 months, or sooner if clinical signs occur such as increased RR/RE, cough, collapse, or exercise intolerance.

Final Diagnosis:

DCM with component of MV disease, CHF
Ventricular and atrial arrhythmia
Grain free diet (taste of the wild lamb)

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM Classification:

- A
- B1
- B2
- C
- D

M-Mode

IVSd	om
LVIDd	om
LVPWd	om
IVSs	om
LVIDs	om
LVPWs	om
%FS	%
Ao Diam	om
LA Diam	om
LA/Ao	
Max LA	om

M-Mode Normalized

IVSdN	{0.29 - 0.52}
LVIDdN	{1.35 - 1.73} !
LVPWdN	{0.33 - 0.53}
IVSsN	{0.43 - 0.71} !
LVIDsN	{0.79 - 1.14} !
LVPWsN	{0.53 - 0.78} !
Ao Diam N	{0.68 - 0.89} !
LA Diam N	{0.64 - 0.90} !

2D

SA LA	om
Ao Diam	om
SA LA / Ao Diam	
IVSd	om
LVIDd	om
LVPWd	om
EDV(Teich)	ml
IVSs	om
LVIDs	om
LVPWs	om



ESV(Teich)
EF(Teich)
%FS
SV(Teich)

B6

ml
%
%
ml

B6

Sample Submission Form

Amino Acid Laboratory
 University of California, Davis
 1020 Vet Med 38
 1089 Veterinary Medicine Drive
 Davis, CA 95616
 Tel: (530)752-5058, Fax: (530)752-4698

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

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

Vet/Tech Contact: **B6**
 Company Name: 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: _____
 Email: **B6** Tel: **B6**

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

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

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

Reference Ranges (nmol/ml)

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

B6

B6

7/3/2018 4:14 PM
 TAURINE (WHOLE BLOOD)
 Lithium Heparin

B6

Client Details

Name Address **B6** Phone **B6**

Patient Details

Name **B6** Species **Canine** Breed **Coton de Tulear** Age Sex **Female Spayed** Referral **B6**

Diagnosis: Congestive Heart Failure (CHF)

Prognosis: Fair - risk of recurrence

Drug Name	Quantity	Instructions
-----------	----------	--------------

B6

Tablets **28 6**

Give one tablet by mouth every 12 hours until directed otherwise. (RN)

Tablets **14 6**

Give one half tablet by mouth every 12 hours until directed otherwise. (RN)

due now at ho

Summary: **B6** was diagnosed with congestive heart failure based on chest x-rays. She was treated with oxygen supplementation **B6** a medication to help the heart contract). Overnight she was able to be weaned out of oxygen and she seems comfortable so we are discharging her to your care. Her blood pressure has been normal (once she got used to us measuring it!), and her oxygen saturation level has been normal on room air today.

Please schedule a follow-up visit with **B6** in the next 1-2 weeks. **B6** will need periodic monitoring of her kidneys. Ideally, a consultation with a cardiologist should be arranged to evaluate what type of heart problem she has - this will help with more specific therapy and provide a more accurate prognosis.

For now, **B6** should be allowed to rest at home - short leashed walks are fine but avoid strenuous walks/hikes and let **B6** rest or return home if she seems to tire.

Evaluate **B6** Resting Respiratory Rate (RRR) at home by counting how many breaths she takes over 60 seconds. Normal for a resting dog is less than 35. Be sure that she has been at rest/calm for about 30 minutes before counting her RRR. If **B6** RRR is greater than 45, and this persists over several minutes, please call for advice. If **B6** seems to have trouble breathing at any time (heavy panting, outstretched neck) or her gums are pale or purplish in color at any time she should recheck with a veterinarian immediately.

Thank you for bringing **B6** to the Emergency at **B6**. We appreciate your confidence in allowing us to care for her. Please do not hesitate to call if you any questions once **B6** is at home. You can always reach us at **B6** -- 24 hrs a day, 7 days a week, 365 days a year. You can also email us at **B6** with non-urgent questions or progress updates at any time.

B6

B6

Tuesday, June 05, 2018

B6

Thank you for your referral of **B6** the **B6** Spayed Female Poodle Mix owned by **B6** presented to **B5, B6** service on Tuesday, June 05, 2018.

History:

Presenting complaint: **B6** presents to Internal Medicine for acute onset signs that started a year ago. Itching first, followed by limping on left forelimb, followed by eating grass, vomiting, diarrhea which resolved and ends with constipation (per owner). Coughing and hacking with excitement more recently. Limping has resolved. Appetite is decreased in the morning. Then she becomes more perky and eats later in the day. Thirst is slightly decreased. Waxing and waning energy. Blood work dated 5/24/18 showed mild hyperbilirubinemia, but was a hemolyzed sample. Hemoconcentration Hct 60%.

Past pertinent history: Hx of biceps tendinitis

Travel: None

Diet: Novel protein (non prescription)

Current meds: CBD oil ; milk thistle

Physical Exam:

B6

Cardiovascular: Regular rhythm. No murmur. Strong and synchronous pulses.

B6

Significant Laboratory Findings:

DATE/TIME TEST

6/5/2018 PCV

6/5/2018 TS

DATE/TIME TEST

6/5/2018 TBIL

RESULT

B6

REFERENCE

RANGE

36 - 55

5.8 - 7.0

REFERENCE

RANGE

0.0 - 0.9

Radiographic Findings:

B6

IM Assessment:

1. Episodic gastrointestinal signs - vomiting, grass eating, diarrhea
2. Episodic limping
3. Episodic pruritis

Thoracic radiographs to evaluate the esophagus, abdominal ultrasound, PCV and Tbilirubin were all normal today. Baseline cortisol is pending to creen for addisons disease.

IM Plan:

- We will call you with baseline cortisol results as soon as they are available.
- We will continue the food trial that **B6** has just recently started.
- Consider conservative treatment for gastritis (H2 blocker, etc.) vs endoscopy in the future.

Thank you again for your support of

B6

Please do not hesitate to contact us if we can be of

further assistance.

Sincerely,

B6

B6

B6

B6

B6

B6

B6

Wednesday, March 14, 2018

B6

Dear **B6**

Thank you for your referral of **B6** the **B6** Neutered Male Goldendoodle owned by **B6** **B6** presented to **B6** Internal Medicine service on Tuesday, February 27, 2018.

History:

Presenting complaint: **B6** presents for recheck. He is doing great. He had one episode of belching a few weeks ago and owner are transitioning away from sweet potato as an ingredient in his diet. Owner are interested today in recheck his thyroid panel. **B6** was previously diagnosed with hypothyroidism started on supplementation. Review of his thyroid panel at a later date revealed that perhaps he didn't need it and it was discontinued. Owner are also interested in exploring the benefit of canine

B6 **B6** has found an evidence based company that provide **B6** **B6** The company will map **B6** microbiome DNA before and after starting the treatment.

Current meds:

B6

Physical Exam:

B6

Cardiovascular: Regular rhythm. No murmur. Strong and synchronous pulses.

B6

Significant Laboratory Findings:

DATE/TIME TEST	RESULT	REFERENCE RANGE
2/28/2018 FREE T4	B6	8 - 40
2/28/2018 TSH		0 - 0.60

Free T4 (Equilibrium Dialysis)

TSH: While many dogs with primary hypothyroidism have elevated cTSH concentrations, up to one third of affected dogs have normal or low cTSH concentrations, for reasons that are unclear. In those cases where TSH concentrations are normal and hypothyroidism is still strongly suspected, consider performing a **B6**

DATE/TIME TEST	RESULT	REFERENCE RANGE
2/28/2018 T4	B6	0.8 - 3.5

IM Assessment:

- 1.
 - 2.
 - 3.
- B6**

IM Plan:

B6

Thank you again for your support of **B6**. Please do not hesitate to contact us if we can be of further assistance.

Sincerely,

B6

B6

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Ceric, Olgica; Jones, Jennifer L; Glover, Mark; Nemser, Sarah; Palmer, Lee Anne; Queen, Jackie L; Reimschuessel, Renate; Rotstein, David
Sent: 3/16/2018 5:41:35 PM
Subject: FW: Acana Lamb & Apple Singles Formula Dog Food; [REDACTED] B6 EON-349594
Attachments: 2043914-report.pdf; 2043914-attachments.zip

I don't think I saw this one sent out. Unknown if there's any product left over or any lot #. The cardiologist made the report.

10yo, 65lb, MN Golden Retriever – dxed DCM, CHF, low blood taurine. Stopped food, supplemented taurine. Dog's values markedly improved and dog is being taken off medications.

From: PFR Event [mailto:ppreventcreation@fda.hhs.gov]
Sent: Friday, March 16, 2018 8:28 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [REDACTED] B6
Subject: Acana Lamb & Apple Singles Formula Dog Food; [REDACTED] B6 - EON-349594

A PFR Report has been received and PFR Event [EON-349594] has been created in the EON System.

A "PDF" report by name "2043914-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 "2043914-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-349594

ICSR #: 2043914

EON Title: PFR Event created for Acana Lamb & Apple Singles Formula Dog Food; 2043914

AE Date	10/25/2017	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	10 Years		
District Involved	PFR-Baltimore DO		

Product information

Individual Case Safety Report Number: 2043914

Product Group: Pet Food

Product Name: Acana Lamb & Apple Singles Formula Dog Food

Description: Suspected that Acana Lamb and Apple Singles Formula diet provides insufficient levels of taurine, contributing to development of [B6] dilated cardiomyopathy. [B6] presented to his primary care veterinarian October 21, 2017 for progressive panting at night over the past 3-4 months. Chest radiographs revealed cardiomegaly and congestive heart failure (CHF). We examined [B6] on 10/25/17 and was diagnosed with dilated cardiomyopathy (DCM) and CHF. A whole blood taurine level was tested on 10/25/17 and the result was [B6] - reference range 200-350 nmol/ml). This is suspected to be due to dietary deficiency. [B6] has been on Acana's limited-ingredient Lamb and Apple grain-free diet for the entirety of his life for the management of [B6]. After diagnosis of DCM and CHF, treatment included [B6] and supplementation with taurine [B6]. His diet was also switched from Acana Lamb and Apple diet to a commercial veterinary prescription diet (Hill's i/d). Since starting medications and supplementation with taurine/[B6] and changing the diet, he has had remarkable improvement in his cardiac size and function. He is no longer at risk for CHF and is being tapered off the [B6]. His systolic function is near normal. We do not see these improvements with medical therapy alone - only with taurine deficiency. - Normal left atrial size - previously severe - Moderate left ventricular enlargement - mildly improved - Mild to moderate right atrial and right ventricular dilation - improved - Low normal, improved decrease in systolic function - previously severe decrease

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

Product Name	Lot Number or ID	Best By Date
Acana Lamb & Apple Singles Formula Dog Food		

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-349594>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=365923>

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

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

Report Details - EON-349594

ICSR:	2043914
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-03-16 08:19:04 EDT

Reported Problem:	Problem Description:	Suspected that Acana Lamb and Apple Singles Formula diet provides insufficient levels of taurine, contributing to development of [B6] dilated cardiomyopathy. [B6] presented to his primary care veterinarian October 21, 2017 for progressive panting at night over the past 3-4 months. Chest radiographs revealed cardiomegaly and congestive heart failure (CHF). We examined [B6] on 10/25/17 and was diagnosed with dilated cardiomyopathy (DCM) and CHF. A whole blood taurine level was tested on 10/25/17 and the result was [B6] reference range 200-350 nmol/ml). This is suspected to be due to dietary deficiency. [B6] has been on Acana's limited-ingredient Lamb and Apple grain-free diet for the entirety of his life for the management of [B6]. After diagnosis of DCM and CHF, treatment included [B6] and supplementation with taurine [B6]. His diet was also switched from Acana Lamb and Apple diet to a commercial veterinary prescription diet (Hill's i/d). Since starting medications and supplementation with taurine [B6] and changing the diet, he has had remarkable improvement in his cardiac size and function. He is no longer at risk for CHF and is being tapered off the [B6]. His systolic function is near normal. We do not see these improvements with medical therapy alone - only with taurine deficiency. - Normal left atrial size - previously severe - Moderate left ventricular enlargement - mildly improved - Mild to moderate right atrial and right ventricular dilation - improved - Low normal, improved decrease in systolic function - previously severe decrease
	Date Problem Started:	10/25/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Acana Lamb & Apple Singles Formula Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Purchase Date:	09/01/2017		
	Possess Unopened Product:	Unknown		
	Possess Opened Product:	Unknown		
	Product Use Information:	Description:	This product was fed to the animal as a main diet source.	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Yes	
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Probably related		
Other Foods or Products Given to the Animal During This Time Period:	Yes			

	Manufacturer /Distributor Information:	Name:	Acana - Champion Petfoods LP			
		Type(s):	Manufacturer			
		Address:	11403 186 St NW Edmonton Alberta T5S 2W6 Canada			
		Contact:	Phone:	780-784-0300		
			Web Address:	https://acana.com		
		Possess One or More Labels from This Product:	Yes			
	Purchase Location Information:					
Animal Information:	Name:	B6				
	Type Of Species:	Dog				
	Type Of Breed:	Retriever - Golden				
	Gender:	Male				
	Reproductive Status:	Neutered				
	Weight:	29.6 Kilogram				
	Age:	10 Years				
	Assessment of Prior Health:	Excellent				
	Number of Animals Given the Product:	1				
	Number of Animals Reacted:	1				
	Owner Information:	Owner Information provided:	Yes			
		Contact:	Name:	B6		
			Phone:			
			Email:			
		Address:	B6			
		United States				
Healthcare Professional Information:	Practice Name:	B6				
	Contact:	Name:	B6			
		Phone:				
		Email:				
	Address:	B6				
		United States				
	Practice Name:	B6				
	Contact:	Name:	B6			
		Phone:				
		Email:				
	Address:	B6				

			B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	10/25/2017
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		
	Address:	B6	
			United States
	Contact:	Phone:	
		Email:	B6
	Permission To Contact Sender:		Yes
	Preferred Method Of Contact:		Email
	Reported to Other Parties:		Other
Additional Documents:	Attachment:	B6	Echo 10-25-17.pdf
	Description:		Echocardiogram 10-25-2017
	Type:		Echocardiogram
	Attachment:	B6	10-26-17.pdf
	Description:		Taurine Level 10-26-2017
	Type:		Laboratory Report
	Attachment:	B6	Echo Data 3-9-18.pdf
	Description:		Echocardiogram 3-9-2018
	Type:		Echocardiogram
	Attachment:	B6	Hx PDVM from Jan2017.pdf
	Description:		Primary care records from January 2017
	Type:		Medical Records
	Attachment:	B6	Echo 11-21-17.pdf
	Description:		Echocardiogram 11-21-2017
	Type:		Echocardiogram

IDEXX VetConnect 1-888-433-9987

Client: B6
Patient: B6
Species: CANINE
Breed: GOLDEN_RETRIEVE
Gender: MALE NEUTERED
Age: 9Y

Date: 10/26/2017
Requisition #: B6
Accession #: B6
Ordered by: B6

CVCA: B6
B6
Account: B6

NOTE FROM IDEXX

Test	Result
------	--------

NOTE: Extra serum sample received. It will be held for 5 days from the date of receipt. Please call Laboratory Services if additional testing is needed within this time frame. Thank you.

TAURINE (WHOLE BLOOD)

Test	Result	Reference Range	Low	Normal	High
TAURINE	B6	200 - 350 NMOL/ML	HIGH		B6

Comments:

1. Testing performed at B6

B6

www.cvcavets.com



Client:
Co-owner:
Patient name:
Species: Canine
Breed: Golden Retriever
Sex: MN
Age: months old
Weight: 29.6kg. / 65.26 lbs

Primary Care Veterinarian:
Primary Care Hospital:

Phone: ext:
Fax:
Email:

Cardiac Evaluation Report

Exam Date: 10/25/2017

Diagnosis

- Advanced dilated cardiomyopathy - ruleout idiopathic vs. taurine-responsive
- Mild to moderate mitral valve regurgitation
- Mild tricuspid valve regurgitation
- Severe left atrial chamber dilation
- Severe eccentric left ventricular chamber dilation
- Severe decrease in contractility/heart muscle function
- Moderate right atrial chamber dilation
- Moderate eccentric right ventricular chamber dilation
- Left- and right-sided congestive heart failure(pericardial and pleural effusion, pulmonary edema)

Medications

B6

Please also begin the following:

Information for

CVCA 03/14/2018

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 for more information about [B6] dilated cardiomyopathy.

Nutrition Recommendations

- Please continue normal diet until results of taurine are back. Ok to increase volume of food fed if he is interested in eating more.
- For more information about sodium content of various foods, please visit:
 - Dog: http://vet.tufts.edu/wp-content/uploads/reduced_sodium_diet_for_dogs.pdf
 - Treats: http://vet.tufts.edu/wp-content/uploads/treats_for_dogs_with_heart_disease.pdf
- CVCA recommends avoiding kidney diets unless [B6] that warrants protein restriction.
- Diet changes should be done gradually (ie. over ~1 month) to avoid GI upset and avoided until [B6] 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/>

B6

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 [B6] may have additional brand recommendations.

Activity Recommendations

- Keep [B6] very quiet for the next 3-4 days with only brief leash walks to eliminate.
- Once his respiratory rate and effort have returned to normal, [B6] may gradually resume activity as he 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 warm [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 or [B6] as 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 of [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 30-35 breaths per minute. Consider using a respiratory rate monitoring application to track [B6] respiratory 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 his 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

- Avoid intravenous or subcutaneous fluid therapy in the future, if possible. If fluid therapy is indicated, please contact CVCA.

- [B6] should not receive [B6] in the future please contact CVCA for recommendations, if [B6] are indicated.
- Avoid elective anesthesia, as [B6] is at high risk for complications due to the degree of cardiac disease. If anesthesia is necessary in the future, please contact CVCA for recommendations for monitoring and anesthetics.

Reevaluation

- Please recheck with [B6] in 2 weeks for a follow up examination, blood pressure and blood chemistry profile with electrolytes and as recommended by [B6]. Please forward these results when available.
- Recheck with CVCA in 3-4 weeks for consultation/examination, blood pressure and abbreviated echocardiogram to evaluate for recurrent pericardial and pleural effusion or sooner if [B6] symptoms recur or he is not doing well

Visit Summary

Heart Rate: 140bpm

BP: 132 mmHg

Cuff size/location: 6/LFL

History: [B6] a 9yo NM Golden Retriever, presents to CVCA 10/25/17 for evaluation of labored breathing, cardiomegaly.

10/21/17- pcDVM for routine exam. Given increase in respiratory rate and cough recommended thoracic radiographs. PE no murmur, gallop or arrhythmia ausculted. Concern for cardiomegaly, pleural effusion. Suspect DCM, referred to cardiology.

[B6] reports [B6] has been panting intermittently with an increased frequency at night for past 3-4months. He dreams very heavily (has torn through a wall before) and thinks increased panting seems to correlate with this. He chronically coughs after drinking water but this has increased in frequency and to other points throughout the day. Normal exercise tolerance, no weakness or collapse. Slowing down a little and slower to rise but suspect secondary to osteoarthritis. No obvious pale gums or abdominal distension. Normal appetite and thirst, no ongoing vomiting or diarrhea.

Diet: Acana Limited ingredient Lamb and apple- has been fed this his entire life to help with recurrent [B6] that resolved with diet change

Previous History:

B6

Current Medications: Fish oil supplements only

B6

TXR- Severe globoid enlargement of cardiac silhouette, diffuse interstitial pattern, mild pleural effusion, no significant dilation of pulmonary vasculature. No masses identified

10/25/17

B6 level (ldexx)- pending

Echocardiographic Findings

Severe left ventricular eccentric hypertrophy, severe secondary left atrial dilation, severely depressed indices of systolic function, significantly increased EPSS, mild to moderate centrally located mitral regurgitant jet, trace aortic and pulmonic valve regurgitations, mild eccentric low velocity tricuspid regurgitation, moderate right ventricular and right atrial dilation, normal left ventricular and decreased right ventricular outflow velocities, TMI E:A wave summation due to elevated heart rate, mild pericardial effusion, mild to moderate pleural effusion. No intra-cardiac masses identified in particular at heart base or right auricular appendage. ECG sinus tachycardia with no ventricular ectopy noted.

Comments

Dear B6

Thank you for sending B6 to see us with B6 today. Unfortunately, B6 has dilated cardiomyopathy causing biventricular congestive heart failure. This may be idiopathic DCM or taurine-deficient related to diet. We submitted a taurine level today as B6 is both a golden retriever and is being fed a limited ingredient diet. We also discussed with B6 today that while he has significant cardiomegaly and signs of failure on today's exam, the presence of a concurrent neoplastic process cannot be completely excluded simply because we did not identify a mass. Fortunately there is not a significant amount of pericardial effusion or evidence of tamponade and no pericardiocentesis was required today. We have begun therapy to control the congestive heart failure, slow down the progression of the heart disease and improve survival. We plan to recheck B6 in a few weeks to verify resolution of pleural and pericardial effusion. If resolved with treatment for congestive heart failure and no major changes in labwork then we will consider adding B6. If there is incomplete resolution or a large reaccumulation of fluid he may require further work up for other potential causes. 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, blood pressure and examinations. Unfortunately, the prognosis is guarded after the onset of congestive heart failure, and we discussed with the B6 family that the average survival is ~ 6-12 months. Survival time is highly individually variable depending on response to therapy and presence of concurrent illness, such as an occult neoplasia, could also significantly impact it. B6 is a very sweet dog and it was a pleasure to meet he B6 today.

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

B6

Client: **B6**
Co-owner: **B6**
Patient name: **B6**
Species: Canine
Breed: Golden Retriever
Sex: MN
Age: **B6** old
Weight: 29.6kg. / 65.26 lbs

Primary Care Veterinarian: **B6**
Primary Care Hospital: **B6**
B6
Phd: **B6**
Fax: **B6**
Email:

Cardiac Evaluation Report

Exam Date: 11/21/2017

Diagnosis

- Improved, dilated cardiomyopathy - suspect taurine-responsive, idiopathic cannot be excluded
 >Low taurine level 10/24/17 on limited ingredient diet
- Improved, now trace to mild mitral valve regurgitation
- Trace to mild tricuspid valve regurgitation
- Improved, now mild to moderate left atrial chamber dilation
- Improved, now moderate eccentric left ventricular chamber dilation
- Improved now mild to moderate decrease in systolic function
- Improved, mild to moderate right atrial and right ventricular chamber dilation
- Previous Left- and right-sided congestive heart failure(pericardial and pleural effusion, pulmonary edema)- controlled
- Chronic diarrhea with weight loss since starting cardiac medications

Medications

B6

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 for more information about [B6] dilated cardiomyopathy.

Nutrition Recommendations

- Please continue feeding [B6] a new diet. His diarrhea may respond to a novel protein formula. Ok to increase volume of food fed if he is interested in eating more to help put weight back on.
- For more information about sodium content of various foods, please visit:
 - Dog: http://vet.tufts.edu/wp-content/uploads/reduced_sodium_diet_for_dogs.pdf
 - Treats: http://vet.tufts.edu/wp-content/uploads/treats_for_dogs_with_heart_disease.pdf
- CVCA recommends avoiding kidney diets unless [B6] that warrants protein restriction.
- Diet changes should be done gradually (ie. over ~1 month) to avoid GI upset and avoided until [B6] 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/>

B6

- In addition to the supplements approved by Tuft's Veterinary Nutrition Service, other reputable brands include Welactin and Nordic Naturals. VCA [B6] may have additional brand recommendations.

Activity Recommendations

- [B6] may gradually continue activity as he 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 warm [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 or [B6] as 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 of [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 30-35 breaths per minute.** Consider using a respiratory rate monitoring application to track [B6] respiratory 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 his 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

- Avoid intravenous or subcutaneous fluid therapy in the future, if possible. If fluid therapy is indicated, please contact CVCA.
- [B6] should not receive [B6] in the future please contact CVCA for recommendations, if [B6] are indicated.

Avoid elective anesthesia, as [B6] is at high risk for complications due to the degree of cardiac disease. If anesthesia is necessary in the future, please contact CVCA for recommendations for monitoring and anesthetics.

Reevaluation

- Recheck with [B6] every 6 months for wellness care as directed, close auscultation, blood pressure and complete lab tests including blood and urine testing (CBC/Chemistry/Urinalysis/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]

Visit Summary

Heart Rate: 88bpm

BP: 132mmHg

Cuff size/location: 6cm / LF

History: [B6] a 9yo NM Golden Retriever, presents to CVCA 11/21/17 as an abbreviated recheck of previously diagnosed (10/25/17) DCM with biventricular CHF after presenting for evaluation of labored breathing, cardiomegaly. He was discharged on [B6] A Taurine level was submitted the day of his first cardiac exam that came back below the reference range so diet change was also recommended in addition to taurine supplementation. Recheck labwork 11/13/17 showed no major abnormalities. [B6] was decreased 11/8/17 after he became acutely pu/pd on medications. Since starting the medications/supplements o reports: Has been having diarrhea since starting the cardiac medications and since switching to Purina Bright Minds have intermittently been on chicken and rice to improve stools but still persistent. Energy is great have to try and limit him. RRR <30bpm. No cough except for occasional after water drinking

Current medications:

B6

Current Diet: varies right now trying to control diarrhea

Previous History:

B6

Other Diagnostics:

10/21/17-

CBC- WBC [B6] HCT [B6] PLT [B6]

CHEM-BUN [B6] CRE [B6] / K [B6] / TBIL [B6]

T4- [B6]

4DX- [B6]

TXR- Severe globoid enlargement of cardiac silhouette, diffuse interstitial pattern, mild pleural effusion, no significant dilation of pulmonary vasculature. No masses identified

10/25/17

Taurine level (Idexx)- [B6]

11/13/17

BUN [B6] CRE [B6]

11/21/17

[B6] sample sent to UC Davis for Golden Retriever Study

Abbreviated Echocardiographic Findings

Improved now moderate left ventricular eccentric hypertrophy, improve now mild secondary left atrial dilation, improved now mild to moderate decreased indices of systolic function with dyssynchronous LV free wall motion, improved still significantly increased EPSS, trace to mild mitral regurgitant jet, trace tricuspid regurgitation, improved mild to moderate right atrial and ventricular dilation, normal mitral inflow pattern, no pericardial or pleural effusion observed; normal sinus rhythm.

Comments

Dear [B6]

Thank you for sending [B6] to see us with [B6] today. [B6] previously advanced dilated cardiomyopathy has improved on medications for congestive heart failure and taurine supplementation. We are seeing significant improvement in his left sided chamber dimensions, mild improvement in systolic function and controlled pleural and pericardial effusion. Based on this we would not recommend any adjustments to his current medication or supplement doses. [B6] has been struggling with chronic diarrhea since starting the cardiac medications a month ago. The diarrhea has not improved with diet change and he has lost weight secondary to this. We recommended switching the [B6] to a no-flavored compounded tiny tablet and recommended following up with your office for a probiotic. If the diarrhea is not resolved with these changes then we may have to further adjust medications or try other diet modifications.

Given the low taurine level and positive response to medications and taurine [B6] may be a case of taurine-responsive dilated cardiomyopathy. He has been entered into a study out of UC Davis to follow the breed with this disease. Regardless of the underlying cause we are really pleased to see improvement in heart size and function and control of congestive heart failure. While on this course of medication, it is important to monitor the chemistry profiles, blood pressure and examinations. Survival time is highly individually variable but so far [B6] has had a nice response to therapies and we hope that we can stabilize his disease. [B6] is a very sweet dog and it was a pleasure to see he and [B6] again today.

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]

Patient Demographics

B6

Study Date: 03/09/2018

Patient ID: B6

Accession #:

Alt ID:

DOB: B6

Age: 10y

Gender: M Ht:

Wt: 65lb 4oz

BSA:

Institution: CVCA B6

Referring Physician:

Physician of Record:

Performed By: B6

Comments:

Adult Echo: Measurements and Calculations

2D

LVIDd (2D) LVPWd (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)	B6	LVAd (A4C) LVAs (A4C) EDV (A4C) ESV (A4C) LV Mass (Cubed) IVS/LVPW (2D) SV (A4C) EF (A4C)	B6	IVSd (2D) RVIDd/LVIDd RVIDd (2D) LA Area LA Dimen (2D) LA/Ao (2D) AoR Diam (2D) HR - AV	B6
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MMode

IVSd (MM) LVIDd (MM) LVPWd (MM) IVSs (MM) LVIDs (MM) LVPWs (MM) IVS/LVPW (MM)	B6	SV (MM-Teich) FS (MM-Teich) EF (MM-Teich) EDV (MM-Cubed) ESV (MM-Cubed) SV (MM-Cubed) EF (MM-Cubed)	B6	LVPW % (MM) RVIDd (MM) LA Dimen (MM) AoR Diam (MM) LA/Ao (MM) MV D-E Slope MV E-F Slope	B6
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B6

B6

03/09/2018

Created: 03:42PM 03/09/2018

1/3

B6

EDV (MM-Teich)	B6	FS (MM-Cubed)	B6	MV EPSS	B6
ESV (MM-Teich)		IVS % (MM)			

Doppler

LVOT Vmax Max PG Vmax	B6	MV E/A	B6	E/A Medial	B6
RVOT Vmax Max PG Vmax		Med E Vel		TR Vmax Max PG Vmax	
MV Peak E Vel PG		E/Med E			
MV Peak A Vel PG		Med A Vel			

Other Measurements

Dimensions: Diameters

LVID/Ao (2D)

EF & Volume: **B6**

Sphericity Id

Dimensions: Diameters

LVEDDN

LVID/Ao (2D)

B6

Images

B6

B6

B6

03/09/2018

Created: 03:42PM 03/09/2018

2/3

B6

Signature

Signature:
Name(Print):

Date:

B6

B6

03/09/2018

Created: 03:42PM 03/09/2018

3/3

Client:
Patient:

B6

Provider:

B6

B6

Record Date: 10-Mar-2018 to 10-Mar-2018

MEDICAL RECORD

Page 1 of 3

Client

Patient

B6

B6

B6

B6

Canine
Retriever, Golden

Golden
Male / Neutered - 65.4 lb
(10-Mar-2018)

Appointment Type: Wellness

Master Concerns (Problem List)

Active

• Dilated cardiomyopathy (10-Nov-2017)

B6

• Wellness (26-Sep-2015)

10-Mar-2018 Exam
08:17

B6

Assisted by: B6

VITALS

Temp (F)	HR	RR	SBP	CRT	MM color	Pain ([0-4])	BCS (1-9)
101.3 - ear	120	40		B6	Pink	0	B6

CLIENT INTERVIEW

General findings

B6

B6

B6

EXAM FINDINGS

Whole body

General findings
Attitude
Hydration

BAR
Exuberant - Sweet!
Hydration normal

Head

General findings
Nose

Normal
no discharge present

Eyes

General findings
Cornea
Conjunctive
Pupil

Menace and palpebral reflexes WNL OU
Clear OU
No discharge OU
PLRs WNL OU

B6

B6

lystetic
scant

Client:
Patient:

B6

Provider:
Record Date:

B6

10-Mar-2018 to 10-Mar-2018

B6

Page 2 of 3

MEDICAL RECORD

10-Mar-2018 Exam
08:17

Assisted by:

B6

B6

Ears	Lens	Nuclear sclerosis - Mild OU
	Sclera	Clear
	General findings	AU no erythema, no odor, not pruritic - Scant tan ceruminous debris external canal only, horizontal canals clean AU

Mouth

B6

Neck

Thorax

Heart	No murmur/arrhythmia detected, pulses ss
Respiratory effort	Eupnea
All lung fields	Clear sounds

Thoracic limbs

Abdomen

Pelvic limbs

B6

Pelvic region

Tail

Behavioral

Digestive

Integument

General findings	Normal
General findings	normal
General findings	Normal

B6

Lymphatic system

Nervous system

Reproductive

Urinary

ASSESSMENTS

Health assessment

Health status: Fair; Prognosis: Fair; Stability: Stable

PLANS

Dilated cardiomyopathy

Updated vaccines

B6

B6

B6

B6

B6

Client: [B6]
Patient: [B6]

Provider: [B6]
Record Date: 10-Mar-2018 to 10-Mar-2018

[B6]

MEDICAL RECORD Page 3 of 3

10-Mar-2018 Exam
08:17

[B6]
Assisted by: [B6]

cont all cardiac meds as directed
Recommend: daily dental care, cont ear cleaning, mo f/t/hw prevention
Discussed with O: [B6] signs of weakness - o elected to hold off on [B6] pr now & monitor it
[B6] BID mixed on food with [B6] & proviable for diarrhea
Nutritional rec: If able gradually transition to RC early cardiac diet
Declined: antech review of FNA cytology, [B6] trial
Recheck: 6mo for follow up labs and as directed by CVCA, or sooner if concerns

10-Mar-2018 Order items

[B6]

[B6]

[B6]
[B6]

Client: **B6**

B6

MEDICAL HISTORY: 10-Mar-2018 to 11-Mar-2018

DIAGNOSTIC REPORT

11-Mar-2018 AC CBC T4 UA SA672; Fecal O&PCmb T808 6mo **B6**

05:27 Source: **B6** Order item: AC CBC T4 UA SA672 [161.680]; Fecal O&PCmb T808 6mo [199.681]
 Sample collected: 05:37 11-Mar-2018 | Submitted: 10-Mar-2018 | Reported: 11-Mar-2018
 Lab reference: **B6**

Test	Results	Ref. range	Unit		
<i>Wellness Chemistries</i>					
Total Protein	B6	5 - 7.4	B6		
Albumin		2.7 - 4.4			
Globulin		1.6 - 3.6			
A/G Ratio		0.8 - 2			
ALT (SGPT)		12 - 118			
Alk Phosphatase		5 - 131			
Urea Nitrogen		6 - 31			
Creatinine		0.5 - 1.6			
BUN/Creatinine Ratio		4 - 27			
Glucose		70 - 138			
Potassium		3.6 - 5.5			
Comment		B6			
<i>Complete Blood Count</i>					
WBC		B6		4 - 15.5	B6
RBC	4.8 - 9.3				
Hemoglobin	12.1 - 20.3				
Hematocrit	36 - 60				
MCV	58 - 79				
MCH	19 - 28				
MCHC	30 - 38				
Platelet Count	170 - 400				
Platelet EST					
Neutrophils	60 - 77				
Bands	0 - 3				
Lymphocytes	12 - 30				
Monocytes	3 - 10				
Eosinophils	2 - 10				
Basophils	0 - 1				
Absolute Neutrophils	2060 - 10600				
Absolute Lymphocytes	690 - 4500				
Absolute Monocytes	0 - 840				
Absolute Eosinophils	0 - 1200				
Absolute Basophils	0 - 150				
<i>Total T4</i>					
T4	B6	0.8 - 3.5	B6		
<i>Urinalysis-Complete</i>					
Collection Method	n/a				
Natural Voiding					

B6
B6

Client: B6

B6

MEDICAL HISTORY: 10-Mar-2018 to 11-Mar-2018

DIAGNOSTIC REPORT

Test	Results	Ref. range	Unit
Color	B6		
Appearance			
Specific Gravity		1.015 - 1.05	
pH		5.5 - 7	
Protein		Negative	
Glucose		Negative	
Ketone		Negative	
Bilirubin		Neg To 1+	
Blood		Negative	
WBC		0-3	/HPF
RBC		0-3	/HPF
Casts		Hyaline 0-3	/LPF
Crystals			
Bacteria		None seen	/HPR
Squamous Epithelia		0-3	/HPF
<i>Ova and Parasite/Giardia (ELISA)</i>			
Ova and Parasite Giardia, elisa	B6		
<i>Urine Microalbumin Canine Reflex</i>			
Microalbuminuria The MA test is normal.	B6		mg/dL

B6
B6

B6

B6

B6

MEDICAL HISTORY

14-Jan-2017 to 22-Oct-2017

Client

B6
C: **B6**

Most recent visit date: 21-Oct-2017

Microchip No.:

Rabies tag ID / date :

B6

Patient

B6
Canine
Retriever, Golden

B6
Golden
Male / Neutered - 64.1 lb (21-Oct-2017)

Patient Alerts: **B6** see notes

Current medical overview: as of 23-Oct-2017

Current Wellness Reminders

B6

Due Date
04-Apr-2018
26-Sep-2018
08-Apr-2018
21-Oct-2018
21-Oct-2018
21-Oct-2018
26-Sep-2018
Doctor to assess
Gets product elsewhere
21-Apr-2018
21-Oct-2018
Gets product elsewhere
21-Oct-2018

Resolved Concerns (since 14-Jan-2017)

B6

Established	Resolved
08-Oct-2016	05-Nov-2016
27-Sep-2014	21-Oct-2017
10-Aug-2017	21-Oct-2017
29-Aug-2017	21-Oct-2017

Medications (since 22-Oct-2016)

B6

Feed as directed.

Weight by Age

Wt.	Record date
9y 8m 29.08 kg 64.1 lb	21-Oct-2017
9y 7m 28.89 kg 63.7 lb	29-Aug-2017
9y 6m 29.94 kg 66 lb	10-Aug-2017
9y 2m 27.03 kg 59.6 lb	08-Apr-2017
8y 11m 27.94 kg 61.6 lb	14-Jan-2017

Active Concerns

Established	
Heart enlarged	21-Oct-2017
Laryngeal noise	29-Aug-2017
B6	13-Dec-2016
	13-Dec-2016
Wellness	26-Sep-2015

Inactive Concerns

n/a

Resolved Concerns (since 14-Jan-2017)

B6

Established	Resolved
27-Sep-2014	25-Oct-2014
15-Dec-2015	09-Apr-2016
09-Apr-2016	08-Oct-2016

Client: **B6**

B6

MEDICAL HISTORY: 14-Jan-2017 to 22-Oct-2017

Outpatient visit (14-Jan-2017 to 14-Jan-2017)

Appointment Type: **Sick** Provider: **B6** Sex / age / weight: **Male - Neutered** / **B6** / **61.6 lb** (14-Jan-2017)

Concerns (Problem List)

Active

- B6**
- B6**
- Wellness (26-Sep-2015)
- B6**

14-Jan-2017 Exam

B6

07:49

Assisted by: **B6**

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain ([0-4])	BCS (1-9)
07:49	100.6 Ear	90	20	--	B6	Pink	0	B6

CLIENT INTERVIEW

General findings

Medication history

Presenting concerns

EXAM FINDINGS

Whole body

Head

Eyes

Ears

Mouth

Neck

Thorax

Thoracic limbs

Abdomen

Pelvic limbs

B6

B6

* Documents are available as separate attachments or files.

B6

Client: B6

B6

MEDICAL HISTORY: 14-Jan-2017 to 22-Oct-2017

14-Jan-2017 Exam

B6

07:49

Assisted by: B6

Pelvic region	General findings	normal
Tail	General findings	normal
Behavioral	General findings	normal
Cardiovascular	General findings	normal
Digestive	General findings	Normal
Integument	B6	
Lymphatic system	General findings	normal
Musculoskeletal	General findings	normal
Nervous system	General findings	normal
Reproductive	General findings	normal
Urinary	General findings	normal

ASSESSMENTS

Health assessment

Health status: Good; Prognosis: Good; Stability: Stable

PLANS

B6

14-Jan-2017 Order items

B6

Lab results

16-Jan-2017

12:04

B6

B6

Outpatient visit (08-Apr-2017 to 08-Apr-2017)

Appointment Type: Wellness Provider: B6 Sex / age / weight: Male - Neutered / B6 / 59.6 lb (08-Apr-2017)

Concerns (Problem List)

Active

B6

• Wellness (26-Sep-2015)

B6

* Documents are available as separate attachments or files.

08-Apr-2017 Exam
09:18

B6
Assisted by: B6

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain ([0-4])	BCS (1-9)
09:18	101.1 ear	80	20	—	B6	Pink	0	B6

CLIENT INTERVIEW

General findings

Medication history

EXAM FINDINGS

Whole body

Head

Eyes

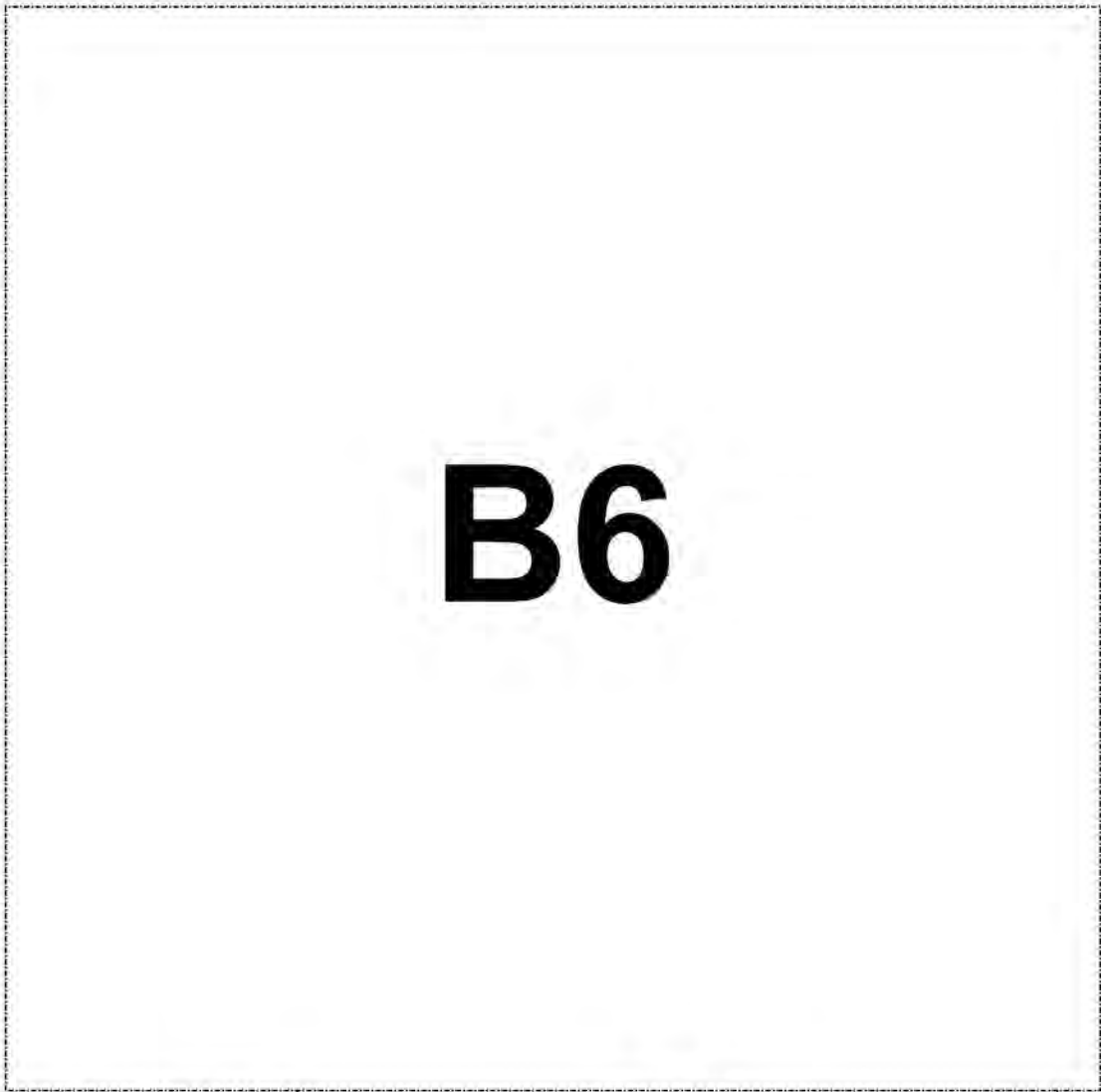
Ears

Mouth

Neck

Thorax

Thoracic limbs



Thoracic limb skin



Abdomen

General findings

Soft, non-painful, no obvious abn detected

Pelvic limbs

General findings

Normal gait, ambulatory, no CPE detected

Pelvic region

General findings

Normal

Tail

General findings

normal

Behavioral

General findings

Normal

Digestive

General findings

Normal

Integument



* Documents are available as separate attachments or files.

Client: [B6]

[B6]

MEDICAL HISTORY: 14-Jan-2017 to 22-Oct-2017

08-Apr-2017 Exam
09:18

[B6]
Assisted by: [B6]

- Lymphatic system
- Musculoskeletal
- Nervous system
- Reproductive
- Urinary

[B6]

ASSESSMENTS

Health assessment

Health status: Good; Prognosis: Good; Stability: Stable

Skin mass

[B6]

PLANS

[B6]

08-Apr-2017 Order items

[B6]

Outpatient visit (10-Aug-2017 to 10-Aug-2017)

Appointment Type: Sick Provider: [B6] Sex / age / weight: Male - Neutered / [B6] / 66 lb (10-Aug-2017)

Concerns (Problem List)

Active

[B6]

- Wellness (26-Sep-2015)

[B6]

10-Aug-2017 Exam
08:28

[B6]
Assisted by: [B6]

VITALS

Temp (F)	HR	RR	SBP	CRT	MM color	Pain ([0-4])	BCS (1-9)
102.0 rectal	160	panting	--	[B6]	Pink	0	[B6]

CLIENT INTERVIEW

General findings

Client comment - Started [B6] 2 days ago. This is the only real change. P is getting the [B6] but has a habit of not chewing food. O wonders if this

* Documents are available as separate attachments or files.

[B6]

B6

Diet history

Diet, specify food - Acana Limited ingredient - Lamb and Apple
3/4 C BID (No issues w/ this product)

Medication history

Non-prescription medications - **B6**

B6

EXAM FINDINGS

Whole body

General findings **BAR**
Attitude **Exuberant**

Head

General findings Normal

Eyes

General findings Normal

Ears

External ear canal **B6**

Mouth

B6

Neck

General findings normal

Thorax

All lung fields **B6**

Thoracic limbs

General findings normal

Abdomen

General findings **Limited range of motion**

Pelvic limbs

General findings Normal

Pelvic region

General findings normal

Tail

General findings normal

Cardiovascular

General findings normal

Digestive

General findings Normal

Integument

B6

Lymphatic system

General findings normal

Musculoskeletal

General findings normal

Reproductive

General findings normal

Urinary

General findings normal

ASSESSMENTS

Health assessment

Health status: Fair; Prognosis: Good; Stability: Stable

B6

* Documents are available as separate attachments or files.

Client: [B6]

B6

MEDICAL HISTORY: 14-Jan-2017 to 22-Oct-2017

10-Aug-2017 Exam
08:28

[B6]
Assisted by: [B6]

PLANS

[B6]

10-Aug-2017 Order items

[B6]

Outpatient visit (29-Aug-2017 to 29-Aug-2017)

Appointment Type: Sick Provider: [B6] Sex / age / weight: Male - Neutered / [B6] / 63.7 lb (29-Aug-2017)

Concerns (Problem List)

Active

[B6]

• Wellness (26-Sep-2015)

[B6]

29-Aug-2017 Exam
09:13

[B6]
Assisted by: [B6]

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain ([0-4])	BCS (1-9)
09:13	99.9 ear	120	panting	--	[B6]	Pink	0	[B6]

CLIENT INTERVIEW

General findings

History - [B6]
[B6]

Diet history

Diet, specify food - Acana Limited ingredient - Lamb and Apple 3/4 c BID

Medication history

Non-prescription medications [B6]

[B6]

Presenting concerns

* Documents are available as separate attachments or files.

[B6]

29-Aug-2017 Exam
09:13

B6
Recorded by: **B6**

B6

Behavioral

EXAM FINDINGS

Whole body

Whole body

Head

Eyes

Ears

Mouth

Neck

Thorax

Thoracic limbs

Abdomen

Pelvic region

Tail

Integument

Attitude

General findings

Head neurologic function

Nose

Cornea

Conjunctiva

Vision

Sclera

General findings

Teeth

Larynx

Heart

All lung fields

General findings

Abdominal palpation Within normal limits - No overt masses or organomegaly

Anus Within normal limits

General findings Within normal limits

General findings

Peripheral lymph nodes Within normal limits

Gait Normal gait

External genitals Within normal limits

External structures Within normal limits

B6

B6

ASSESSMENTS

Health assessment

Health status: Good; Prognosis: Good; Stability: Stable

B6

B6

PLANS

B6

* Documents are available as separate attachments or files.

Client: B6

B6

MEDICAL HISTORY: 14-Jan-2017 to 22-Oct-2017

29-Aug-2017 Exam
09:13

B6

Assisted by: B6

B6

See Home Care Instructions

Laryngeal noise

Discussed B6 and being mindful of walking pet on hot days

Vomiting

O to d/i B6 as planned and monitor

29-Aug-2017 Order items

- Exam/Consultation SemiAnnual [1.30]: 1.00 each
 - *Re: Exam (6mo) [608.34]: 1.00 each
- Cytology [199.250]: 1.00 test
- Gross Evaluation of FNA [101.400]: 1.00 test

Lab results

30-Aug-2017 Cytology(per Site) CYTO

B6

07:44 Source: B6 submitted: 29-Aug-2017 | Reported: 30-Aug-2017

[Report (if included in export) is located at the end of this document.]

Outpatient visit (21-Oct-2017 to 21-Oct-2017)

Appointment Type: **Wellness** Provider: B6 Sex / age / weight: **Male - Neutered** / B6 / **64.1 lb** (21-Oct-2017)

Concerns (Problem List)

Active

- **Heart enlarged** (21-Oct-2017)

B6

- **Wellness** (26-Sep-2015)

21-Oct-2017 Exam
08:19

B6

Assisted by: B6

VITALS

	Temp (F)	HR	RR	SBP	CRT	MM color	Pain ([0-4])	BCS (1-9)
08:19	100.6 ear	110	panting	110 RF Green cuff	B6	Pink	0	B6

CLIENT INTERVIEW

General findings

B6

* Documents are available as separate attachments or files.

VCA: B6

21-Oct-2017 Exam

B6

08:19

Assisted by: B6

Diet history **Diet, specify food** - Acana Limited ingredient - Lamb and Apple 3/4 c BID

EXAM FINDINGS

Whole body	General findings Attitude Hydration	Bright, Alert, Responsive Exuberant - Sweet! Hydration normal
Head	General findings	Normal palpation
Eyes	Lens	Nuclear sclerosis
Ears	General findings	B6
Mouth	Gingiva	
Neck	Teeth Larynx	
Thorax	Heart All lung fields	
Thoracic limbs		B6
Abdomen	General findings	Normal - Normal palpation. No pain or mass effects noted.
Pelvic limbs	General findings	Limited range of motion
Pelvic region	General findings	Normal - Normal perianal examination. Rectal exam normal.
Tail	General findings	Normal
Behavioral	General findings	Normal - Bright, alert and responsive. Good mentation and behavior.
Cardiovascular	General findings	Normal - No murmurs or arrhythmias. No muffled sounds, crackles or wheezed. PSS.
Digestive	General findings	Normal
Integument		B6
Lymphatic system	General findings	Normal
Musculoskeletal	General findings	Normal - Good ROM. No atrophy noted. Normal gait.
Nervous system	General findings	Normal
Reproductive	General findings	Normal
Urinary	General findings	Normal

ASSESSMENTS

Health assessment

Health status: Fair; Prognosis: B6 Stability: Stable

Heart enlarged

B6 in hosp 13 r/o DCM vs. HW vs. other primary heart disease

PLANS

Wellness

B6

* Documents are available as separate attachments or files.

Client: [B6]

MEDICAL HISTORY: 14-Jan-2017 to 22-Oct-2017

B6

21-Oct-2017 Exam

[B6]

08:19

Assisted by:

[B6]

[B6]

Discussed leash walking for elimination purposes, CVCA for Echo and EKG with medical management of heart disease if present. No overt signs of CHF.

21-Oct-2017 Order items

B6

Documents*

21-Oct-2017

[B6]

2017-10-23

[B6]

Lab results

22-Oct-2017

[B6]

AC770

[B6]

04:07 Source: [B6] | Submitted: 21-Oct-2017 | Reported: 22-Oct-2017

[Report (if included in export) is located at the end of this document.]

* Documents are available as separate attachments or files.

[B6]

Client: B6

B6

MEDICAL HISTORY: 14-Jan-2017 to 22-Oct-2017

DIAGNOSTIC REPORT

16-Jan-2017 Cytology(per Site) CYTO

B6

12:04 Source: B6 Order item: Cytology(per Site) CYTO [199.250]
Sample collected: 08:22 14-Jan-2017 | Submitted: 14-Jan-2017 | Reported: 16-Jan-2017
Lab reference: NYCC00041489

Test	Results	Ref. range	Unit
<i>Cytology</i>			
Cytology	<div style="border: 1px dashed black; padding: 10px; text-align: center;"> <p>CLINICAL INFORMATION: B6</p> <h1 style="margin: 0;">B6</h1> </div>		

B6

Client: B6

B6

MEDICAL HISTORY: 14-Jan-2017 to 22-Oct-2017

DIAGNOSTIC REPORT

30-Aug-2017 Cytology(per Site) CYTO

B6

07:44 Source: B6 Order item: Cytology(per Site) CYTO [199.250]
Sample collected: 08:00 30-Aug-2017 | Submitted: 29-Aug-2017 | Reported: 30-Aug-2017
Lab reference: NYCC00659118

Test	Results	Ref. range	Unit
Cytology			
Cytology			

CLINICAL INFORMATION: B6

B6

B6

DIAGNOSTIC REPORT

22-Oct-2017 BestCare Sr K9 (Accuplex) AC770

B6

04:07 Source: B6 Order item: BestCare Sr K9 (Accuplex) AC770 [163.109]
 Sample collected: 04:30 22-Oct-2017 | Submitted: 21-Oct-2017 | Reported: 22-Oct-2017
 Lab reference: NYAE25240212

Test	Results	Ref. range	Unit
<i>Superchem</i>			
Total Protein	B6	5 - 7.4	g/dL
Albumin		2.7 - 4.4	g/dL
Globulin		1.6 - 3.6	g/dL
A/G Ratio		0.8 - 2	
AST (SGOT)		15 - 66	U/L
ALT (SGPT)		12 - 118	U/L
Alk Phosphatase		5 - 131	U/L
GGTP		1 - 12	IU/L
Total Bilirubin		0.1 - 0.3	mg/dL
Urea Nitrogen		6 - 31	mg/dL
Creatinine		0.5 - 1.6	mg/dL
BUN/Creatinine Ratio		4 - 27	
Phosphorus		2.5 - 6	mg/dL
Glucose		70 - 138	mg/dL
Calcium		8.9 - 11.4	mg/dL
Corrected Calcium			
Magnesium		1.5 - 2.5	mEq/L
Sodium		139 - 154	mmol/L
Potassium		3.6 - 5.5	mmol/L
Na/K Ratio		27 - 38	
Chloride	102 - 120	mmol/L	
Cholesterol	92 - 324	mg/dL	
Triglycerides	29 - 291	mg/dL	
Amylase	290 - 1125	U/L	
PrecisionPSL	24 - 140	U/L	

B6

CPK B6 59 - 895 U/L

Comment B6

Complete Blood Count

WBC	B6	4 - 15.5	10 ³ /uL
RBC		4.8 - 9.3	10 ⁶ /uL
Hemoglobin		12.1 - 20.3	g/dL
Hematocrit		36 - 60	%
MCV		58 - 79	fL
MCH		19 - 28	pg
MCHC		30 - 38	g/dL
Platelet Count		170 - 400	10 ³ /uL

B6

DIAGNOSTIC REPORT

Test	Results	Ref. range	Unit
Platelet EST	B6		
Neutrophils		60 - 77	%
Bands		0 - 3	%
Lymphocytes		12 - 30	%
Monocytes		3 - 10	%
Eosinophils		2 - 10	%
Basophils		0 - 1	%
Absolute Neutrophils		2060 - 10600	/uL
Absolute Lymphocytes		690 - 4500	/uL
Absolute Monocytes		0 - 840	/uL
Absolute Eosinophils		0 - 1200	/uL
Absolute Basophils		0 - 150	10^9/L

Total T4

T4	Results	Ref. range	Unit
	B6	0.8 - 3.5	ug/dL

Urinalysis-Complete

Other	Results
	B6

Accuplex 4

B6

From: Reimschuessel, Renate </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C00C47AE2794134B2906D6B9252FCF6-RREIMSCH>
To: Jones, Jennifer L; Carey, Lauren; Ceric, Olgica; Glover, Mark; Nemser, Sarah; Palmer, Lee Anne; Queen, Jackie L; Rotstein, David
Sent: 3/21/2018 2:40:34 PM
Subject: RE: Acana Lamb & Apple Singles Formula Dog Food [REDACTED] - EON-349594

ok

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

From: Jones, Jennifer L
Sent: Tuesday, March 20, 2018 9:00 AM
To: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@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: RE: Acana Lamb & Apple Singles Formula Dog Food: [REDACTED] - EON-349594

I recommend trend. See the excerpt below from an ACVIM Cardiologist Listserve. They've tested the diets and suspect low cys/met with an inherent taurine handling in golden retrievers.

Hi All - I have been working with a few other cardiologists to collect a group of golden retrievers with taurine-deficiency and DCM. We have a total of 24 unrelated golden retrievers and the vast majority of these were eating diets that are labeled as grain free and use a large amount of peas or lentils in the ingredients.

Our nutritionists at UCD have been involved and analyzed some of the diets but certainly not all. We have reported the findings to the FDA. We are working on the assumption that the low level of cysteine/methionine in these foods coupled with the inherent taurine handling differences in golden retrievers is to blame. We are also interested in the trend that many of the designer diets include higher quality meats with relative little organ meat or byproducts. Perhaps this switch is also important as there is a fair amount of taurine to be found in the lower quality organ meats / byproducts that these designer diets try to avoid.

We have seen a fair number of other breeds as well but have not included them in our data gathering. A few of our cases were in CHF and have resolved with supplementation. Almost all have improved on supplementation. We have initial screening data and 3-4month follow-up on each of these cases now and I have a student working on writing this up. Many dogs had pretty low whole blood taurine levels, but a few had "low normal" values yet still responded favorable to supplementation.

Would love to chat with anyone interested.

Joshua Stern

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



From: Carey, Lauren
Sent: Friday, March 16, 2018 1:42 PM

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: Acana Lamb & Apple Singles Formula Dog Food [REDACTED] EON-349594

I don't think I saw this one sent out. Unknown if there's any product left over or any lot #. The cardiologist made the report.

10yo, 65lb, MN Golden Retriever – dxed DCM, CHF, low blood taurine. Stopped food, supplemented taurine. Dog's values markedly improved and dog is being taken off medications.

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Friday, March 16, 2018 8:28 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [REDACTED]
Subject: Acana Lamb & Apple Singles Formula Dog Food [REDACTED] EON-349594

A PFR Report has been received and PFR Event [EON-349594] has been created in the EON System.

A "PDF" report by name "2043914-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 "2043914-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-349594

ICSR #: 2043914

EON Title: PFR Event created for Acana Lamb & Apple Singles Formula Dog Food; 2043914

AE Date	10/25/2017	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	10 Years		
District Involved	PFR-Baltimore DO		

Product information

Individual Case Safety Report Number: 2043914

Product Group: Pet Food

Product Name: Acana Lamb & Apple Singles Formula Dog Food

Description: Suspected that Acana Lamb and Apple Singles Formula diet provides insufficient levels of taurine, contributing to development of [REDACTED] dilated cardiomyopathy [REDACTED] presented to his primary care veterinarian October 21, 2017 for progressive panting at night over the past 3-4 months. Chest radiographs

revealed cardiomegaly and congestive heart failure (CHF). We examined [B6] on 10/25/17 and was diagnosed with dilated cardiomyopathy (DCM) and CHF. A whole blood taurine level was tested on 10/25/17 and the result was [B6] reference range 200-350 nmol/ml). This is suspected to be due to dietary deficiency. [B6] has been on Acana's limited-ingredient Lamb and Apple grain-free diet for the entirety of his life for the management of [B6]. After diagnosis of DCM and CHF, treatment included: [B6] and [B6]. His diet was also switched from Acana Lamb and Apple diet to a commercial veterinary prescription diet (Hill's i/d). Since starting medications and supplementation with [B6] and changing the diet, he has had remarkable improvement in his cardiac size and function. He is no longer at risk for CHF and is being tapered off the [B6]. His systolic function is near normal. We do not see these improvements with medical therapy alone - only with taurine deficiency. - Normal left atrial size - previously severe - Moderate left ventricular enlargement - mildly improved - Mild to moderate right atrial and right ventricular dilation - improved - Low normal, improved decrease in systolic function - previously severe decrease

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

Product Name	Lot Number or ID	Best By Date
Acana Lamb & Apple Singles Formula Dog Food		

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-349594>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=365923>

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Report Details - EON-349594

ICSR: 2043914
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-03-16 08:19:04 EDT

Reported Problem:

Problem Description: Suspected that Acana Lamb and Apple Singles Formula diet provides insufficient levels of taurine, contributing to development of [B6] dilated cardiomyopathy. [B6] presented to his primary care veterinarian October 21, 2017 for progressive panting at night over the past 3-4 months. Chest radiographs revealed cardiomegaly and congestive heart failure (CHF). We examined [B6] on 10/25/17 and was diagnosed with dilated cardiomyopathy (DCM) and CHF. A whole blood taurine level was tested on 10/25/17 and the result was [B6] reference range 200-350 nmol/ml). This is suspected to be due to dietary deficiency. [B6] has been on Acana's limited-ingredient Lamb and Apple grain-free diet for the entirety of his life for the management of [B6]. After diagnosis of DCM and CHF, treatment included [B6] supplementation with [B6]. His diet was also switched from Acana Lamb and Apple diet to a commercial veterinary prescription diet (Hill's i/d). Since starting medications and supplementation with [B6] and changing the diet, he has had remarkable improvement in his cardiac size and function. He is no longer at risk for CHF and is being tapered off the [B6]. His systolic function is near normal. We do not see these improvements with medical therapy alone - only with taurine deficiency. - Normal left atrial size - previously severe - Moderate left ventricular enlargement - mildly improved - Mild to moderate right atrial and right ventricular dilation - improved - Low normal, improved decrease in systolic function - previously severe decrease

Date Problem Started: 10/25/2017

Concurrent Medical Problem: No

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: Acana Lamb & Apple Singles Formula Dog Food

Product Type: Pet Food

Lot Number:

Package Type: BAG

Purchase Date: 09/01/2017

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Product Use Information:

Description:	This product was fed to the animal as a main diet source.
Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	Yes
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Probably related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:	Name:	Acana - Champion Petfoods LP	
	Type(s):	Manufacturer	
	Address:	11403 186 St NW Edmonton Alberta T5S 2W6 Canada	
	Contact:	Phone: 780-784-0300 Web Address: https://acana.com	
	Possess One or More Labels from This Product:	Yes	
Purchase Location Information:			
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	29.6 Kilogram	
	Age:	10 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6 Phone: B6 Email: B6
		Address:	B6 United States
		Healthcare Professional Information:	Practice Name: CVCA Cardiac Care for Pets
	Healthcare Professional Information:	Contact:	Name: B6 Phone: B6 Email: B6
Address:		B6 United States	
Practice Name:		CVCA Cardiac Care for Pets	
Contact:		Name: B6 Phone: B6 Email: B6	
Address:	B6		

			B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	10/25/2017
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		
	Address:	B6	
		United States	
	Contact:	Phone:	
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	
Additional Documents:	Attachment:	B6	Echo 10-25-17.pdf
	Description:	Echocardiogram 10-25-2017	
	Type:	Echocardiogram	
	Attachment:	B6	BW Taurine 10-26-17.pdf
	Description:	Taurine Level 10-26-2017	
	Type:	Laboratory Report	
	Attachment:	B6	Echo Data 3-9-18.pdf
	Description:	Echocardiogram 3-9-2018	
	Type:	Echocardiogram	
	Attachment:	B6	Hx PDVM from Jan2017.pdf
	Description:	Primary care records from January 2017	
	Type:	Medical Records	
	Attachment:	B6	Echo 11-21-17.pdf
	Description:	Echocardiogram 11-21-2017	
	Type:	Echocardiogram	

Vet-LIRN Final Report: No Further Action (NFA) Consumer Complaints

Date the Complaint was Submitted

2018-03-16

Date the Complaint is NFA

2018-03-20

Complaint Number (e.g. EON or CC)

EON-349594

Owner Last Name

B6

Species

Canine

Product

Acana Lamb & Apple Singles Formula Dog Food

Brief Reason for Complaint

Dilated Cardiomyopathy

Reviewed Medical Records

Yes

Gathered Additional Product Information

No

Completed Owner Interview

No

Notified OS&C of Vet-LIRN Recommendation

Yes

Reason for NFA

Trending

Other Reason for NFA

Vet-LIRN Personnel

Jennifer Jones

Submit by Email

From: Carey, Lauren </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0226BD682844FA2B71EA3750D4FCB82-LAUREN.CARE>
To: Jones, Jennifer L
Sent: 4/3/2018 7:10:27 PM
Subject: FW: Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe [B6] EON-350263
Attachments: 2044821-report.pdf; 2044821-attachments.zip

And this one?

From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Friday, March 30, 2018 3:48 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [B6]
Subject: Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe: [B6] - EON-350263

A PFR Report has been received and PFR Event [EON-350263] has been created in the EON System.

A "PDF" report by name "2044821-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 "2044821-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350263

ICSR #: 2044821

EON Title: PFR Event created for Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe; 2044821

AE Date	08/21/2017	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Terrier - Bull		
Age	8 Years		
District Involved	PFR-Baltimore DO		

Product information

Individual Case Safety Report Number: 2044821

Product Group: Pet Food

Product Name: Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe

Description: [B6] is an 8 year old intact male Bull Terrier who was first diagnosed with severe degenerative valve disease with moderate decrease in contractility on 8/21/17. At that time, he was started on [B6]

and [B6] [B6] supplementation was recommended but not started. On [B6] he presented to the emergency service for a sudden increase in respiratory rate and effort and was hospitalized for congestive heart failure. Echo findings on [B6] included progressive valve disease and severe, progressive decrease in contractility, the latter of which may either be a component of dilated cardiomyopathy vs secondary to [B6] grain free diet (Nature's Recipe Salmon and Yam). Clinically, [B6] has been tiring more quickly recently. He has had weight loss (3 kg since 8/2017) despite a good appetite. Prior to his [B6] presentation, he had a 2-3 week history of collapsing/fainting episodes, in which he would go limp and paddle - no loss of bowels. Health history includes [B6] - previously on [B6] - but otherwise no major illnesses or injuries. I have recommended adjustments to [B6] medications as well as taurine supplementation; he will continue the Nature's Recipe Salmon and Yam diet due to significant [B6] when changing the diet.

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe		

Sender information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-350263>

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<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=366632>

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Report Details - EON-350263

ICSR: 2044821
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-03-30 15:41:47 EDT

Reported Problem:

Problem Description: B6 is an 8 year old intact male Bull Terrier who was first diagnosed with severe degenerative valve disease with moderate decrease in contractility on 8/21 /17. At that time, he was started on B6 B6 supplementation was recommended but not started. On B6 he presented to the emergency service for a sudden increase in respiratory rate and effort and was hospitalized for congestive heart failure. Echo findings on B6 included progressive valve disease and severe, progressive decrease in contractility, the latter of which may either be a component of dilated cardiomyopathy vs secondary to B6 grain free diet (Nature's Recipe Salmon and Yam). Clinically, B6 has been tiring more quickly recently. He has had weight loss (3 kg since 8/2017) despite a good appetite. Prior to his B6 presentation, he had a 2-3 week history of collapsing/fainting episodes, in which he would go limp and paddle - no loss of bowels. Health history includes B6 previously on B6 - but otherwise no major illnesses or injuries. I have recommended adjustments to B6 medications as well as taurine supplementation; he will continue the Nature's Recipe Salmon and Yam diet due to significant B6 when changing the diet.

Date Problem Started: 08/21/2017

Concurrent Medical Problem: Yes

Pre Existing Conditions: B6 and Nature's Recipe diet.
History of B6

Outcome to Date: Worse/Declining/Deteriorating

Product Information:

Product Name: Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: No

Possess Opened Product: No

Product Use Information:

Description: Used for daily feeding as main diet.

Last Exposure Date: 03/30/2018

Product Use Stopped After the Onset of the Adverse Event: No

Perceived Relatedness to Adverse Event: Probably related

Manufacturer /Distributor Information:

Name: J.M. Smucker Co. (formerly Big Heart Pet Brands)

Type(s): Manufacturer

Address: 1 Strawberry Lane
Orrville
Ohio
44667-9555
United States

Contact: **Phone:** (888) 550-9555
Web: <https://www.naturesrecipe.com/dog-recipes>

			Address: /grain-free/salmon-sweet-potato-and-pumpkin-recipe	
	Possess One or More Labels from This Product:	Yes		
	Purchase Location Information:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Terrier - Bull		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	26.3 Kilogram		
	Age:	8 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:	Owner Information provided:	No	
	Healthcare Professional Information:	Practice Name:	B6	
Contact: Name:		B6		
Phone:		B6		
Email:		B6		
Address:		B6 United States		
Sender Information:	Name:	B6		
	Address:	B6 United States		
	Contact: Phone:	B6		
	Email:	B6		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
	Reported to Other Parties:	Other		
Additional Documents:	Attachment:	B6	Echo 8-21-2017.pdf	
	Description:	Echo Report 8/21/2017		
	Type:	Echocardiogram		
	Attachment:	B6	Echo Data 8-22-2018.pdf	
	Description:	Echo Data 8/22/2018		
	Type:	Echocardiogram		

Attachment:	B6	Echo	B6	.pdf
Description:	Echocardiogram Report B6			
Type:	Echocardiogram			
Attachment:	B6	Echo Data 8-21-2017.pdf		
Description:	Echo Data 8/21/2017			
Type:	Echocardiogram			

B6

www.cvcavets.com



Client: **B6**
Co-owner: **B6**
Patient name: **B6**
Species: Canine
Breed: Bull Terrier
Sex: M
Age: **B6** months old
Weight: 26.3kg. / 57.98 lbs

Primary Care Veterinarian: **B6**
Primary Care Hospital: **B6**
Phone: **B6** ext: **B6**
Fax: **B6**
Email: **B6**

Cardiac Evaluation Report

Exam Date: **B6**

Diagnosis

- Advanced, progressive degenerative valvular disease
 - > Severe, stable mitral and mild tricuspid valve regurgitation causing heart murmur
 - > Severe, stable left atrial dilation
 - > Moderate to severe, stable left ventricular dilation
- Severe, progressive decrease in contractility - R/O component of dilated cardiomyopathy vs. secondary to grain-free diet
- Recurrent left-sided congestive heart failure (8/21/2017 and **B6**)
- History of **B6** with activity **B6** with recent recurrence
- **B6**

Medications

B6

In 2 weeks, if **B6** is eating and feeling well:

B6

Information for **B6**

CVCA **B6** 03/30/2018

- Please call if you note any decrease in appetite, vomiting, diarrhea, lethargy, weakness, or any other signs of illness while beginning/adjusting the medications or if the respiratory rate and effort do not return to normal or the cough does not resolve within the next 2-3 days.

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 for more information about [B6] degenerative valvular disease and congestive heart failure.

Nutrition Recommendations

- Continue the Nature's Recipe Salmon and Yam diet.

Activity Recommendations

- Keep [B6] very quiet for the next 3-4 days with only brief leash walks to eliminate.
- Once his respiratory rate and effort have returned to normal [B6] may gradually resume activity as he wants and is able to do. Please allow [B6] to take more breaks and rest during activity.
- Please avoid vigorous activity, especially 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 [B6] resting respiratory rate several times a week.
 - > Normal resting respiratory rates should be less than 30-35 breaths per minute.
 - > Consider using a respiratory rate monitoring application to track your pet's respiratory rate - Cardalis or BI Pharma have reliable phone applications. Please contact us if you note a persistent or progressive increase.
- Monitor for signs of cough, respiratory difficulty, exercise intolerance, weakness, lethargy, etc. If you note any of these symptoms, please notify CVCA or [B6] as these symptoms may indicate recurrent congestive heart failure.
 - > If you note a mild increase in cough, respiratory rate or effort, please feel free to give an additional dose of [B6] while contacting CVCA.
 - > If he ever appears in distress, please seek emergency veterinary care.

Future Anesthesia/Fluid Recommendations

Avoid intravenous or subcutaneous fluid therapy in the future, if possible. If fluid therapy is indicated for [B6] in the future, please contact CVCA.

[B6] in the future - please contact CVCA if [B6] are indicated.

- Avoid elective anesthesia, as [B6] is at high risk for complications due to the degree of cardiac disease. If anesthesia is necessary in the future, please contact CVCA for recommendations for monitoring and anesthetics.

Reevaluation

- 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 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].

Visit Summary

Heart Rate: 130 bpm

BP: 172 mmHg (120 based on MR jet - echo)

Cuff size/location:

Information for [B6]

CVCA [B6] 03/30/2018

5 cm RF

History: Recheck [B6]; had been doing well until yesterday when noted sudden increase in RR/RE - presented to ER and hospitalized for CHF overnight - came directly from ER this am for appointment; has been tiring a bit more quickly recently; good appetite but 3 kg weight loss since 8/2017; 2-3 week history of collapsing episodes - goes limp, paddling, no loss of bowels

- Hx of [B6]
- Diet - Nature's Recipe.
- 6/27/17: pcDVM visit for suspected syncope (outside playing last week and last night, acutely fell over, rapid recovery). PE - no obvious murmur. AIS Rad Report [B6]
- [B6] Rx [B6]
- 7/15/17: pcDVM visit for recheck radiographs. PE - new Gr 3/6 heart murmur. Mild improvement on radiographs. Rx: [B6]
- 7/28/17: [B6] while boarding. Rx: [B6]
- Current Hx: Syncopal event yesterday - fell over after walking down stairs. No RR/RE changes; always has seemed to breathe heavy at rest +/- moreso recently. No coughing. Good energy and appetite; have stopped exertional play pending cardiac workup. No current Rx.

Physical Exam Findings: Loud 4/6 pansystolic murmur, PMI - mitral valve, regular rhythm; LUNGS - panting, sl. harsh all fields, Pink mm; PP - SS; PLN - WNL; SI. thin body condition with some dorsal muscle wasting (BCS - 4/9); ABD - Hepatomegaly; BAR/anxious
CAUTION -- aggressive in hospital; Used basket muzzle today and did well -- barked a lot; well-behaved on echo table/easy to restrain.

Referral Diagnostics:

ER Chest Rads: Moderate to severe generalized cardiomegaly; distended pulmonary vessels; moderate, diffuse interstitial infiltrate consistent with cardiogenic pulmonary edema; no masses, effusions.

Echocardiographic Findings

Moderate to severe myxomatous type change to both mitral valve leaflets but especially the anterior mitral valve leaflet, severe mitral valve regurgitation eccentrically directed towards the left atrial free wall - stable; severe left atrial dilation on 2D imaging and severely increased LA:Ao ratio on m-mode imaging, moderate dilation of left auricular appendage - all LA dimensions stable compared to previous exam, moderate to severe dilation of left ventricular diastolic internal dimensions with moderate increase in systolic dimensions - stable, normal septal/wall thickness, severely depressed left ventricular systolic function - progression compared to previous exam, mild tricuspid valve regurgitation - normal pulmonary pressures, subjectively normal right heart, normal right ventricular outflows, mildly thickened aortic valve leaflets and mildly elevated LV outflow tract velocities - consistent with borderline aortic stenosis; trace to mild low velocity pulmonic valve regurgitation, restrictive E/A with elevated Emax on transmitral spectral Doppler tracings, normal E'/A' on TDI, elevated E:E', normal estimated systemic blood pressure based on mitral regurgitant pressure gradient, no masses, effusions or heartworms observed.

Comments

Dear [B6]

Thank you for sending [B6] to see us again with [B6] today. Sadly, [B6] has had a bout of congestive heart failure secondary to his advanced degenerative valvular disease. He has had continued progression of his left ventricular systolic dysfunction. Cardiologists have concern about an association between dilated cardiomyopathy and grain-free diets. It is unclear if all diets are the culprit. I discussed this with the family. Because of the [B6] it sounds like we are unable to change [B6] diet so I have recommended supplementing taurine. We have also increased the [B6] to delay the onset of overt congestive heart failure, slow down the progression of the heart disease and improve survival. Continued monitoring of the chemistry profiles is recommended. We will continue to closely monitor [B6] via serial echocardiography and institute further therapy if progression occurs. We are hopeful that we can restabilize [B6] heart disease and that he will do well with treatment.

As always, we sincerely appreciate all of your continued referrals and trust in CVCA to care for your cardiac patients. Please feel free to call us with any questions or concerns about this case or any others. In an effort to continue to improve CVCA's service to both you and your clients, please take time to visit our website at www.cvcavets.com and complete our online referring veterinarian survey.

Sincerely,

B6 DVM, DACVIM (Cardiology)

B6

www.cvcavets.com



Client: **B6**
Co-owner: **B6**
Patient name: **B6**
Species: Canine
Breed: Bull Terrier
Sex: M
Age: **B6** months old
Weight: 26.3kg. / 57.98 lbs

Primary Care Veterinarian: **B6**
Primary Care Hospital: **B6**
Phone: **B6** ext: **B6**
Fax: **B6**
Email: **B6**

Cardiac Evaluation Report

Exam Date: 08/21/2017

Diagnosis

- Advanced degenerative valvular disease
 - > Severe mitral and mild tricuspid valve regurgitation causing heart murmur
 - > Severe left atrial dilation
 - > Moderate to severe left ventricular dilation with moderate decrease in contractility
- Concern for impending left-sided congestive heart failure
- Syncope (fainting) with activity
 - > Rule out due to decreased cardiac output secondary to decreased heart muscle function vs neurally-mediated vs impending heart failure

Medications

B6

Information for **B6**

CVCA **B6** 03/30/2018

B6

- Please call if you note any decrease in appetite, vomiting, diarrhea, lethargy, weakness, or any other signs of illness while beginning/adjusting the medications or if the respiratory rate and effort do not return to normal or the cough does not resolve within the next 2-3 days.

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 for more information about B6 degenerative valvular disease and congestive heart failure.

Nutrition Recommendations:

- A normal diet may be continued.

Activity Recommendations:

- B6 may gradually resume activity as he wants and is able to do. Please allow B6 to take more breaks and rest during activity.
- Please avoid vigorous activity, especially 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 B6 resting respiratory rate several times a week.
 - > **Normal resting respiratory rates should be less than 30-35 breaths per minute**
 - > Consider using a respiratory rate monitoring application to track your pet's respiratory rate - Cardalis or BI Pharma have reliable phone applications. Please contact us if you note a persistent or progressive increase.
- Monitor for signs of cough, respiratory difficulty, exercise intolerance, weakness, lethargy, etc. If you note any of these symptoms, please notify CVCA or B6 as these symptoms may indicate recurrent congestive heart failure.
 - > **If you note a mild increase in cough, respiratory rate or effort, please feel free to give an additional dose of B6**
 - > If he ever appears in distress, please seek emergency veterinary care.

Future Anesthesia/Fluid Recommendations

- **Caution with intravenous or subcutaneous fluid therapy in the future as B6 is at a high risk for fluid overload and development of congestion (ie: heart failure)** If fluids are needed, these should be given very cautiously and breathing rate carefully monitored as fluids are given. Oral or NE feeding tends to be better tolerated in patients with severe heart disease and should be considered if applicable.
- **B6 is at a high risk for complications related to anesthesia and I would recommend avoiding elective anesthetic procedures.** Should the need arise for emergency surgery we recommend the following precautions be taken: judicious use of IV fluids (1-3 mls/kg/hr, or as clinically indicated), avoidance of the following medications: alpha-2-agonists (such as Dexmedetomidine), ketamine, Telazol, and atropine and the atropine derivatives (unless indicated by bradycardia), and careful monitoring of heart rate and rhythm, blood pressure, and oxygen status during the procedure. If a pressor is indicated recommend dobutamine starting at 5 ug/kg/min and titrated to maintain a systolic blood pressure >90-100 mmHg. Prior to anesthesia do not give benazepril for 24 hours and obtain thoracic radiographs prior to induction. Monitor closely for several hours upon recovery and consider repeat thoracic radiographs if there are any concerns. There is a risk with any anesthetic event. Consider a consult with an anesthesiologist. We also recommend careful monitoring for congestive heart failure for 2-3 days after the procedure.

Reevaluation

- Please recheck with B6 in 2 weeks for a follow up examination and blood chemistry profile with electrolytes, or as recommended by B6. Please forward these results when available.
- Please recheck with B6 every 4-5 months for a follow up examination and blood chemistry profile with electrolytes or as recommended by B6. Please forward these results when available.

• Please recheck with CVCA in 4-5 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: 140 bpm

BP: 160-165/xx mmHg

Cuff size/location: by MR PG

History:

- Hx of **B6** - previously on **B6**
- Diet - Nature's Recipe.
- 6/27/17: pcDVM visit for suspected syncope (outside playing last week and last night, acutely fell over, rapid recovery). PE - no obvious murmur. AIS Rad Report - **B6**
B6 Rx **B6**
- 7/15/17: pcDVM visit for recheck radiographs. PE - new Gr 3/6 heart murmur. Mild improvement on radiographs.
Rx: **B6**
- 7/28/17: **B6** while boarding. Rx: **B6**
- Current Hx: **B6** event yesterday - fell over after walking down stairs. No RR/RE changes; always has seemed to breathe heavy at rest +/- moreso recently. No coughing. Good energy and appetite; have stopped exertional play pending cardiac workup. No current Rx.

Physical Exam Findings:

****CAUTION** -- aggressive in hospital; pcDVM uses basket muzzle +/- sedation to facilitate visits** Used basket muzzle today and did well -- barked a lot, but was not lunging or overtly aggressive; well-behaved on echo table/easy to restrain.

BW: 66 lbs = 30 kg

Gen: BAR/H, BCS 6/9

EENT: MM pink, no oral exam, no cough

CV/R: Gr 4/6 high frequency systolic murmur PMI left apex, regular rhythm (HR 140), normal pulse quality and synchronous with heart rate, mildly increased lung sounds bilaterally, eupneic (RR heavy panting)

B6

Referral Diagnostics:

- 6/27/17: CXR - mild generalized cardiomegaly, moderate broncho-interstitial pattern and peribronchial markings, normal pleural space, prominent to mildly dilated pulmonary vessels, normal trachea **B6**
- 7/15/17: CXR - improved lung pattern.

CVCA Additional Diagnostics

- Lead II ECG - sinus tachycardia, HR 180 bpm.

Echocardiographic Findings

Moderate myxomatous type change to both mitral valve leaflets but especially the anterior mitral valve leaflet, severe mitral valve regurgitation eccentrically directed towards the left atrial free wall, severe left atrial dilation on 2D imaging and severely increased LA:Ao ratio on m-mode imaging, moderate dilation of left auricular appendage, moderate to severe dilation of left ventricular diastolic internal dimensions with moderate increase in systolic dimensions, normal septal/wall thickness, moderately depressed left ventricular systolic function, mild tricuspid valve regurgitation - unable to estimate pulmonary pressures (too much respiratory motion for alignment), subjectively normal right heart, low normal left and normal right ventricular outflows, trace to mild low velocity pulmonic valve regurgitation, restrictive E/A with elevated Emax on transmitral spectral Doppler tracings, normal E'/A' on TDI, elevated E:E', decreased S' velocity, high normal estimated systemic blood pressure based on mitral regurgitant pressure gradient, no masses, effusions or heartworms observed.

Comments

Dear **B6**

Thank you for sending **B6** to see us with **B6** today. Sadly, **B6** has advanced degenerative valvular disease severe secondary left atrial and moderate to severe left ventricular dilation with systolic dysfunction placing him at high risk for imminent left-sided congestive heart failure. We have begun **B6** and

Information for **B6**

CVCA **B6** 03/30/2018

B6 to delay the onset of overt congestive heart failure, slow down the progression of the heart disease and improve survival.^{1,2,3} While on this course of medication, it is important to monitor the chemistry profiles and blood pressure. We will continue to closely monitor **B6** via serial echocardiography and institute further therapy if progression occurs. We are hopeful that **B6** will do well with treatment. However, we discussed with the family that average survival with mitral regurgitation and congestive heart failure is ~ 12-18 months. Survival time is highly individually variable depending on response to therapy.

As always, we sincerely appreciate all of your continued referrals and trust in CVCA to care for your cardiac patients. Please feel free to call us with any questions or concerns about this case or any others. In an effort to continue to improve CVCA's service to both you and your clients, please take time to visit our website at www.cvcavets.com and complete our online referring veterinarian survey.

Sincerely,

B6 DVM, DACVIM (Cardiology)

Footnotes:

¹ Bernay F., Bland J.M., Haggstrom, J., Baduel, L., Combes, B., Lopez, A., Kaltsatos, V. (2010 November - December). Efficacy of Spironolactone on Survival in Dogs with Naturally Occurring Mitral Regurgitation Caused by Myxomatous Mitral Valve Disease. *Journal of Veterinary Internal Medicine*. 24(6), 1245-6.

² Atkins, C., Bonagura, J., Ettinger, S., Fox, P., Gordon, S., Haggstrom, J., Hamlin, R., Keene, B., Luis-Fuentes, V., Stepien, R. (2009 November - December). Guidelines for the Diagnosis and Treatment of Canine Chronic Valvular Heart Disease. *Journal of Veterinary Internal Medicine*. 23(6), 1142-50.

³ Häggström, J., Boswood, A., O'Grady, M., Jöns, O., Smith, S., Swift, S., Borgarelli, M., Gavaghan, B., Kresken, J.G., Patteson, M., Ablad, B., Bussadori, C.M., Glaus, T., Kovacevic, A., Rapp, M., Santilli, R.A., Tidholm, A., Eriksson, A., Belanger, M.C., Deinert, M., Little, C.J., Kvarn, C., French, A., Rønn-Landbo, M., Wess, G., Eggertsdóttir, A.V., O'Sullivan, M.L., Schneider, M., Lombard, C.W., Dukes-McEwan, J., Willis, R., Louvet, A., DiFrancia, R. (2008 September - October). Effect of Pimobendan or Benazepril Hydrochloride on Survival Times in Dogs with Congestive Heart Failure Caused By Naturally Occuring Myxomatous Mitral Valve Disease: The QUEST Study. *Journal of Veterinary Internal Medicine*. 22(5), 1124-35.

Patient Demographics

B6		Study Date: B6	
Patient ID: B6	Accession #:	Alt ID:	
DOB: B6	Age: 8y	Gender: M	Ht: Wt: 66lb 0oz BSA:
Institution: CVCA B6	Referring Physician:		
Physician of Record:		Performed By: B6	
Comments:			

Adult Echo: Measurements and Calculations

2D

LVIDd (2D) LVPWd (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)	B6	LVAd (A4C) LVAs (A4C) EDV (A4C) ESV (A4C) LV Mass (Cubed) IVS/LVPW (2D) SV (A4C) EF (A4C)	B6	IVSd (2D) RVIDd/LVIDd RVIDd (2D) LA Area LA Dimen (2D) LA/Ao (2D) AoR Diam (2D) MPA Diam	B6
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MMode

IVSd (MM) LVIDd (MM) LVPWd (MM) IVSs (MM) LVIDs (MM) LVPWs (MM) IVS/LVPW (MM)	B6	SV (MM-Teich) FS (MM-Teich) EF (MM-Teich) EDV (MM-Cubed) ESV (MM-Cubed) SV (MM-Cubed) EF (MM-Cubed)	B6	LVPW % (MM) RVIDd (MM) LA Dimen (MM) AoR Diam (MM) LA/Ao (MM) MV D-E Slope MV E-F Slope	B6
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B6

B6

B6

Created: 04:20PM

B6

1/2

EDV (MM-Teich) ESV (MM-Teich)	B6	FS (MM-Cubed) IVS % (MM)	B6	MV EPSS	B6
----------------------------------	-----------	-----------------------------	-----------	---------	-----------

Doppler

LVOT Vmax Max PG Vmax	B6	MV Peak E Vel Vel PG	B6	Med E` Vel	B6
RVOT Vmax Max PG Vmax		MV Peak A Vel Vel PG		E/Med E`	
MR Vmax Max PG Vmax		MV E/A		Med S Vel	

Other Measurements

Dimensions: Diameters

LVID/Ao (2D)

EF & Volume: Simpson's

Sphericity Id

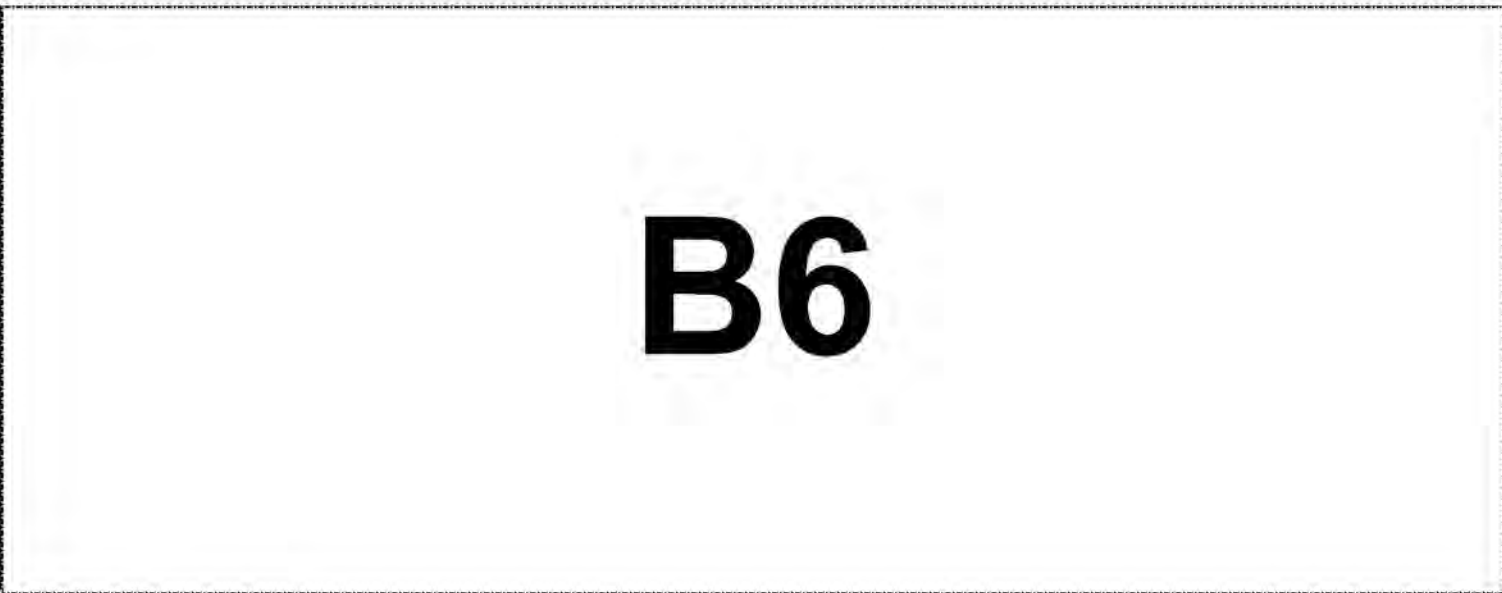
Dimensions: Diameters

LVEDDN

LVID/Ao (2D)

B6

Images



Signature

Signature:

Name(Print):

Date:

B6

B6

B6

Created: 04:20PM

B6

Patient Demographics

B6		Study Date: B6	
Patient ID: B6	Accession #:	Alt ID:	
DOB: B6	Age: 8y	Gender: M	Ht: Wt: 58lb 0oz BSA:
Institution: CVCA		Performed By: B6	
Referring Physician:			
Physician of Record:			
Comments:			

Adult Echo: Measurements and Calculations

2D

LVIDd (2D) LVPWd (2D) EDV (2D-Teich) EDV (2D-Cubed) LV Mass (Cubed)	B6	IVS/LVPW (2D) IVSd (2D) RVIDd/LVIDd RVIDd (2D) LA Area	B6	LA Dimen (2D) LA/Ao (2D) AoR Diam (2D) HR - AV	B6
---	----	--	----	---	----

MMode

IVSd (MM) LVIDd (MM) LVPWd (MM) IVSs (MM) LVIDs (MM) LVPWs (MM) IVS/LVPW (MM) EDV (MM-Teich) ESV (MM-Teich)	B6	SV (MM-Teich) FS (MM-Teich) EF (MM-Teich) EDV (MM-Cubed) ESV (MM-Cubed) SV (MM-Cubed) EF (MM-Cubed) FS (MM-Cubed) IVS % (MM)	B6	LVPW % (MM) RVIDd (MM) LA Dimen (MM) AoR Diam (MM) LA/Ao (MM) MV D-E Slope MV E-F Slope MV EPSS	B6
---	----	--	----	--	----

B6

B6

B6

Created: 12:40PM B6

1/4

Doppler

LVOT Vmax Max PG Vmax	B6	MV Peak E Vel Vel PG	B6	E/ Med E [*]	B6
RVOT Vmax Max PG Vmax		MV Peak A Ve Vel PG		Med A [*] Vel	
MR Vmax Max PG Vmax		MV E/A		E [*] /A [*] Medial	
IVRT		Med E [*] Vel		TR Vmax Max PG Vmax	

Other Measurements

Dimensions: Diameters

LVID/Ao (2D)

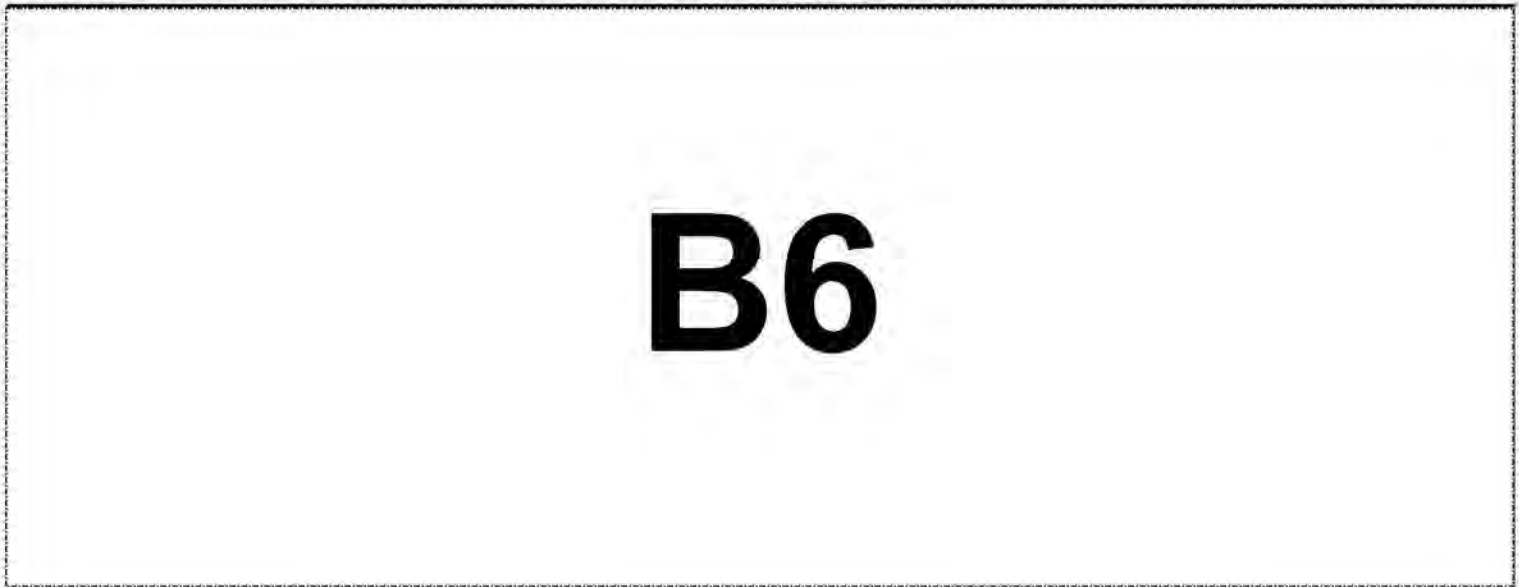
B6

Dimensions: Diameters

LVEDDN

LVID/Ao (2D)

Images



B6

B6

B6

Created: 12:40PM

B6

2/4

B6

B6

B6

B6

Created: 12:40PM

B6

3/4

B6

Signature

Signature:

Name(Print):

Date:

B6

B6

B6

Created: 12:40PM

B6

4/4

From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: Carey, Lauren
Sent: 4/3/2018 7:11:34 PM
Subject: RE: Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe [B6]
EON-350263

No, I hadn't gotten this one...

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



From: Carey, Lauren
Sent: Tuesday, April 03, 2018 3:10 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: FW: Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe [B6] EON-350263

And this one?

From: PFR Event [<mailto:pfpreventcreation@fda.hhs.gov>]
Sent: Friday, March 30, 2018 3:48 PM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [B6]
Subject: Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe: [B6] - EON-350263

A PFR Report has been received and PFR Event [EON-350263] has been created in the EON System.

A "PDF" report by name "2044821-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 "2044821-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350263

ICSR #: 2044821

EON Title: PFR Event created for Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe; 2044821

AE Date	08/21/2017	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Worse/Declining/Deteriorating
Breed	Terrier - Bull		
Age	8 Years		

District Involved	PFR-Baltimore DO	
--------------------------	------------------	--

Product information

Individual Case Safety Report Number: 2044821

Product Group: Pet Food

Product Name: Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe

Description: [B6] is an 8 year old intact male Bull Terrier who was first diagnosed with severe degenerative valve disease with moderate decrease in contractility on 8/21/17. At that time, he was started on [B6] and [B6] was recommended but not started. On [B6] he presented to the emergency service for a sudden increase in respiratory rate and effort and was hospitalized for congestive heart failure. Echo findings on [B6] included progressive valve disease and severe, progressive decrease in contractility, the latter of which may either be a component of [B6]. Clinically, [B6] has been tiring more quickly recently. He has had weight loss (3 kg since 8/2017) despite a good appetite. Prior to his [B6] presentation, he had a 2-3 week history of collapsing/fainting episodes, in which he would go limp and paddle - no loss of bowels. Health history includes allergies/dermatitis - previously on [B6] - but otherwise no major illnesses or injuries. I have recommended adjustments to [B6] medications as well as [B6] he will continue the Nature's Recipe Salmon and Yam diet due to significant [B6] when changing the diet.

Submission Type: Initial

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

Outcome of reaction/event at the time of last observation: Worse/Declining/Deteriorating

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Grain Free Easy to Digest Salmon Sweet Potato & Pumpkin Recipe		

Sender information

[B6]

USA

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

<https://eon.fda.gov/eon//browse/EON-350263>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=366632>

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'cvca [B6]@cvcavets.com'
Sent: 4/17/2018 11:47:34 AM
Subject: RE: FDA Case investigation for [B6] 8 yr MI Bull Terrier (EON-350263)

Good morning [B6]

Because we have not received a response from you, we are closing the case.
Thank you,
Dr. Jones

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



From: Jones, Jennifer L
Sent: Monday, April 09, 2018 2:15 PM
To: 'cvca [B6]@cvcavets.com' <cvca [B6]@cvcavets.com>
Subject: RE: FDA Case investigation for [B6] 8 yr MI Bull Terrier (EON-350263)

Good afternoon [B6]

Are you able to provide the information for our case investigation? Please see below.
Thank you and have a great week,
Jen

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



From: Jones, Jennifer L
Sent: Thursday, April 05, 2018 11:56 AM
To: 'cvca [B6]@cvcavets.com' <cvca [B6]@cvcavets.com>
Subject: FDA Case investigation fo [B6] 8 yr MI Bull Terrier (EON-350263)

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).
- Do you have any information on the Grain Free Food, including lot or best by date?
 - Additionally, is there any open or unopened product available?

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>



U.S. FOOD & DRUG
ADMINISTRATION



Vet-LIRN Final Report:No Further Action (NFA) Consumer Complaints

Date the Complaint was Submitted

2018-04-04

Date the Complaint is NFA

2018-04-09

Complaint Number (e.g. EON or CC)

EON-350487

Owner Last Name

B6

Species

Canine

Product

Taste of the Wild Grain Free-different varieties

Brief Reason for Complaint

Dilated Cardiomyopathy

Reviewed MedicalRecords

Yes

Gathered Additional Product Information

Yes

Completed Owner Interview

No

Notified OS&C of Vet-LIRN Recommendation

Yes

Reason for NFA

Food is an Unlikely Cause of Illness per the Medical Records

Other Reason for NFA

Vet-LIRN Personnel

Jennifer Jones

Submit by Email

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS /CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Nemser, Sarah; Ceric, Olgica; Palmer, Lee Anne; Carey, Lauren; Glover, Mark; Queen, Jackie L
Sent: 4/4/2018 8:22:55 PM
Subject: Fwd: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: [B6] - EON-350487
Attachments: 2045119-report.pdf; 2045119-attachments.zip

Breed that gets DCM....

From: PFR Event <pfpreventcreation@fda.hhs.gov>
Date: April 4, 2018 at 4:20:51 PM EDT
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>, HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>, [B6]
[B6]
Subject: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: [B6] - EON-350487

A PFR Report has been received and PFR Event [EON-350487] has been created in the EON System.

A "PDF" report by name "2045119-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 "2045119-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350487

ICSR #: 2045119

EON Title: PFR Event created for Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon; 2045119

AE Date	03/19/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Hound - Afghan		

Age	11 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2045119

Product Group: Pet Food

Product Name: Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon

Description: **B6** has a history of cough - she was initially treated for kennel cough. Developed **B6** and was evaluated by cardiology practice on 3/19/18. Diagnosed with advanced dilated cardiomyopathy, atrial fibrillation with rapid ventricular response rate and right-sided congestive heart failure with ascites. Started on medical therapy and taurine and l-carnitine supplementation - will recheck echo in 4-5 months. Diet is Taste of the Wild Grain Free - rotates through all varieties except for those containing chicken. There is concern that the diet provides insufficient levels of taurine, contributing to the development of **B6** dilated cardiomyopathy.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon		

Sender information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-350487>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jsps?decorator=none&e=0&issueType=12&issueId=366875>

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Report Details - EON-350487

ICSR: 2045119
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-04-04 16:10:23 EDT

Reported Problem:

Problem Description: B6 has a history of cough - she was initially treated for kennel cough. Developed B6 and was evaluated by cardiology practice on 3/19/18. Diagnosed with advanced dilated cardiomyopathy, atrial fibrillation with rapid ventricular response rate and right-sided congestive heart failure with ascites. Started on medical therapy and taurine and l-carnitine supplementation - will recheck echo in 4-5 months. Diet is Taste of the Wild Grain Free - rotates through all varieties except for those containing chicken. There is concern that the diet provides insufficient levels of taurine, contributing to the development of B6 dilated cardiomyopathy.

Date Problem Started: 03/19/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: Recent treatment for possible B6 with course of B6
 Otherwise previously healthy

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon

Product Type: Pet Food

Lot Number:

Package Type: BAG

Product Use Information:

Description: Daily as main diet

Product Use Stopped After the Onset of the Adverse Event: Unknown

Perceived Relatedness to Adverse Event: Probably related

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Hound - Afghan

Gender: Female

Reproductive Status: Neutered

Weight: 32.4 Kilogram

Age: 11 Years

Assessment of Prior Health: Excellent

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information: Owner Information provided: No

Healthcare Professional Practice Name: B6

Information:	Contact:	Name:	B6
		Phone:	
		Email:	
	Address:	B6 United States	
Type of Veterinarian:	Referred veterinarian		
Permission to Release Records to FDA:	Yes		

Sender Information:	Name:	B6		
	Address:	B6 United States		
	Contact:	Phone:	B6	
		Email:		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Reported to Other Parties:	Other			

Additional Documents:	Attachment:	B6	ECG	B6	pdf
	Description:	ECG B6			
	Type:	Other			
	Attachment:	B6	Echo Report	B6	pdf
Description:	Echo Report B6				
Type:	Echocardiogram				
Attachment:	B6	ECG	B6	pdf	
Description:	ECG B6				
Type:	Other				
Attachment:	B6	Echo Data	B6	pdf	
Description:	Echo Data B6				
Type:	Echocardiogram				

~~Search~~ B6

PORT

B6 25 PM

0.50 25mm/
RESP X2 RR: 3
2: --- °F
PR: ---
--- EtCO2: --- InCO2: ---
--- (---)

~~Report~~ B6

REPORT

B6 03:26 PM

XU.50 25mm/
9 RESP X2 RR: 16
7 T2: --- °F
--- PR: ---
RR: --- EtCO2: --- InCO2: ---
--- (---)

~~Search~~ B6

REPORT

B6 03:27 PM

1 X0.50 25mm
92 RESP X2 RR: 22
1.7 T2: --- °F
84% PR: 116
wRR: --- EtCO2: --- InCO2: ---
--- (---)

~~Report~~ B6

REPORT

B6 03:27 PM

1 X0.25 25mm/
14 RESP X2 RR: 20
9 T2: --- °F
--- PR: ---
wRR: --- EtCO2: --- InCO2: ---
--- (---)

B6

~~Report~~
REPORT

B6

B6

03:27 PM

X0.25 25mm

19 RESP X2 RR: 16

9 T2: --- °F

PR: ---

vRR: --- EtCO2: --- InCO2: ---

--- (---)

B6

B6

NAME: [B6]
ON 8S REPORT
TIME: [B6] 05:48 PM
CG 11 XO.50 25mm/
R: 157 RESP X2 RR: 23
T1: 73.7 T2: --- °F
PO2: --- PR: ---
O2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

NAME: [B6]
ON 8S REPORT
TIME: [B6] 05:48 PM
CG 11 XO.50 25mm/
R: 123 RESP X2 RR: 21
T1: 73.7 T2: --- °F
PO2: --- PR: ---
O2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

NAME: [B6]
ON 8S REPORT
TIME: [B6] 05:46 PM
CG 11 XO.50 25mm/
R: 106 RESP X2 RR: 30
T1: 73.5 T2: --- °F
PO2: --- PR: ---
O2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

B6

①

AME: B6
ON 8S REPORT
IME: B6 05:46 PM
CG 11 XO.50 25mm/
R: 113 RESP X2 RR: 25
I: 73.5 T2: --- °F
PO2: --- PR: ---
O2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

AME: B6
ON 8S REPORT
IME: B6 05:47 PM
CG 11 XO.50 25mm/
R: 141 RESP X2 RR: 24
I: 73.5 T2: --- °F
PO2: --- PR: ---
O2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

AME: B6
ON 8S REPORT
IME: B6 05:47 PM
CG 11 XO.50 25mm/
R: 119 RESP X2 RR: 26
I: 73.5 T2: --- °F
PO2: --- PR: ---
O2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

B6

NAME: **B6**
MON 8S REPORT
TIME: **B6** 05:47 PM
ECG I1 X0.50 25mm/
HR: 122 RESP X2 RR: 26
T1: 73.7 T2: --- °F
SPO2: --- PR: ---
CO2 AwRR: --- EtCO2: --- InCO2: ---
NIBP: ---/--- (---)

B6

Patient Demographics

B6		Study Date: B6	
Patient ID: B6	Accession #:	Alt ID:	
DOB: B6	Age: 11y	Gender: F	Ht: Wt: 71lb 7oz BSA:
Institution: B6			
Referring Physician:			
Physician of Record:	Performed By: B6 DVM, DACVIM		
Comments:			

Adult Echo: Measurements and Calculations

2D

LVIDd (2D)	B6	SV (2D-Cubed)	B6	IVS % (2D)	B6
LVPWd (2D)		FS (2D-Cubed)		LVPW % (2D)	
IVSs (2D)		EF (2D-Cubed)		IVS/LVPW (2D)	
LVIDs (2D)		A4Cd		SV (A4C)	
		LV Vol			
		LV Length			
		LV Area			
LVPWs (2D)		A4Cs		EF (A4C)	
		LV Vol			
		LV Length			
		LV Area			
EDV (2D-Teich)		LVLd (A4C)		IVSd (2D)	
ESV (2D-Teich)		LVLs (A4C)		RVIDd/LVIDd	
SV (2D-Teich)	LVAAd (A4C)	RVIDd (2D)			
FS (2D-Teich)	LVAAs (A4C)	LA Area			
EF (2D-Teich)	EDV (A4C)	LA Dimen (2D)			
EDV (2D-Cubed)	ESV (A4C)	LA/Ao (2D)			
ESV (2D-Cubed)	LV Mass (Cubed)	AoR Diam (2D)			

MMode

IVSd (MM)	B6	ESV (MM-Teich)	B6	FS (MM-Cubed)	B6
LVIDd (MM)		SV (MM-Teich)		IVS % (MM)	
LVPWd (MM)		FS (MM-Teich)		LVPW % (MM)	
IVSs (MM)		EF (MM-Teich)		RVIDd (MM)	

B6

B6

B6

Created: 05:54PM

B6

1/3

LVIDs (MM)	B6	EDV (MM-Cubed)	B6	LA Dimen (MM)	B6
LVPWs (MM)		ESV (MM-Cubed)		AoR Diam (MM)	
IVS/LVPW (MM)		SV (MM-Cubed)		LA/Ao (MM)	
EDV (MM-Teich)		EF (MM-Cubed)		MV EPSS	

Doppler

LVOT Vmax Max PG Vmax	B6	AV VR	B6	TR Vmax Max PG Vmax	B6
AV Vmax Max PG Vmax		MR Vmax Max PG Vmax		PV Vmax Max PG Vmax	
AV VTI Mean PG VTI Vmean		MV Peak E Vel Vel PG			

Other Measurements

Dimensions: Diameters

LVID/Ao (2D)

EF & Volume: Simpson's

Sphericity Id

EDVI

ESVI

Dimensions: Diameters

LVEDDN

LVID/Ao (2D)

B6

Images

B6

B6

B6

B6

Created: 05:54PM

B6

2/3

B6

Signature

Signature:

Name(Print):

Date:

B6

B6

B6

Created: 05:54PM

B6

3/3

B6

www.cvcavets.com



Client: **B6**

Co-owner:

Patient name: **B6**

Species: Canine

Breed: Afghan

Sex: FS

Age: **66** months old

Weight: 32.4kg / 71.43 lbs

Primary Care Veterinarian: **B6**

Primary Care Hospital: **B6**

Phone: **B6** ext:

Fax: **B6**

Email: **B6**

Cardiac Evaluation Report

Exam Date: 03/19/2018

Diagnosis

- Advanced dilated cardiomyopathy
- Moderate mitral valve regurgitation
- Moderate tricuspid valve regurgitation
- Severe left atrial chamber dilation
- Severe eccentric left ventricular chamber dilation
- Severe decrease in contractility/heart muscle function
- Severe right atrial chamber dilation
- Moderate eccentric right ventricular chamber dilation
- Atrial fibrillation with rapid ventricular response rate
- Right-sided congestive heart failure with ascites (fluid in belly)
- Increased cough > rule out secondary to heart enlargement, early left sided congestive heart failure, concurrent bronchitis

Medications

B6

B6

In 5 days, if eating better / acting normally:

- Begin **B6** thereafter.
- Continue with monthly **B6** control as prescribed by **B6**
- Please call if you notice a decrease in appetite, vomiting, lethargy, weakness or any other signs of illness while beginning/adjusting the medications or the cough does not improve by 7 days.

In 2 weeks, if **B6 is eating and feeling well:**

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 for more information about **B6** dilated cardiomyopathy.

Nutrition Recommendations:

- Continue current diet and try to avoid salty foods/ treats. For more information about sodium content of various foods, please visit:

- Dog: http://vet.tufts.edu/wp-content/uploads/reduced_sodium_diet_for_dogs.pdf
- Treats: http://vet.tufts.edu/wp-content/uploads/treats_for_dogs_with_heart_disease.pdf

- 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 **B6** 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/>

Activity Recommendations

- Keep **B6** very quiet for the next 3-4 days with only brief leash walks to eliminate.
- Once her respiratory rate and effort have returned to normal, **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 warm **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 or **B6** as 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 of **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** respiratory 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

- Avoid intravenous or subcutaneous fluid therapy in the future, if possible. If fluid therapy is indicated, please contact CVCA. **B6** should not receive **B6** in the future please contact CVCA for recommendations, if **B6** are indicated.
- Avoid elective anesthesia, as **B6** is at high risk for complications due to the degree of cardiac disease. If anesthesia is necessary in the future, please contact CVCA for recommendations for monitoring and anesthetics.

Reevaluation

- Please recheck with **B6** in 2 weeks for a physical exam, including auscultation, heart rate/ ECG, blood pressure check, and blood chemistry profile with electrolytes and digoxin level (6-8 hours post dosage) Doppler method is preferred for monitoring blood pressure measurements as this has been shown to be more accurate than oscillometric methods. Please forward these results when available.
- Please recheck with **B6** every 4-6 months for a follow up examination, blood chemistry profile with electrolytes and serum digoxin level (drawn 6-8 hours after the morning dose) and as recommended by **B6**. Please forward these results when available.
- Please recheck with CVCA in 4-5 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: 188-196

BP: 160-170

Cuff size/location: #5/LFL & RFL

History: 4/5 afghans got kennel cough (9 mo - 12 yrs old) at dog show - January maybe - all went on **B6** she did not tolerate **B6** - did course of **B6** no improvement / continues to cough - worse with stress but also in middle of night; owner noted abdominal distension recently; appetite not great since ? (o free feeds) still goes for walks but arthritic; on grain free taste of the wild adult dog food.

Physical Exam Findings: QAR-H; nervous / agitated; mm pink; normal fundic exam; frequent hacking wheezing cough at rest ; no tracheal palpation; H/L:188 -196 bpm; irregular a fib rhythm; grade 3/6 systolic murmur PMI MV +TV; panting mild tachypnea when mouth held closed; markedly increase BV tones; abd palp moderate ascites; femoral pulses variable intensity

Other Diagnostics:

Echocardiographic Findings

Severe left ventricular eccentric hypertrophy with apical rounding and increased sphericity, moderate centrally located mitral regurgitant jet, severe secondary left atrial dilation on 2D imaging and severely increased LA:Ao ratio on m-mode imaging, mild eccentric low velocity tricuspid regurgitation, moderate right ventricular and severe right atrial dilation, depressed left ventricular and right ventricular outflow velocities, severely depressed indices of systolic function (FS% and EF% by modified Simpson's), increased EPSS, high TMI E: atrial fibrillation 200 bp[m ; moderate ascites with hepatic venous distension; echo done standing

Comments

Dear **B6**

Thank you for sending **B6** to see us with **B6** today. Sadly, **B6** has dilated cardiomyopathy and it may be the atrial fibrillation that pushed her into congestive heart failure. We have begun therapy to control the congestive heart failure, slow heart rate, slow down the progression of the heart disease and improve survival. 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, serum **B6** levels, blood pressure and ECG. Unfortunately, the prognosis is guarded after the onset of congestive heart failure, and we discussed with the **B6** family that the average survival is ~ 6-12 months and for some breeds atrial fib drops survival to 3-4 months. Survival time is highly individually variable depending on response to therapy. Hopefully we will get a favorable response to meds.

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

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Nemser, Sarah; Ceric, Olgica; Palmer, Lee Anne; Carey, Lauren; Glover, Mark; Queen, Jackie L
Sent: 4/5/2018 4:24:38 PM
Subject: RE: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: [B6] - EON-350487

Sounds good! Thanks

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Date: April 5, 2018 at 12:23:25 PM EDT
To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Glover, Mark <Mark.Glover@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Subject: RE: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: [B6] - EON-350487

We can collect full MRx for review.

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



From: Rotstein, David
Sent: Wednesday, April 04, 2018 4:23 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Subject: Fwd: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: [B6] - EON-350487

Breed that gets DCM...

From: PFR Event <pfpreventcreation@fda.hhs.gov>
Date: April 4, 2018 at 4:20:51 PM EDT
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>, HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>, [B6] [B6]
Subject: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: [B6] - EON-350487

A PFR Report has been received and PFR Event [EON-350487] has been created in the EON System.

A "PDF" report by name "2045119-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 "2045119-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350487

ICSR #: 2045119

EON Title: PFR Event created for Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon; 2045119

AE Date	03/19/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Hound - Afghan		
Age	11 Years		
District Involved	PFR [B6]		

Product information

Individual Case Safety Report Number: 2045119

Product Group: Pet Food

Product Name: Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon

Description: [B6] has a history of cough - she was initially treated for kennel cough. Developed [B6] and was evaluated by cardiology practice on 3/19/18. Diagnosed with advanced dilated cardiomyopathy, atrial fibrillation with rapid ventricular response rate and right-sided congestive heart failure with [B6]. Started on medical therapy and taurine and l-carnitine supplementation - will recheck echo in 4-5 months. Diet is Taste of the Wild Grain Free - rotates through all varieties except for those containing chicken. There is concern that the diet provides insufficient levels of taurine, contributing to the development of [B6] dilated cardiomyopathy.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon		

Sender information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-350487>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=366875>

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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.

From: CVCA [B6] CVCA [B6] <[B6]@cvcavets.com>
To: Jones, Jennifer L
Sent: 4/5/2018 6:02:52 PM
Subject: Re: FDA Case Investigation for [B6] (11 yr FS Afghan Hound)
Attachments: 69633A 3192018 [B6] 20061018_2018031917551902.pdf; [B6]
[B6] ECG (pcDVM).pdf; [B6] ECG 2.pdf; [B6] Echo Report.pdf; [B6]
[B6] hx (pDVM).pdf; [B6] pDVM BW.pdf; [B6] pDVM update.pdf; [B6] bw
pDVM.pdf; [B6] Rads.zip

Good Afternoon,

Please find complete medical history for [B6] attached below. I have called the client to see if we were able to get any additional information on the grain free food product but had to leave a message. If we hear back from her, we will be sure to forward that information as well. Please let us know if you need anything else from us.

Thank you,

[B6] Team Leader, Veterinary Nurse

On Thu, Apr 5, 2018 at 12:36 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 any information on the Grain Free Food, including lot or best by date?
 - Additionally, is there any open or unopened product available?

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>



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The Doctors and Staff of CVCA
CVCA - Cardiac Care for Pets

B6

Visit our website at: www.cvcavets.com

"Like" our Fan Page at: www.facebook.com/CVCAVETS

"Follow" us on Instagram at: <https://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.

Note -- ** Images are usually posted within 1 month.

Patient Demographics

B6		Study Date: B6	
Patient ID: B6	Accession #:	Alt ID:	
DOB: B6	Age: 11y	Gender: F	Ht: Wt: 71lb 7oz BSA:
Institution: CVCA B6	Referring Physician:		
Physician of Record:		Performed By: B6 DVM, DACVIM	
Comments:			

Adult Echo: Measurements and Calculations

2D

LVIDd (2D)	B6	SV (2D-Cubed)	B6	IVS % (2D)	B6
LVPWd (2D)		FS (2D-Cubed)		LVPW % (2D)	
IVSs (2D)		EF (2D-Cubed)		IVS/LVPW (2D)	
LVIDs (2D)		A4Cd		SV (A4C)	
		LV Vol			
		LV Length			
		LV Area			
LVPWs (2D)		A4Cs		EF (A4C)	
		LV Vol			
		LV Length			
		LV Area			
EDV (2D-Teich)		LVLd (A4C)		IVSd (2D)	
ESV (2D-Teich)		LVLs (A4C)		RVIDd/LVIDd	
SV (2D-Teich)	LVAAd (A4C)	RVIDd (2D)			
FS (2D-Teich)	LVAAs (A4C)	LA Area			
EF (2D-Teich)	EDV (A4C)	LA Dimen (2D)			
EDV (2D-Cubed)	ESV (A4C)	LA/Ao (2D)			
ESV (2D-Cubed)	LV Mass (Cubed)	AoR Diam (2D)			

MMode

IVSd (MM)	B6	ESV (MM-Teich)	B6	FS (MM-Cubed)	B6
LVIDd (MM)		SV (MM-Teich)		IVS % (MM)	
LVPWd (MM)		FS (MM-Teich)		LVPW % (MM)	
IVSs (MM)		EF (MM-Teich)		RVIDd (MM)	

LVIDs (MM)	B6	EDV (MM-Cubed)	B6	LA Dimen (MM)	B6
LVPWs (MM)		ESV (MM-Cubed)		AoR Diam (MM)	
IVS/LVPW (MM)		SV (MM-Cubed)		LA/Ao (MM)	
EDV (MM-Teich)		EF (MM-Cubed)		MV EPSS	

Doppler

LVOT Vmax Max PG Vmax	B6	AV VR	B6	TR Vmax Max PG Vmax	B6
AV Vmax Max PG Vmax		MR Vmax Max PG Vmax		PV Vmax Max PG Vmax	
AV VTI Mean PG VTI Vmean		MV Peak E Vel Vel PG			

Other Measurements

Dimensions: Diameters

LVID/Ao (2D)

EF & Volume: Simpson's

Sphericity Id

EDVI

ESVI

Dimensions: Diameters

LVEDDN

LVID/Ao (2D)

B6

Images

B6

B6

B6

B6

Created: 05:54PM

B6

2/3

B6

Signature

Signature:

Name(Print):

Date:

B6

B6

B6

Created: 05:54PM

B6

3/3

~~Search~~ B6

PORT

B6 25 PM

0 50 25mm/
RESP X2 RR: 3
2: --- "F
PR: ---
--- EtCO2: --- InCO2: ---
--- (---)

~~Search~~ B6

REPORT

B6 03:26 PM

X0 50 25mm/
9 RESP X2 RR: 16
7 T2: --- "F
--- PR: ---
RR: --- EtCO2: --- InCO2: ---
--- (---)

~~Search~~ B6

REPORT

B6 03:27 PM

1 X0 50 25mm/
92 RESP X2 RR: 22
1.7 T2: --- "F
84% PR: 116
wRR: --- EtCO2: --- InCO2: ---
--- (---)

~~Search~~ B6

REPORT

B6 03:27 PM

1 X0 25 25mm/
74 RESP X2 RR: 20
9 T2: --- "F
--- PR: ---
wRR: --- EtCO2: --- InCO2: ---
--- (---)

B6

~~Report~~

B6

REPORT

B6

03:27 PM

X0.25 25mm

19 RESP X2 RR: 16

9 T2: --- °F

PR: ---

vRR: --- EtCO2: --- InCO2: ---

--- (---)

B6

B6

NAME: B6
ION 8S REPORT
TIME: B6 05:48 PM
CG 11 X0.50 25mm/
R: 157 RESP X2 RR: 23
T1: 73.7 T2: --- °F
PO2: --- PR: ---
AO2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

NAME: B6
ION 8S REPORT
TIME: B6 05:48 PM
CG 11 X0.50 25mm/
R: 123 RESP X2 RR: 21
T1: 73.7 T2: --- °F
PO2: --- PR: ---
AO2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

NAME: B6
ION 8S REPORT
TIME: B6 05:46 PM
CG 11 X0.50 25mm/
R: 106 RESP X2 RR: 30
T1: 73.5 T2: --- °F
PO2: --- PR: ---
AO2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

B6

①

AME: **B6**
ON 8S REPORT
IME: **B6** 05:46 PM
CG 11 XO.50 25mm/
R: 113 RESP X2 RR: 25
I: 73.5 T2: --- °F
PO2: --- PR: ---
O2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

AME: **B6**
ON 8S REPORT
IME: **B6** 05:47 PM
CG 11 XO.50 25mm/
R: 141 RESP X2 RR: 24
I: 73.5 T2: --- °F
PO2: --- PR: ---
O2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

AME: **B6**
ON 8S REPORT
IME: **B6** 05:47 PM
CG 11 XO.50 25mm/
R: 119 RESP X2 RR: 26
I: 73.5 T2: --- °F
PO2: --- PR: ---
O2 AwRR: --- EtCO2: --- InCO2: ---
IBP: ---/--- (---)

B6

(2)

NAME: B6
MON 8S REPORT
TIME: B6 05:47 PM
ECG I1 X0.50 25mm/
HR: 122 RESP X2 RR: 26
T1: 73.7 T2: --- °F
SPO2: --- PR: ---
CO2 AwRR: --- EtCO2: --- InCO2: ---
NIBP: ---/--- (---)

B6

B6

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Client: **B6**
Co-owner:
Patient name: **B6**
Species: Canine
Breed: Afghan
Sex: FS
Age: **B6**
Weight: 32.4kg. / 71.43 lbs

Primary Care Veterinarian: **B6**
Primary Care Hospital: **B6**
Phone: **B6** ext:
Fax: **B6**
Email: **B6**

Cardiac Evaluation Report

Exam Date: **B6**

Diagnosis

- Advanced dilated cardiomyopathy
- Moderate mitral valve regurgitation
- Moderate tricuspid valve regurgitation
- Severe left atrial chamber dilation
- Severe eccentric left ventricular chamber dilation
- Severe decrease in contractility/heart muscle function
- Severe right atrial chamber dilation
- Moderate eccentric right ventricular chamber dilation
- Atrial fibrillation with rapid ventricular response rate
- Right-sided congestive heart failure with ascites (fluid in belly)
- Increased cough > rule out secondary to heart enlargement, early left sided congestive heart failure, concurrent bronchitis

Medications

B6

B6

In 5 days, if eating better / acting normally:

- Begin [B6] - Give 1 tablet twice daily for 4 days then increase to 1 and 1/2 tablets twice daily thereafter.
- Continue with monthly [B6] control as prescribed by [B6]
- Please call if you notice a decrease in appetite, vomiting, lethargy, weakness or any other signs of illness while beginning/adjusting the medications or the cough does not improve by 7 days.

In 2 weeks, if [B6] is eating and feeling well:

[B6]

- You may purchase the taurine and L-carnitine at any health food or nutrition store or www.puritanspride.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.**

Please Note

- Please see our website www.cvcavets.com for more information about [B6] dilated cardiomyopathy.

Nutrition Recommendations:

- Continue current diet and try to avoid salty foods/ treats. For more information about sodium content of various foods, please visit:
 - Dog: http://vet.tufts.edu/wp-content/uploads/reduced_sodium_diet_for_dogs.pdf
 - Treats: http://vet.tufts.edu/wp-content/uploads/treats_for_dogs_with_heart_disease.pdf
- 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 [B6] 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/>

Activity Recommendations:

- Keep [B6] very quiet for the next 3-4 days with only brief leash walks to eliminate.
- Once her respiratory rate and effort have returned to normal, [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 warm [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 or [B6] as 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 of [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] respiratory 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:

- Avoid intravenous or subcutaneous fluid therapy in the future, if possible. If fluid therapy is indicated, please contact CVCA.
- [B6] should not receive [B6] in the future please contact CVCA for recommendations, if [B6] are indicated.
- Avoid elective anesthesia, as [B6] is at high risk for complications due to the degree of cardiac disease. If anesthesia is necessary in the future, please contact CVCA for recommendations for monitoring and anesthetics.

Reevaluation

- Please recheck with [B6] in 2 weeks for a physical exam, including auscultation, heart rate/ ECG, blood pressure check, and blood chemistry profile with electrolytes and digoxin level (6-8 hours post dosage). Doppler method is preferred for monitoring blood pressure measurements as this has been shown to be more accurate than oscillometric methods. Please forward these results when available.
- Please recheck with [B6] every 4-6 months for a follow up examination, blood chemistry profile with electrolytes and serum digoxin level (drawn 6-8 hours after the morning dose) and as recommended by [B6]. Please forward these results when available.
- Please recheck with CVCA in 4-5 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: 188-196 **BP:** 160-170 **Cuff size/location:** #5/LFL & RFL

History: 4/5 afghans got kennel cough (9 mo - 12 yrs old) at dog show - January maybe - all went on a [B6] she did not tolerate [B6] did course of [B6] no improvement / continues to cough - worse with stress but also in middle of night; owner noted abdominal distension recently; appetite not great since ? (o free feeds) ; still goes for walks but arthritic; on grain free taste of the wild adult dog food.

Physical Exam Findings: QAR-H; nervous / agitated; mm pink; normal fundic exam; frequent hacking wheezing cough at rest ; no tracheal palpation; H/L:188 -196 bpm; irregular a fib rhythm; grade 3/6 systolic murmur PMI MV +TV; panting mild tachypnea when mouth held closed; markedly increase BV tones; abd palp moderate ascites; femoral pulses variable intensity

Other Diagnostics:

Echocardiographic Findings

Severe left ventricular eccentric hypertrophy with apical rounding and increased sphericity, moderate centrally located mitral regurgitant jet, severe secondary left atrial dilation on 2D imaging and severely increased LA:Ao ratio on m-mode imaging, mild eccentric low velocity tricuspid regurgitation, moderate right ventricular and severe right atrial dilation, depressed left ventricular and right ventricular outflow velocities, severely depressed indices of systolic function (FS% and EF% by modified Simpson's), increased EPSS, high TMI E: atrial fibrillation 200 bp[m ; moderate ascites with hepatic venous distension; echo done standing

Comments

Dear [B6]

Thank you for sending [B6] to see us with [B6] today. Sadly [B6] has dilated cardiomyopathy and it may be the atrial fibrillation that pushed her into congestive heart failure. We have begun therapy to control the congestive heart failure, slow heart rate, slow down the progression of the heart disease and improve survival. 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, serum [B6] levels, blood pressure and ECG. Unfortunately, the prognosis is guarded after the onset of congestive heart failure, and we discussed with the [B6] family that the average survival is ~ 6-12 months and for some breeds atrial fib drops survival to 3-4 months. Survival time is highly individually variable depending on response to therapy. Hopefully we will get a favorable response to meds.

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

B6

Patient Chart

Printed: 03-15-18 at 1:19p

CLIENT INFORMATION

Name
Address
Phone

B6

Spouse **B6**

PATIENT INFORMATION

Name **B6**
Sex Female, Spayed
Birthday
ID **B6**
Color Black Masked Red
Reminded 02-10-18

Species Canine
Breed Afghan Hound
Age 11y
Rabies **B6**
Weight 61.20 lbs
Codes

Reminders for: **B6** Last done

B6

B6 weight history (in lbs)

B6

MEDICAL HISTORY

Date By Code Description Qty (Variance)

B6

Date	By	Code	Description	Qty (Variance)
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B6

ASSESSMENT SECTION

NOTES

B6 developing
cardiomyopathy, open

DIAGNOSES

HEART MURMUR
B6

PLAN SECTION

NOTES

B6 May
reconsider if going to be boarded or around other dogs. Discussed CVCA consultation for mild heart
murmur, but potentially **B6** murmur is mild/physiologic/age related valve insufficiency. O reports no
exercise intolerance, coughing or abnormal respiratory effort.
Continue routine **B6**

TREATMENT PLAN

B6

Date	By	Code	Description	Qty (Variance)
------	----	------	-------------	----------------

B6

Date	By	Code	Description	Qty (Variance)
------	----	------	-------------	----------------

B6

Date	By	Code	Description	Qty (Variance)
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B6

Date	By	Code	Description	Qty (Variance)
------	----	------	-------------	----------------

B6

Date	By	Code	Description	Qty (Variance)
------	----	------	-------------	----------------

B6

Date	By	Code	Description	Qty (Variance)
B6				

02-28-18 B6 NOTES Doctor notes/comments
owner called B6 coughing after on B6 4 days, dispensed 2 weeks ago. vomiting pills. B6 was also dispensed for B6
Owner reports that B6 is not showing any other signs of kennel cough - breathing good; not exercise intolerant or lethargic; eating well. Would like to try a few days of another antibiotic and see if that helps, and if not, will bring her in.

Doctor's Instructions - xxxxxx

B6

B6 B6 ER Exam Recheck (medical)

Age: 11y Weight: 61.20 Temp: 101.50
BCS: 3.00 / 5.00

SUBJECTIVE SECTION

owner dropped off for work up for continued coughing. She had minimal to no response to a course of B6 and then a round of B6 She is still coughing fairly regular and frequent

OBJECTIVE SECTION

H/L arrhythmia now present, heart very irregular, B6 panting and excited but still very abnormal. also pulses irregular w/ heart
abd: naf, although whined some during palp-- somewhat nervous and reactive dog.
LN ok
BAR teeth: mild tarter abdomen on palpation does seems slightly taught or slightly distended.
Repeating auscultation of heart reveals a heart rate that at times seems twice her pulse rate. She has a consistent pulse at times but then has a bounding occasional pulse femoral. Upper right side heart base I can detect the murmur that is 2 to 3/6 systolic. Radiographs show a remarkably tall enlarged heart with the vertebral heart score of 13. Her lungs have some patchy opacities and slight increase in the hilar area but not dramatic. An EKG strip was evaluated. I believe there is atrial fibrillation.

CLINICAL EXAM FINDINGS

Normal Systems: Vital Signs, Eyes, Ears, Coat, Glandular/Lymph Nodes, Gait, Skin, Extremities, Respiratory, Oral, Teeth, Musculoskeletal, Abdomen, Urogenital, CNS Neurologic

ASSESSMENT SECTION

NOTES

Lat/VD chest: cardiomegaly evident, tracheal elevation, may have early CHF around perihilar area.
VHS 13-13.5

Date	By	Code	Description	Qty (Variance)
			suspect dilated cardiomyopathy (DCM) rule out heart based mass. Possible atrial fibrillation found on EKG. Questionable pulse deficits. Heart rate nears 200 most of the time tachycardia. Mild increased respiratory effort.	

PLAN SECTION

NOTES

Recommend cardiology referral, could do **B6** but with arrythmia best to consult with a cardiologist directly. I spoke to owner and strongly recommended that CVCA consult. I called and gave a referral information to the cardiology Center. We will fax records and labs when available an email x-rays and/or labs as needed prior to an appointment. Owner was reluctant but agreed to have an echocardiogram to try to determine a diagnosis . No medications were administered chemistry and CBC and T4 sent to **B6**

03-13-18	B6	XR1417 K9AN	X-Ray 14x17 2 VIEWS Physical Exam Canine	
----------	-----------	----------------	---	--

Age: 11y

03-13-18	B6	SA120	Total Body Function(Superchem, CBC, T4) Requisition 5364-AVI606803	
----------	-----------	-------	---	--

Test	Result	Flag	Normal Range		Measure
			Low	High	
Superchem 03-14-18.8:01a					
Total Protein	B6	L	5.0	7.4	g/dL
Albumin			2.7	4.4	g/dL
Globulin		L	1.6	3.6	g/dL
A/G Ratio		H	0.8	2.0	
AST (SGOT)			15	66	IU/L
ALT (SGPT)			12	118	IU/L
Alk Phosphatase			5	131	IU/L
GGTP			1	12	IU/L
Total Bilirubin			0.1	0.3	mg/dL
Urea Nitrogen			6	31	mg/dL
Creatinine			0.5	1.6	mg/dL
BUN/Creatinine Rat			4	27	
Phosphorus	B6		2.5	6.0	mg/dL
Glucose			70	138	mg/dL
Calcium			8.9	11.4	mg/dL
Corrected Calcium					
Magnesium			1.5	2.5	mEq/L
Sodium			139	154	mEq/L
Potassium			3.6	5.5	mEq/L
Na/K Ratio			27	38	
Chloride			102	120	mEq/L
Cholesterol			92	324	mg/dL
Triglycerides			29	291	mg/dL
Amylase			290	1125	IU/L
PrecisionPSL			24	140	IU/L
B6					
CPK	B6	H	59	895	IU/L
Comment Hemolysis 1+ No significant interference.					
B6					

B6

Date	By	Code	Description	Qty (Variance)		Measure
			Absolute Eosinophils	0	1200	/mL
	B6		Absolute Basophils	0	150	/mL
	B6					
			<u>Test</u>	<u>Result</u>	<u>Flag</u>	<u>Normal Range</u>
						<u>Low</u> <u>High</u>
			Total T4 04-03-18 9:11a			
			T4	0.8	3.5	mg/dL
04-02-18	B6					
			T735	B6		
			B6			
			Requisition 5364-AVI609126			
			<u>Test</u>	<u>Result</u>	<u>Flag</u>	<u>Normal Range</u>
						<u>Low</u> <u>High</u>
			B6 04-03-18 9:11a	B6		
				0.8	2.0	ng/mL

B6

B6

Patient Chart

Printed: 04-03-18 at 4:58p

CLIENT INFORMATION

Name
Address
Phone

B6

Spouse **B6**

PATIENT INFORMATION

Name **B6**
Sex Female, Spayed
Birthday **B6**
ID **B6**
Color Black Masked Red
Reminded 02-10-18

Species Canine
Breed Afghan Hound
Age 11y
Rabies **B6**
Weight 59.50 lbs
Codes

B6 1:51p: Congestive heart failure & severe cardiac disease!

Reminders for: **B6** Last done

B6

B6 weight history (in lbs)

B6

MEDICAL HISTORY

Date	By	Code	Description	Qty (Variance)
04-02-18	B6	APPT\$	Appointment notes for 04-02-18 follow up from CVCA, reauscult heart, HWT, cbc/chem, B6 levels B6 8 hours post pill send results to CVCA	
		APPT\$	Appointment notes for 04-02-18 save time for cardiac patient	
		EM	Exam Medical Office Visit	

Date	By	Code	Description	Qty (Variance)
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Age: 11y Weight: 59.50

SUBJECTIVE SECTION

11-year-old spayed female here to recheck her cardiac status EKG blood pressure . Follow-up from recent CVCA consult and echocardiogram No coughing, seems much better, has been a lot more active and clearly has lost all the fluid distention in her abdomen gave **B6** at 11:15
Meds:

B6

OBJECTIVE SECTION

Bright alert and responsive capillary refill time 1.0. Mucous membranes are pink. Cardiac auscultation reveals a very irregular heartbeat still. Occasionally there is a stretch of normal heartbeats but generally it is irregularly irregular. Lungs seem clear. She has not had any significant coughing since being on medication. She is also more bright and has better energy. Her abdominal distention has clearly disappeared along with that she has lost 10 pounds to the owner believes is off fluid weight loss, and I concur most likely that is correct.
Blood pressure obtained by oscillometric method lately elevated but reasonable with a mean pressure around 125 to 130.
EKG repeated shows what appears to be atrial fibrillation still. There are variable intensity pulses and some pulse deficits. She is tolerating all the medications okay. However the owner has started the carnitine in the taurine and she's having some difficulty due to the extreme large size of these pills.
Overall exam is fairly normal

ASSESSMENT SECTION

NOTES

Dilated cardiomyopathy with right-sided congestive heart failure see detailed report from CVCA. She is tolerating medications well overall she is greatly improved from initial diagnosis

PLAN SECTION

NOTES

Blood pressure, EKG, chemistry CBC T4 and digoxin level to lab
physical exam recheck
no change on any medications at this time
EKG strips were saved and the owner will drop them off for **B6** to review

04-02-18	B6	ZC3663 ZH0086 BP	CARDIOMYOPATHY, DILATED, CONGESTIVE HEART FAILURE, RIGHT SIDE Blood pressure
----------	-----------	------------------------	--

All blood pressures were taken with oscillometric readings ranged from systolic 148 diastolic 105 with a mean of 121 next measurement mean was 155 third measurement systolic 159 diastolic 136 with a mean of 151

Date	By	Code	Description	Qty (Variance)
			suspect dilated cardiomyopathy (DCM) rule out heart based mass. Possible atrial fibrillation found on EKG. Questionable pulse deficits. Heart rate nears 200 most of the time tachycardia. Mild increased respiratory effort.	

PLAN SECTION

NOTES

Recommend cardiology referral, could do B6 but with arrythmia best to consult with a cardiologist directly. I spoke to owner and strongly recommended that CVCA consult. I called and gave a referral information to the cardiology Center. We will fax records and labs when available an email x-rays and/or labs as needed prior to an appointment. Owner was reluctant but agreed to have an echocardiogram to try to determine a diagnosis . No medications were administered chemistry and CBC and T4 sent to: B6

03-13-18 B6 XR1417 X-Ray 14x17 2 VIEWS
 K9AN Physical Exam Canine

Age: 11y

03-13-18 B6 SA120 Total Body Function(Superchem, CBC, T4)
 B6 Requisition 5364-AVI606803

Test	Result	Flag	Normal Range		Measure
			Low	High	
Superchem 03-14-18:01a					
Total Protein		L	5.0	7.4	g/dL
Albumin			2.7	4.4	g/dL
Globulin		L	1.6	3.6	g/dL
A/G Ratio		H	0.8	2.0	
AST (SGOT)			15	66	IU/L
ALT (SGPT)			12	118	IU/L
Alk Phosphatase			5	131	IU/L
GGTP			1	12	IU/L
Total Bilirubin			0.1	0.3	mg/dL
Urea Nitrogen			6	31	mg/dL
Creatinine			0.5	1.6	mg/dL
BUN/Creatinine Ratio			4	27	
Phosphorus	B6		2.5	6.0	mg/dL
Glucose			70	138	mg/dL
Calcium			8.9	11.4	mg/dL
Corrected Calcium					
Magnesium			1.5	2.5	mEq/L
Sodium			139	154	mEq/L
Potassium			3.6	5.5	mEq/L
Na/K Ratio			27	38	
Chloride			102	120	mEq/L
Cholesterol			92	324	mg/dL
Triglycerides			29	291	mg/dL
Amylase			290	1125	IU/L
PrecisionPSL			24	140	U/L

B6

B6					
CPK	B6	H	59	895	IU/L
Comment	B6				

Hemolysis 1+ No significant interference.

Test	Result	Flag	Normal Range	Measure
------	--------	------	--------------	---------

Date	By	Code	Description	Qty (Variance)	
			Low High		
Complete Blood Count 03-14-18 8:01a					
	B6		WBC	4.0 15.5 10 ³ /mL	
		RBC	4.8 9.3 10 ⁶ /mL		
		Hemoglobin	12.1 20.3 g/dL		
		Hematocrit	36 60 %		
		MCV	58 79 fL		
		MCH	19 28 pg		
		MCHC	30 38 g/dL		
		Platelet Count	170 400 10 ³ /mL		
		Platelet EST			
		Neutrophils	60 77 %		
		Bands	0 3 %		
		Lymphocytes	12 30 %		
		Monocytes	3 10 %		
		Eosinophils	2 10 %		
		Basophils	0 1 %		
	Absolute Neutrophils	2060 10600 /mL			
	Absolute Lymphocyt	690 4500 /mL			
	Absolute Monocytes	0 840 /mL			
	Absolute Eosinophils	0 1200 /mL			
	Absolute Basophils	0 150 /mL			
	Test	Result	Flag	Normal Range <u>Low</u> <u>High</u>	Measure
Total T4 03-14-18 8:01a					
		B6	T4	0.8 3.5 mg/dL	B6

B6

B6

B6

From: CVCA [B6] CVCA [B6] <[B6]>
To: Jones, Jennifer L
Sent: 4/5/2018 8:47:58 PM
Subject: Re: FDA Case Investigation for [B6] (11 yr FS Afghan Hound)

[B6] gave the information below (said that it was very hard to read, some numbers/letters may be off):

#1 Best By: 2/20/2019 - 8051 OA (?) - TDSG208D31STP B015-14

#2 Best By: 2/18/2019 - 8049 - TDp0214D12SCPO02-02

#3 TC50208D31sTPB 05-18(?)

Thank you,

[B6] Veterinary Nurse

On Thu, Apr 5, 2018 at 2:02 PM, CVCA [B6] CVCA [B6] <[B6]> wrote:
Good Afternoon,

Please find complete medical history for [B6] attached below. I have called the client to see if we were able to get any additional information on the grain free food product but had to leave a message. If we hear back from her, we will be sure to forward that information as well. Please let us know if you need anything else from us.

Thank you,

[B6], Team Leader, Veterinary Nurse

On Thu, Apr 5, 2018 at 12:36 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 any information on the Grain Free Food, including lot or best by date?
 - Additionally, is there any open or unopened product available?

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>



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The Doctors and Staff of CVCA

B6

Visit our website at: www.cvcavets.com

"Like" our Fan Page at: www.facebook.com/CVCAVETS

"Follow" us on Instagram at: <https://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.

Note -- ** Images are usually posted within 1 month.

--

The Doctors and Staff of CVCA

B6

Visit our website at: www.cvcavets.com

"Like" our Fan Page at: www.facebook.com/CVCAVETS

"Follow" us on Instagram at: <https://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.

Note -- ** Images are usually posted within 1 month.

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Nemser, Sarah; Ceric, Olgica; Palmer, Lee Anne; Carey, Lauren; Glover, Mark; Queen, Jackie L
Sent: 4/9/2018 5:06:21 PM
Subject: RE: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: **B6** - EON-350487

agreed

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: Jones, Jennifer L
Sent: Monday, April 09, 2018 1:05 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Subject: RE: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: **B6** EON-350487

Recommend NFA-Trend-dog initially had a mild murmur at 8 yr old (2/2015) and it wasn't diagnosed on other PEs until 2/2018; When murmur was initially detected, I suspect a different food was fed, because this dog at Fromm's dry dog food in 3/2017. Also the dog was getting a variety of the TOW Flavors. The lot/bb info for those is attached.

Presenting complaint 2/12/2018: vet prescribed **B6** b/c 4/5 dogs got kennel cough at a dog show in January à owner called 2/28-dog coughing after 4 days of **B6** vomiting pills, not exercise intolerant à vet prescribed **B6** à **B6** to rDVM for continued regular & frequent coughing à to cardiologist on 3/19: cough is worse with stress and middle of night, recent abdominal distension, hyporexia, arthritic, on Grain Free Taste of the Wild Adult Dog food à treated for CHF with **B6**
B6 arecheck 4/2: irregular heart beat, no significant cough, better energy, no abdominal distention, 10 lb weight loss, some pulse deficits
PE **B6** irregular heart, occ bounding pulses, irregular with heart, slight taught/distended abdomen, Gr II-III/VI systolic, upper right heart base, mild increased respiratory effort, HR ~200 at times
3/19: frequent hacking/wheezing cough at rest, nervous, aggitated, HR 188-196, irregular A-fib rhythm, Gr III/VI PMI MV & TV, pant, mild tachypnea when closed mouth, markedly increased bronchovesicular sounds, abdomen w/ moderate ascites, femoral pulse variable intensity
Labs: **B6** **CBC:** nsf

B6

B6

4/2
4/2

Rads B6 cardiomegaly, tracheal elevation, may be early CHF-patchy perihilar opacities;

EKG B6 suspected atrial fibrillation

-4/2: a-fib

Echo 3/19: sev LV hypertrophy, mod MV regurge, sev LA dilation, mild TV regurg, mod RV & sev RA dilation, sev decreased indices of systolic function, A-fib, mod ascites, hepatic venous distension = CHF

Prior MHx: 2/2015 Gr I/VI systolic murmur PMI near MV (8 yr old), declined cardiac consultation, no clinical cough, dyspnea, or exercise intolerance; 2/2016:

B6

3/2017 Fromms dry dog food,

B6

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



From: Rotstein, David

Sent: Thursday, April 05, 2018 12:25 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>

Subject: RE: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: B6 - EON-350487

Sounds good! Thanks

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

Date: April 5, 2018 at 12:23:25 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Glover, Mark <Mark.Glover@fda.hhs.gov>, Queen, Jackie L <Jackie.Queen@fda.hhs.gov>

Subject: RE: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: B6 - EON-350487

We can collect full MRx for review.

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



From: Rotstein, David

Sent: Wednesday, April 04, 2018 4:23 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Ceric,

Olgica <Olgica.Ceric@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>

Subject: Fwd: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: [B6] - EON-350487

Breed that gets DCM....

From: PFR Event <pfpreventcreation@fda.hhs.gov>

Date: April 4, 2018 at 4:20:51 PM EDT

To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>, HQ Pet Food Report Notification

<HQPetFoodReportNotification@fda.hhs.gov>, [B6]

<[B6]>

Subject: Taste of the Wild -Pacific Stream Canine Formula with Smoked Salmon: [B6] - EON-350487

A PFR Report has been received and PFR Event [EON-350487] has been created in the EON System.

A "PDF" report by name "2045119-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 "2045119-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-350487

ICSR #: 2045119

EON Title: PFR Event created for Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon; 2045119

AE Date	03/19/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Hound - Afghan		
Age	11 Years		
District Involved	PFR [B6]		

Product information

Individual Case Safety Report Number: 2045119

Product Group: Pet Food

Product Name: Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon

Description: [B6] has a history of cough - she was initially treated for kennel cough. Developed [B6] and was

evaluated by cardiology practice on 3/19/18. Diagnosed with advanced dilated cardiomyopathy, atrial fibrillation with rapid ventricular response rate and right-sided congestive heart failure with [B6] Started on medical therapy and taurine and l-carnitine supplementation - will recheck echo in 4-5 months. Diet is Taste of the Wild Grain Free - rotates through all varieties except for those containing chicken. There is concern that the diet provides insufficient levels of taurine, contributing to the development of [B6] dilated cardiomyopathy.

Submission Type: Initial

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

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

Number of Animals Treated With Product: 1

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon		

Sender information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-350487>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=366875>

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From: Jones, Jennifer L </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f6ca12eaa9348959a4cbb1e829af244-Jennifer.Jo>
To: 'CVCA [B6] CVCA [B6]'
Sent: 3/15/2019 1:50:25 PM
Subject: RE: FDA Case Investigation for [B6] (11 yr FS Afghan Hound)

Good morning [B6],
Can you share [B6] recent echo results from February? I'm glad to see her values have improved.
Thank you kindly,
Jen

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



From: CVCA [B6] CVCA [B6] <[B6]>
Sent: Thursday, April 05, 2018 4:48 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: Re: FDA Case Investigation for [B6] (11 yr FS Afghan Hound)

[B6] gave the information below (said that it was very hard to read, some numbers/letters may be off):

#1 Best By: 2/20/2019 - 8051 OA (?) - TDSG208D31STP B015-14

#2 Best By: 2/18/2019 - 8049 - TDp0214D12SCPO02-02

#3 TC50208D31sTPB 05-18(?)

Thank you,

[B6] Veterinary Nurse

On Thu, Apr 5, 2018 at 2:02 PM, CVCA [B6] CVCA [B6] <[B6]> wrote:
Good Afternoon,

Please find complete medical history for [B6] attached below. I have called the client to see if we were able to get any additional information on the grain free food product but had to leave a message. If we hear back from her, we will be sure to forward that information as well. Please let us know if you need anything else from us.

Thank you,

[B6] Team Leader, Veterinary Nurse

On Thu, Apr 5, 2018 at 12:36 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 any information on the Grain Free Food, including lot or best by date?
 - Additionally, is there any open or unopened product available?

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>



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The Doctors and Staff of CVCA
CVCA - Cardiac Care for Pets

B6

Visit our website at: www.cvcavets.com

"Like" our Fan Page at: www.facebook.com/CVCAVETS

"Follow" us on Instagram at: <https://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.

*Note -- ** Images are usually posted within 1 month.*

--
The Doctors and Staff of CVCA
CVCA - Cardiac Care for Pets

B6

Email: B6

Visit our website at: www.cvcavets.com

"Like" our Fan Page at: www.facebook.com/CVCAVETS

"Follow" us on Instagram at: <https://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.

*Note -- ** Images are usually posted within 1 month.*

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren; Queen, Jackie L; Ceric, Olgica; Nemser, Sarah
Sent: 6/12/2018 3:11:44 PM
Subject: FW: 4health Grain Free Beef & Potato Formula: [B6] - EON-356322
Attachments: 2049280-report.pdf; 2049280-attachments.zip

Here you go!

I think we've got the PFR/RFR issue sorted out.

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



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From: PFR Event [mailto:pfpreventcreation@fda.hhs.gov]
Sent: Tuesday, June 12, 2018 11:08 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; [B6]
Subject: 4health Grain Free Beef & Potato Formula: [B6] - EON-356322

A PFR Report has been received and PFR Event [EON-356322] has been created in the EON System.

A "PDF" report by name "2049280-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 "2049280-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-356322
ICSR #: 2049280
EON Title: PFR Event created for 4health Grain Free Beef & Potato Formula; 2049280

AE Date	05/24/2018	Number Fed/Exposed	1
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Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	B6 Years		
District Involved	PFR B6 DO		

Product information

Individual Case Safety Report Number: 2049280

Product Group: Pet Food

Product Name: 4health Grain Free Beef & Potato Formula

Description: **B6** presented at **B6** for difficulty breathing/ enlarged heart. **B6** was diagnosed on Thursday with an enlarged heart with RDVM. RDVM sent **B6** home with instructions to limit activity. **B6** collapsed twice this weekend. Once was when **B6** was outside walking and saw a squirrel and the other episode was when **B6** saw the neighbor and came running to neighbor. **B6** has been eating normal, but **B6** did have soft stool yesterday. **B6** has continued to breathe heavy throughout the weekend and has been experiencing coughing/ barking episodes of discomfort. **B6** is up to date on vaccines. **B6** littermate was diagnosed with a heart murmur at 1.5 years old.

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

Product Name	Lot Number or ID	Best By Date
4health Grain Free Beef & Potato Formula		

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-356322>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=372843>

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Report Details - EON-356322

ICSR: 2049280
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-06-12 11:05:01 EDT

Reported Problem:
Problem Description: B6 presented at B6 for difficulty breathing/enlarged heart. B6 was diagnosed on Thursday with an enlarged heart with RDVM. RDVM sent B6 home with instructions to limit activity. B6 collapsed twice this weekend. Once was when B6 was outside walking and saw a squirrel and the other episode was when B6 saw the neighbor and came running to neighbor. B6 has been eating normal, but B6 did have soft stool yesterday. B6 has continued to breathe heavy throughout the weekend and has been experiencing coughing/ barking episodes of discomfort. B6 is up to date on vaccines. B6 littermate was diagnosed with a heart murmur at 1.5 years old.
Date Problem Started: 05/24/2018
Date of Recovery: 05/30/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: 4health Grain Free Beef & Potato Formula
Product Type: Pet Food
Lot Number:
UPC: 104615599
Package Type: BAG
Package Size: 30 Pound
Possess Unopened Product: No
Possess Opened Product: Yes
Product Use Information:
Description: 1 and 1/2 cup dry food fed BID since 2013. Also fed Old Mother Hubbard Mini Treats, Marrow Bones, and small amounts of peanut butter, green beans, bananas, and carrots. Pet also licks plates. Pet receives Mature Made Fish Oil-1 1200mg capsule PO SID.
First Exposure Date: 05/01/2013
Last Exposure Date: 05/29/2018
Product Use Stopped After the Onset of the Adverse Event: Unknown
Perceived Relatedness to Adverse Event: Probably related
Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:
Purchase Location Information: Name: Tractor Supply
 Address: B6
 United States

Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Retriever - Golden	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 34.5 Kilogram	
	Age: B6 Years	
	Assessment of Prior Health: Good	
	Number of Animals Given the Product: 1	
	Number of Animals Reacted: 1	
	Owner Information:	Owner Information provided: Yes
		Contact: Name: B6 Phone: B6 Email: B6
		Address: B6 United States
		Healthcare Professional Information:
	Practice Name:	B6
Contact: Name: B6 Phone: B6 Other Phone: B6 Email: B6		
Address: B6 United States		
Sender Information:		
Name: B6		
Address: B6 United States		
Contact: Phone: B6 Other Phone: B6 Email: B6		
Permission To Contact Sender: Yes		
Preferred Method Of Contact: Email		
Additional Documents:	Attachment: cardio0052.pdf	
	Description: Echo report, labwork, vetrad report from rDVM prior to presentation to us. taurine results.	
	Type: Medical Records	

B6

B6

Patient Information

Patient: **B6** Age: 6 years Referring Veterinarian: **B6**
Patient Number: **B6** Weight:(kg) 34.60 Cardiologist: **B6** DVM, DACVIM
(Cardiology)
Breed: Golden Retriever Sex: MN Client Number: **B6**
Exam Date: **B6** 14:01 BSA: 1.07

History: **B6** was presented to **B6** as an emergency for difficulty breathing and cardiomegaly. **B6** was diagnosed on Thursday with an enlarged heart by the regular veterinarian and the owner has been limiting activity. **B6** collapsed twice this weekend; once while outside walking, and the other episode was when **B6** saw the neighbor and came running. **B6** has been eating normally, but **B6** did have soft stool yesterday. **B6** has continued to breathe heavily throughout the weekend and has been experiencing coughing/barking episodes of discomfort. **B6** is up to date on vaccines. **B6** littermate was diagnosed with a heart murmur at 1.5 year old. He is fed Four Health Beef and Potato diet (see completed diet history form).

Physical Examination: Temp: 102.2 Heart Rate: 128 bpm, RR: Pant
Muffled heart sounds with grade 3/6 systolic left apical murmur. Irregular rhythm consistent with (and confirmed by telemetry as) sinus arrhythmia. Fine crackles left hilar. Panting, tachypneic, mildly dyspneic. Normal abdominal palpation. Fair femoral pulses. Well hydrated. Good body condition. mm pink, normal refill.

Diagnostic Tests: **B6**
Blood pressure: 134 mmHg with 6 cm cuff on left forelimb.
CBC: within normal limits
Chemistry Profile: ALP 19 U/L, lipase 2143 U/L, otherwise within normal limits
ECG (ER): Sinus tachycardia, HR 140 bpm
Thoracic radiographs: Progressive cardiomegaly, cardiogenic pulmonary edema.
Echo - see below. ECG during echo showed a sinus tachycardia.

B6
Thoracic radiographs: decrease in size of cardiac silhouette with nearly resolved pulmonary infiltrates
Taurine (plasma and whole blood levels): pending, will call with results.
Blood pressure: 120 mmHg with 5 cm cuff on left forelimb.

Hospitalization:

B6 was hospitalized in the ICU with continuous telemetry monitoring. An intravenous catheter was placed in the cephalic vein. Telemetry showed a sinus rhythm (varying between sinus tachycardia and sinus arrhythmia, peak rates of tachycardia were 220-230bpm but were very transient and intermittent). He was treated with **B6** and became progressively more comfortable and repeat radiographs showed resolving congestive heart failure.

Echocardiographic Report

2D ECHO

LA Systolic Diameter LN

DOPPLER

AV Peak Velocity

AV Peak Gradient

Mitral E Point Velocity

Mitral E to A Ratio

MR Peak Velocity

M-MODE

LV Diastolic Diameter MM

LV Systolic Diameter MM

LV Fractional Shortening MM

LV Diastolic Volume Cube

LV Systolic Volume Cube

LV Ejection Fraction Cube

IVS Diastolic Thickness MM

IVS Systolic Thickness MM

IVS Percent Thickening MM

PV Peak Velocity

PV Peak Gradient

TR Peak Velocity

TR Peak Gradient

B6

LVPW Diastolic Thickness MM

LVPW Systolic Thickness MM

LVPW Percent Thickening MM

IVS to PW Ratio MM

LV Mass MM

LV Mass Normalized MM

LA Systolic Diameter MM

Aortic Root Diameter MM

MV E Point Septal Separation

B6

Left Ventricle:	Severe dilation with poor global contractility and globoid shape.
Left Atrium:	Moderate dilation.
Right Ventricle:	Moderate dilation with decreased contractility.
Right Atrium:	Moderate dilation.
Mitral Valve:	Valve morphology appears unremarkable; poor excursion with increased EPSS. 3-4+ regurgitation. High E:A ratio, grade III diastolic dysfunction.
Aortic Valve:	Normal.
Tricuspid Valve:	1+ central regurgitation.
Pulmonic Valve:	Normal with trace insufficiency.
Aorta:	Normal.
Pericardium:	Trace effusion

Diagnosis

Dilated cardiomyopathy - This is a disease characterized by weakening of the heart muscle and dilation of the heart chambers. As the disease progresses, it can lead to congestive heart failure (fluid in the lungs causing shortness of breath and cough). Abnormal heart rhythms are common and can result in sudden death. Most commonly this is an inherited disease, though it can occur secondary to a deficiency in an amino acid called taurine particularly in Goldens.

Congestive Heart Failure - B6 had developed fluid in his lungs secondary to his heart disease which was causing him to have difficulty breathing and cough. This has resolved with medication in the hospital, but is likely to be recurrent in the future unless his heart function responds to diet change and supplementation.

Collapse - I suspect that this is due to B6 poor heart muscle function and inability to respond to increased bodily demands. We monitored his heart rhythm while he was here to look for a potential arrhythmogenic cause and did not find any significant arrhythmias.

Recommendations

Please give all medications as directed:

B6

We would also like for you to start **B6** on a taurine supplementation regimen. Taurine can be purchased at pharmacies and health food stores. We do not advise purchase over the internet. **B6** should receive 1000mg taurine every 12 hours. Start tonight or tomorrow.

One thing that can be very helpful for home monitoring is checking sleeping or resting respiratory rates. A recent study showed that even pets with severe heart disease rarely have resting respiratory rates greater than 30 breaths per minute unless they are starting to decompensate for that disease. Elevated respiratory rates at home may be even more sensitive than chest radiographs at picking up early decompensation. Count your pet's respiratory rate when he/she is at rest or sleeping (not within 20 minutes of being active). If his/her respiratory rate is greater than 30 breaths per minute, recheck again in a couple of hours. If persistently elevated above this level, call.

With advanced heart disease, our biggest dietary concerns are adequate calorie content and low sodium content. We aim for less than 80mg sodium per 100 kilocalories (kcal) in patients that have developed congestive heart failure, and less than 100mg/100kcal in animals that have advanced heart disease without heart failure. We do not advise protein restriction unless there is concurrent kidney disease (i.e. kidney diets are not advised unless there is concurrent kidney disease). With our dogs on grain free diets with dilated cardiomyopathy we have a few diets that we are recommending. Please refer to the attached handout.

Exercise is also a concern in advanced heart disease. While cage rest is ideal with active heart failure, some exercise is permissible in asymptomatic disease. However, vigorous or extended exercise should be avoided.

We would like to see **B6 back in 7-10 days, at which time we will recheck blood pressure, renal panel with electrolytes.

B6

DVM, DACVIM (Cardiology)

(Electronically Signed)

Final Date: 30 May 2018 17:46

Like us on Facebook!

www.facebook.com

B6

Notes to our clients

- Please bring all medications to your pet's scheduled appointments.
- We require a 48 hour notice for all refills. When you call to request a refill, please leave the pharmacy phone number or clearly indicate if you plan on picking up the medication at our facility. PRESCRIPTION REFILLS ARE NOT AVAILABLE AFTER **B6** REGULAR BUSINESS HOURS (Evenings, Fridays, holidays and weekends).
- Check out WWW.GOODRX.COM and enter your local zip code to search for the best prices on your medications at your local pharmacies.
- If an emergency arises with your pet **B6** is a 24 hour facility.

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: **B6** Owner's name: **B6** today's date: 4/20/16

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
 _____ Excellent

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

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

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

Food (include specific product and flavor) Form Amount How often? Fed since
 Examples are shown in the table - please provide enough detail that we could go to the store and buy the exact same food

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 1/2 cup	2x/day	Jan 2018
85% lean hamburger	microwaved	3 oz	1x/week	Jan 2015
Pupperoni original beef flavor	treat	1/2	1x/day	Aug 2015
Rawhide	treat	6 inch twist	1x/week	Dec 2015
Four Health Grain Free Chicken & Potato	Dry	1 1/2 cup	2x/day	2018
RED HOOK HULLER CHICKEN TERIYAKI - VANILLA FLAVOR		2-3	2-3x/week	
WARRIOR PUPPY TREATS - OCCASIONAL			occasional	
PEANUT BUTTER & TARTAR OF				
CARROTS, GR. BEANS, BANANAS				
sticks, The plate				

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

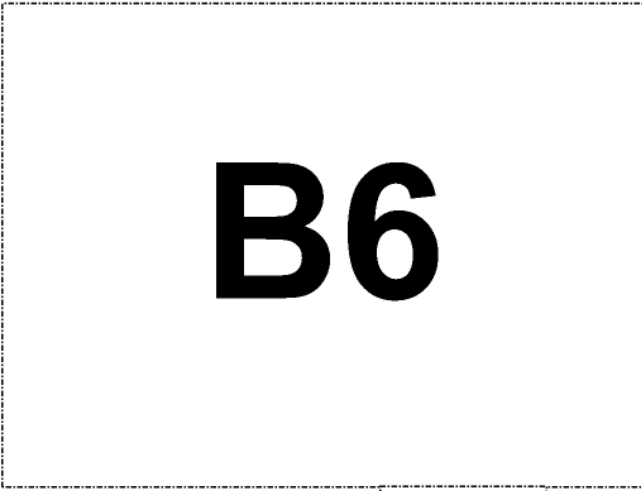
5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)? Yes No If yes, please list which ones and give brands and amounts:

	Brand/Concentration	Amount per day
Taurine	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Carnitine	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Antioxidants	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Multivitamin	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Fish oil	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <u>NATURE'S BOUNTY</u>	<u>1 capsule 2x per day</u>
Coenzyme Q10	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	_____
Other (please list): Example: Vitamin C	<u>Nature's Bounty</u>	<u>500 mg tablets - 1 per day</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____

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

Information below to be completed by the veterinarian:

Current body weight: _____ kg Current body condition score (1-9): _____/9
 Muscle Condition Score: normal muscle mild muscle loss moderate muscle loss severe muscle loss



B6

Final Report for Exam B6

Patient ID: B6

Patient Name: B6

Sex: M ALTERED

Birthdate: B6

Wt: 73.20lbs

Hospital Name: B6

Doctor Name: B6

Date of Exam: B6

Reader: DVM, Diplomate ACVR

Confirmation Date: 5/24/2018 9:07:59 PM UTC

HISTORY

Consult Type: FILMINTERP, SIG: DOB: 4.3.2012, Age: 6.14 Y, Sex: M ALTERED, Wt: 73.20lbs, Breed: Golden Retriever, Species: CANINE, Images: 3, Case Details: Tachypnea. Breathes very heavily at rest, with short shallow respiration. Will wake up from sleep and suddenly starts panting as if just having exercised. Very lethargic at times. Will be sleeping on couch, will get off couch take a few steps on floor and go right back to sleep. Litter mate had subaortic stenosis. General lab panel pending, but thyroid panel performed previously was WNL. No murmur auscultated, but sounds like has crescendo/de-crescendo beats...gets loud then gets soft. Lungs sound clear.

Findings

The study includes 4 projections of the thorax dated may 24th 2018.

The cardiac silhouette is generally enlarged with a vertebral heart score of 13.5. The pulmonary vessels and parenchyma are within normal limits. There are no abnormalities of the pleural space. The cranial abdominal structures included within collimation are unremarkable. The musculoskeletal structures include within collimation are also within normal limits.

Conclusion

1. Generalized cardiomegaly. The primary differentials include pericardial effusion and dilated cardiomyopathy. There is no definitive evidence of congestive heart failure.

Recommendations

A cardiac ultrasound/echocardiogram is warranted for further evaluation.

Read By:

B6

DVM, Diplomate ACVR

Contact Information:

Thank you for this imaging referral. If I can be of further assistance, you can contact me at

B6

Contact information is for veterinary use only.

Thank you very much for this referral. Please let me know if I can be of further assistance.

B6



B6

PET OWNER:

B6

SPECIES: CANINE

BREED: GOLDEN RETRIEVER

GENDER: MALE NEUTERED

AGE:

B6

B6

ACCOUNT #:

B6

ORDERED BY:

B6

ACCESSION #

B6

REQUISITION #:

111508676

DATE OF COLLECTION:

05/25/2018

DATE OF RECEIPT:

05/25/2018

DATE OF REPORT:

05/25/2018

B6 SERVICES:

1013 TOTAL HEALTH

HEMATOLOGY

TEST	RESULT	REF. RANGE
RBC		(5.39 - 8.70) MA/L
Hematocrit		(38.3 - 56.5) %
Hemoglobin		(13.4 - 20.7) g/dL
MCV		(59 - 76) fL
MCH		(21.8 - 26.1) pg
MCHC		(32.6 - 38.2) g/dL
% Reticulocyte		%
Reticulocyte		(10 - 110) K/uL
WBC		(4.9 - 17.6) K/uL
% Neutrophil		%
% Lymphocyte		%
% Monocyte		%
% Eosinophil		%
% Basophil		%
Neutrophil		(2940 - 12670)
Lymphocyte		(1080 - 4850) /uL
Monocyte		(130 - 1150) /uL
Eosinophil		(70 - 1480) /uL
Basophil		(0 - 100) /uL
Platelet		(143 - 448) K/uL
Remarks		

B6

Anion Gap

Total Protein

Albumin

Globulin

Alb:Glob Ratio

ALT

AST

ALP

GGT

Bilirubin - Total

Bilirubin -

Unconjugated

Bilirubin - Conjugated

Cholesterol

Amylase

H Lipase

H Creatine Kinase

Hemolysis Index ^b

Lipemia Index ^c

B6

(11 - 26) mmol/L

(5.5 - 7.5) g/dL

(2.7 - 3.9) g/dL

(2.4 - 4.0) g/dL

(0.7 - 1.5)

(18 - 121) U/L

(16 - 55) U/L

(5 - 160) U/L

(0 - 13) U/L

(0.0 - 0.3) mg/dL

(0.0 - 0.2) mg/dL

(0.0 - 0.1) mg/dL

(131 - 345) mg/dL

(337 - 1468) U/L

(138 - 755) U/L

(18 - 200) U/L

CHEMISTRY

TEST	RESULT	REF. RANGE
Glucose		(63 - 114) mg/dL
IDEXX SDMA ^a		(0 - 14) ug/dL
Creatinine		(0.5 - 1.5) mg/dL
BUN		(8 - 31) mg/dL
BUN:Creatinine Ratio		
Phosphorus		(2.5 - 6.1) mg/dL
Calcium		(8.4 - 11.8) mg/dL
Sodium		(142 - 152)
Potassium		(4.0 - 5.4) mmol/L
Na:K Ratio		(28 - 37)
Chloride		(108 - 118)
TCO2 (Bicarbonate)		(13 - 27) mmol/L

B6

Get deeper insights: For complete access to this patient's diagnostic results, including historic values and images, login to

B6

Final report generated May 25, 2018

PAGE 1 of 2

B6



B6

PET OWNER: B6

DATE OF REPORT: 05/25/2018

ACCESSION #: B6

B6 SERVICES: 1013 TOTAL HEALTH

NOTES

CHEMISTRY

- a BOTH SDMA AND CREATININE ARE WITHIN THE REFERENCE INTERVAL which indicates kidney function is likely good. Evaluate a complete urinalysis and confirm there is no other evidence of kidney disease.
- b Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
- c Index of N, 1+, 2+ exhibits no significant effect on chemistry values.

Get deeper insights: For complete access to this patient's diagnostic results, including historic values and images, login to
Final report generated May 25, 2018

B6

PAGE 2 of 2

Sample Submission Form

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

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

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

Vet/Tech Contact: Account # **B6** / Contact: **B6** Date: 5-30-18

Company Name **B6**
 Address: **B6**

Email: **B6**
 Tel: **B6** Fax: **B6**

Billing Contact: **B6** DVM, DACVIM (C) TAX ID:
 Email: **B6** Tel: **B6**

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

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

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

Reference Ranges (nmol/ml)

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

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Carey, Lauren; Jones, Jennifer L; Palmer, Lee Anne; Queen, Jackie L; Ceric, Olgica; Nemser, Sarah
Sent: 6/12/2018 5:29:33 PM
Subject: RE: 4health Grain Free Beef & Potato Formula: B6 - EON-356322

Agreed!!!

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: Carey, Lauren
Sent: Tuesday, June 12, 2018 1:27 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Queen, Jackie L <Jackie.Queen@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 4health Grain Free Beef & Potato Formula: B6 - EON-356322

Thanks, Dave. J Much better info when these come in as PFRs.

From: Rotstein, David
Sent: Tuesday, June 12, 2018 11:12 AM
To: Jones, Jennifer L <Jennifer.Jones@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>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: FW: 4health Grain Free Beef & Potato Formula: B6 - EON-356322

Here you go!

I think we've got the PFR/RFR issue sorted out.

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



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From: PFR Event [<mailto:pfreventcreation@fda.hhs.gov>]
Sent: Tuesday, June 12, 2018 11:08 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov> [B6]
Subject: 4health Grain Free Beef & Potato Formula [B6] - EON-356322

A PFR Report has been received and PFR Event [EON-356322] has been created in the EON System.

A "PDF" report by name "2049280-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 "2049280-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-356322

ICSR #: 2049280

EON Title: PFR Event created for 4health Grain Free Beef & Potato Formula; 2049280

AE Date	05/24/2018	Number Fed/Exposed	1
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Better/Improved/Recovering
Breed	Retriever - Golden		
Age	[B6] Years		
District Involved	PFR-[B6]		

Product information

Individual Case Safety Report Number: 2049280

Product Group: Pet Food

Product Name: 4health Grain Free Beef & Potato Formula

Description: [B6] presented at [B6] for difficulty breathing/ enlarged heart. [B6] was diagnosed on Thursday with an enlarged heart with RDVM. RDVM sent [B6] home with instructions to

limit activity. [B6] collapsed twice this weekend. Once was when [B6] was outside walking and saw a squirrel and the other episode was when [B6] saw the neighbor and came running to neighbor. [B6] has been eating normal, but [B6] did have soft stool yesterday. [B6] has continued to breathe heavy throughout the weekend and has been experiencing coughing/ barking episodes of discomfort. [B6] is up to date on vaccines. [B6] littermate was diagnosed with a heart murmur at 1.5 years old.

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

Product Name	Lot Number or ID	Best By Date
4health Grain Free Beef & Potato Formula		

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-356322>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=372843>

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

The information is provided as part of the Federal-State Integration initiative. As a Commissioned Official and state government official, you are reminded of your obligation to protect non-public information, including trade secret and confidential commercial information that you receive from the U.S. Food and Drug Administration

from further disclosure. The information in the report is intended for situational awareness and should not be shared or acted upon independently. Any and all actions regarding this information should be coordinated through your local district FDA office.

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

Report Details - EON-356322

ICSR: 2049280
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-06-12 11:05:01 EDT

Reported Problem:
Problem Description: B6 presented at B5, B6 for difficulty breathing/enlarged heart. B6 was diagnosed on Thursday with an enlarged heart with RDVM. RDVM sent B6 home with instructions to limit activity. B6 collapsed twice this weekend. Once was when B6 was outside walking and saw a squirrel and the other episode was when B6 saw the neighbor and came running to neighbor. B6 has been eating normal, but B6 did have soft stool yesterday. B6 has continued to breathe heavy throughout the weekend and has been experiencing coughing/ barking episodes of discomfort. B6 is up to date on vaccines. B6 littermate was diagnosed with a heart murmur at 1.5 years old.
Date Problem Started: 05/24/2018
Date of Recovery: 05/30/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: 4health Grain Free Beef & Potato Formula
Product Type: Pet Food
Lot Number:
UPC: 104615599
Package Type: BAG
Package Size: 30 Pound
Possess Unopened Product: No
Possess Opened Product: Yes
Product Use Information:
Description: 1 and 1/2 cup dry food fed BID since 2013. Also fed Old Mother Hubbard Mini Treats, Marrow Bones, and small amounts of peanut butter, green beans, bananas, and carrots. Pet also licks plates. Pet receives Mature Made Fish Oil-1 1200mg capsule PO SID.
First Exposure Date: 05/01/2013
Last Exposure Date: 05/29/2018
Product Use Stopped After the Onset of the Adverse Event: Unknown
Perceived Relatedness to Adverse Event: Probably related
Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:
Purchase Location Information: Name: Tractor Supply
 Address: B6
 United States

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	34.5 Kilogram		
	Age:	B6 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:	Owner Information provided:	Yes	
		Contact:	Name:	B6
			Phone:	
Email:				
Address:	B6 United States			
Healthcare Professional Information:	Practice Name:	B6 United States		
	Contact:			
	Address:			
Sender Information:	Name:	B6 United States		
	Address:			
	Contact:	Phone:	B6	
		Other Phone:		
		Email:		
	Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email			
Additional Documents:	Attachment:	cardio0052.pdf		
	Description:	Echo report, labwork, vetrad report from rDVM prior to presentation to us. taurine results.		
	Type:	Medical Records		

B6

Client ID:

B6

Client Name:

Spouse/Other:

Address:

B6

Telephone:

Patient ID:

B6

Name:

Breed:

Boxer Mix

Sex:

Neutered Male

Color:

brindle

Age:

9 Yrs. 0 Mos.

DOB:

B6

Referring Veterinarian:

Practice:

Phone:

FAX:

B6

Dear

B6

This message is in regards to a mutual patient, [B6] was presented to [B6] last week, at which time a blood sample was collected to check a CBC and chemistry profile, the results of which only now became available. Please find a copy of these values attached. [B6] has reviewed the results, notes the slight elevation in renal values, and recommends a decrease in [B6]. As the owner was sent home with a months worth of [B6] 50mg tablets, we recommend [B6] get 1 tablet (50mg) in the mornings and 1/2 tablet (25mg) in the evenings, at 12 hour intervals. The owner should continue to monitor resting respiratory rates, as well as any abdominal distention. We will recheck [B6] as recommended, in 2 weeks for a long ECG, +/- Holter monitor. Please feel free to contact us with any questions or concerns.

Sincerely,

B6

B6

PET OWNER: **B6**
SPECIES: Canine
BREED: BOXER
GENDER: Male
AGE: 9 Years
PATIENT ID: **B6**

B6

ACCOUNT #:
ATTENDING VET:

B6

LAB ID: 2600087862
ORDER ID: 112356561
COLLECTION DATE: 6/28/18
DATE OF RECEIPT: 6/29/18
DATE OF RESULT: 6/29/18

IDEXX Services: **Chemistry Panel 4 with CIALP-Canine, CBC, Comprehensive**

B6

Hematology 

6/29/18 (Order Received)
6/29/18 12:41 PM (Last Updated)

6/23/18
8:19 PM

TEST	RESULT	REFERENCE VALUE
RBC	B6	5.39 - 8.7 M/ μ L
Hematocrit		38.3 - 56.5 %
Hemoglobin		13.4 - 20.7 g/dL
MCV		59 - 76 fL
MCH		21.9 - 26.1 pg
MCHC		32.6 - 39.2 g/dL
% Reticulocyte		%
Reticulocyte		10 - 110 K/ μ L
WBC		4.9 - 17.6 K/ μ L

B6

B6

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SPECIES: Canine
BREED: BOXER
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B6

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MCV		59 - 76 fL
MCH		21.9 - 26.1 pg
MCHC		32.6 - 39.2 g/dL
% Reticulocyte		%
Reticulocyte		10 - 110 K/ μ L
WBC		4.9 - 17.6 K/ μ L

B6

B6

PET OWNER:

B6

DATE OF RESULT: **6/29/18**

LAB ID: 2600087862

Chemistry (continued)

TEST	RESULT	REFERENCE VALUE
Globulin	B6	2.4 - 4.0 g/dL
Albumin: Globulin Ratio		0.7 - 1.5
ALT		18 - 121 U/L
AST		16 - 55 U/L
ALP		5 - 160 U/L
ALP (LI)		0 - 35 U/L
Corticosteroid-Induced ALP		
GGT		
LDH		50 - 380 U/L
Bilirubin - Total		0.0 - 0.3 mg/dL
Cholesterol		131 - 345 mg/dL
Triglyceride		20 - 150 mg/dL
Amylase		337 - 1,469 U/L
Lipase		138 - 755 U/L
Creatine Kinase		10 - 200 U/L
Hemolysis Index	b	
Lipemia Index	c	

B6

- a BOTH SDMA AND CREATININE ARE WITHIN THE REFERENCE INTERVAL which indicates kidney function is likely good. Evaluate a complete urinalysis and confirm there is no other evidence of kidney disease.
- b Index of N, 1+, 2+ exhibits no significant effect on chemistry values.
- c Index of N, 1+, 2+ exhibits no significant effect on chemistry values.

B6

Patient Information

Patient: **B6** Age: 9 years Referring Veterinarian: **B6**
Patient Number: **B6** Weight:(kg) 21.30 Cardiologist: **B6**
Breed: Boxer Mix Sex: MN Client Number: **B6**
Exam Date: 06/29/2018 08:14 BSA: 0.78

History: **B6** was presented to **B6** for evaluation of cardiomegaly and suspected dilated cardiomyopathy. **B6** developed a dry cough in last May and was initially treated with antibiotics, but did not improve. Additionally, **B6** was very lethargic, inappetent, extremely exercise intolerant, and had increased respiratory effort. Radiographs taken by the regular veterinarian showed cardiomegaly and it was suspected that **B6** had developed pneumonia. **B6** was presented to **B6** on 6/23 for further evaluation, at which time **B6** was diagnosed with heart failure and cardiac medications were initiated as follows: **B6**

B6 The owner reports that **B6** responded right away to cardiac medications, with improved appetite, energy levels, and a dramatic decrease in cough. **B6** has developed diarrhea in the last 24 hours and the owner has been feeding a bland diet of burger and rice, along with canned Blue Buffalo to administer medications. The owner reports that **B6** has lost a noticeable amount of weight since his ER visit, despite doubling the amount of food offered. **B6** previous diet was Zignature Kangaroo, which he had been fed for at least 13 months. **B6** has a history of being **B6** **B6** (February 2018). He is current on heartworm prevention.

Physical Examination:

Diagnostic Tests:

B6

Echocardiographic Report

2D ECHO

LA Systolic Diameter LX

DOPPLER

AV Peak Velocity
AV Peak Gradient
MR Peak Velocity
PV Peak Velocity

M-MODE

LV Diastolic Diameter MM
LV Systolic Diameter MM
LV Fractional Shortening MM
LV Diastolic Volume Cube
LV Systolic Volume Cube
LV Ejection Fraction Cube
IVS Diastolic Thickness MM
IVS Systolic Thickness MM
IVS Percent Thickening MM

B6

Aortic Root Diameter

PV Peak Gradient
TR Peak Velocity
TR Peak Gradient

LVPW Diastolic Thickness MM
LVPW Systolic Thickness MM
LVPW Percent Thickening MM
IVS to PW Ratio MM
LV Mass MM
LV Mass Normalized MM
RV Diastolic Diameter MM
MVE Point Septal Separation

B6

- Left Ventricle:** Severe dilation (nLVIDd 2.04) with marked global myocardial dysfunction (nLVIDs 1.73)
- Left Atrium:** Severe dilation.
- Right Ventricle:** Moderate dilation with subjective decreased contractility.
- Right Atrium:** Moderate dilation.
- Mitral Valve:** Mildly thickened valve leaflets. 1-2+ central mitral regurgitation.
- Aortic Valve:** Normal
- Tricuspid Valve:** Normal valve morphology. Trace to 1+ tricuspid regurgitation.
- Pulmonic Valve:** Normal
- Aorta:** Normal
- Pericardium:** Normal. No pleural or peritoneal effusion.

Diagnosis

Dilated cardiomyopathy - This is a disease characterized by weakening of the heart muscle and dilation of the heart chambers. As the disease progresses, it can lead to congestive heart failure (fluid in the lungs causing shortness of breath and cough). Abnormal heart rhythms are common and can result in sudden death. Most commonly this is an inherited disease, though it can occur secondary to a deficiency in an amino acid called taurine.

Ventricular arrhythmias - These are abnormal heart beats from the lower heart chambers. As single beats, these rarely cause any symptoms. However, when these abnormal beats come in rapid succession (ventricular tachycardia) they can result in weakness, collapse, and even sudden death. These can occur as a primary electrical disturbance in the heart, in association with other heart disease, or secondary to severe systemic diseases. There is a strong association between ventricular arrhythmias and masses in the spleen. Some dog breeds are predisposed to develop ventricular arrhythmias (boxers, Dobermans) and unfortunately have a significant risk of sudden death associated with them.

Biventricular Congestive Heart Failure- controlled

Recommendations

Please give all medications as directed:

CONTINUE:

B6

ADD:

B6

B6 heart failure is well controlled today. However, he did have some ventricular arrhythmias that warrant further evaluation of his heart rhythm with Holter monitoring. Unfortunately, B6 skin did not react well to being shaved so we did not proceed with placing the monitor. I think that had we continued we would have compromised his skin severely and caused a significant decrease in his quality of life. We can consider other monitoring options like hospitalization for continuous ECG but will hold off for now since he is a high stress dog and you would really like to focus on making him comfortable and happy. We could consider starting an anti-arrhythmic therapy (mexiletine). The most common side effect of mexiletine is GI upset. We have elected not to do this at this time since B6 has a sensitive GI tract and we do not have a clear indication to treat.

As we discussed, we are seeing a correlation between certain diets and heart muscle disease in dogs and certain foods including the Zignature Kangaroo and Lentils diet. We are recommending checking taurine levels and starting supplementation in any dog with dilated cardiomyopathy that is on a diet that may be in question. We do not know the exact underlying cause at this time.

I know that B6 has not been eating this food for several weeks but I still think it is warranted to investigate and put him on a balanced diet that we know is cardiac friendly.

We will call you with the rest of B6 bloodwork results next week.

One thing that can be very helpful for home monitoring is checking sleeping or resting respiratory rates. A recent study showed that even pets with severe heart disease rarely have resting respiratory rates greater than 30 breaths per minute unless they are starting to decompensate for that disease. Elevated respiratory rates at home may be even more sensitive than chest radiographs at picking up early decompensation. Count your pet's respiratory rate when he/she is at rest or sleeping (not within 20 minutes of being active). If his/her respiratory rate is greater than 30 breaths per minute, recheck again in a couple of hours. If persistently elevated above this level, call.

With advanced heart disease, our biggest dietary concerns are adequate calorie content and low sodium content. We aim for less than 80mg sodium per 100 kilocalories (kcal) in patients that have developed congestive heart failure, and less than 100mg/100kcal in animals that have advanced heart disease without heart failure. We do not advise protein restriction unless there is concurrent kidney disease (i.e. kidney diets are not advised unless there is concurrent kidney disease). Please refer to our diet handouts with a list of currently adequate diets and treats, though this list is not exclusive. If you wish to feed a diet that is not on these lists, you will need to call the manufacturer of the diet to obtain a sodium content.

Exercise is also a concern in advanced heart disease. While cage rest is ideal with active heart failure, some exercise is permissible in asymptomatic disease. However, vigorous or extended exercise should be avoided.

***We discussed seeing B6 back in two weeks for a long ECG to make sure we are not seeing progressive arrhythmias. Please call on Monday to set up this appointment. We would like to re-evaluate B6 for his heart failure in 4-6 weeks. At this time we will recheck his kidney values/electrolytes and repeat chest x-rays (and possible perform a long ECG).

B6

(Electronically Signed)

Final Date:

B6

Notes to our clients

- Please bring all medications to your pet's scheduled appointments.
- We require a 48 hour notice for all refills. When you call to request a refill, please leave the pharmacy phone number or clearly indicate if you plan on picking up the medication at our facility. **PRESCRIPTION REFILLS ARE NOT AVAILABLE AFTER [B6] REGULAR BUSINESS HOURS (Evenings, Fridays, holidays and weekends).**
- Check out WWW.GOODRX.COM and enter your local zip code to search for the best prices on your medications at your local pharmacies.
- If an emergency arises with your pet, **[B6]** is a 24 hour facility.

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

Pet's name **B6** Owner's name **B6** Today's date 6/29/18

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

Poor _____ | _____ Excellent

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

3. Over the last few weeks, has your pet (check one)
 Lost weight Gained weight Stayed about the same weight Don't know 6.6 lbs in 6 days

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

Food (include specific product and flavor) Form Amount How often? Fed since
Examples are shown in the table - please provide enough detail that we could go to the store and buy the exact same food.

Food (include specific product and flavor)	Form	Amount	How often?	Fed since
Nutro Grain Free Chicken, Lentil, & Sweet Potato Adult	dry	1 1/2 cup	2x/day	Jan 2018
85% lean hamburger	microwaved	3 oz	1x/week	Jan 2015
Pupperoni original beef flavor	treat	1/2	1x/day	Aug 2015
Rawhide	treat	6 inch twist	1x/week	Dec 2015
<u>Signature Kangaroo</u>	<u>Dry</u>		<u>2x Day</u>	<u>July 18</u>
<u>Yelpizan Jerky</u>	<u>treat</u>			<u>July 18</u>
<u>Bully Stick</u>	<u>treat</u>	<u>1</u>	<u>occasional</u>	
<u>Bland Diet rice/Beef 85-93% lean</u>		<u>2 cup</u>	<u>2x-4x</u>	<u>3 weeks</u>
<u>Blue Buffalo baked treats</u>				

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

increased Feedings this past week

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

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

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): _____

Information below to be completed by the veterinarian:

Current body weight: _____ kg Current body condition score (1-9): _____/9
 Muscle Condition Score: normal muscle mild muscle loss moderate muscle loss severe muscle loss

B6

Name: B6 Client: B6

Age: 9 Yrs. 0 Mos. DOB: B6

Breed: Boxer Mix Sex: Neutered Male

Current History: ER visit B6

Concurrent Condition: hx of allergies-chrx?

pleural effusion
peritoneal effusion
suspect DCM
cough started late mon. Initially treated for kennel cough treated w/ Abx then thought pneumonia

Respiratory symptoms (cough, difficulty breathing, voice changes): tested +

B6

— 1 resp effort by ER r.r. 24hr now responded

Exercise tolerance (activity level, lameness, weakness/lethargy): well to cardiac meds, though has restricted activity now

Heartworm prevention (seasonal vs. year round, brand, last heartworm test): monthly Chewable since I got him

Ownership period (rescue/breeder):

— 13 months from pound

Diet (brand, canned vs. dry, appetite):

— Signature Kangaroo V.A.P.P. since getting him. Appetite while on Abx, 11 Appetite since Saturday.

Indoor and/or Outdoor (feline patients):

Travel History:

B6

Abnormal weight loss/gain:

Yes No Explain: down in weight since Saturday.

Current Medications: B6

Refills needed? (30 vs. 90 day supply):

B6

5mg BID
5mg BID
5mg BID

Diagnostic Plan:

- Blood pressure
- Thoracic Radiographs
- ECG
- Sedation
- Holter/Event
- Echocardiogram
- PCV/TP
- U/A
- CBC
- Profile
- Renal
- Urine culture
- Digoxin
- T4
- TSH
- Abdominal US

Other diagnostics: ___

Technician: B6

Veterinarian:

Wt - 21.3kg
F - 1010
P - 160
R - 36
BR - 108/5 / AF

B6

Report Details - EON-358128

ICSR: 2051197
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-07-02 16:02:14 EDT

Reported Problem:

Problem Description: Developed dry, harsh coughing in late May, which rDVM initially treated with [B6]. Cough did not resolve and [B6] became very lethargic, inappetent, extremely exercise intolerant, and has increased respiratory effort. rDVM radiographs showed cardiomegaly and it was suspected that [B6] had developed pneumonia. [B6] was presented to [B6] for further evaluation, at which time [B6] was diagnosed with heart failure and cardiac medications were initiated. [B6] responded right away to cardiac medications, with improved appetite, energy levels, and a dramatic decrease in cough. The owner reports that [B6] has lost a noticeable amount of weight since the ER visit, a week ago, despite doubling the amount of food offered. Taurine level pending

Date Problem Started: 05/29/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: [B6] Rx'd [B6], which caused GI upset. Owner feeding bland diet of lean ground beef and rice for 3 weeks. Recently added in canned Blue Buffalo to help medicated [B6]

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: Zignature Kangaroo and Lentil

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: Unknown

Possess Opened Product: Yes

Product Use Information:

Description: Zignature diet Fed BID for the last 12 months; also offered Venison Jerky and bully sticks as treats. For the past 3 weeks, owner has offered bland diet of 85-93% lean ground beef and rice at 2-4 cups a day, as well as canned Blue Buffalo for administering medications.

Product Use Stopped After the Onset of the Adverse Event: No

Perceived Relatedness to Adverse Event: Probably related

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

Manufacturer /Distributor Information:

Purchase Location Information: Address: [B6] United States

Animal Information:

Name: [B6]

Type Of Species: Dog

Type Of Breed: Mixed (Dog)

	Gender: Male
	Reproductive Status: Neutered
	Weight: 21.3 Kilogram
	Age: 9 Years
	Assessment of Prior Health: Fair
	Number of Animals Reacted: 1
	Owner Information: Yes
	Owner Information provided:
	Contact: Name: B6
	Phone: B6
	Email: B6
	Address: B6
	United States
	Healthcare Professional Information: Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Other Phone: B6
	Email: B6
	Address: B6
	United States
Sender Information:	Name: B6
	Address: B6
	United States
	Contact: Phone: B6
	Other Phone: B6
	Email: B6
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
	Reported to Other Parties: None
Additional Documents:	Attachment: cardio0012.pdf
	Description: echo report, diet hx, labwork attached
	Type: Medical Records

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Ceric, Olgica; Nemser, Sarah; Palmer, Lee Anne; Queen, Jackie L
Sent: 7/9/2018 1:13:14 PM
Subject: more DCMFW: Halo grain-free dry food (exact variety unknown): Lisa Freeman - EON-358522
Attachments: 2051557-report.pdf

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



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From: PFR Event [mailto:pfreventcreation@fda.hhs.gov]
Sent: Monday, July 09, 2018 9:00 AM
To: Cleary, Michael * <Michael.Cleary@fda.hhs.gov>; HQ Pet Food Report Notification <HQPetFoodReportNotification@fda.hhs.gov>; **B6**
Subject: Halo grain-free dry food (exact variety unknown): Lisa Freeman - EON-358522

A PFR Report has been received and PFR Event [EON-358522] has been created in the EON System.

A "PDF" report by name "2051557-report.pdf" is attached to this email notification for your reference.

Below is the summary of the report:

EON Key: EON-358522

ICSR #: 2051557

EON Title: PFR Event created for Halo grain-free dry food (exact variety unknown); 2051557

AE Date	06/29/2018	Number Fed/Exposed	
Best By Date		Number Reacted	1
Animal Species	Dog	Outcome to Date	Stable
Breed	Great Dane		

Age	B6 years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2051557

Product Group: Pet Food

Product Name: Halo grain-free dry food (exact variety unknown)

Description: DCM and CHF Taurine not measured

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

Product Name	Lot Number or ID	Best By Date
Halo grain-free dry food (exact variety unknown)		

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-358522>

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

<https://eon.fda.gov/eon//EventCustomDetailsAction!viewReport.jspx?decorator=none&e=0&issueType=12&issueId=375146>

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From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
To: Jones, Jennifer L
Sent: 9/25/2018 6:04:02 PM
Subject: RE: updates

No worries. Also, I just saw [redacted B6] yesterday – a mini schnauzer that was previously reported by the owner with severe DCM and CHF.

I'll send you my nutrition report in the next couple days.

Thanks

Lisa

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

From: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Sent: Tuesday, September 25, 2018 1:27 PM
To: Freeman, Lisa <lisa.freeman@tufts.edu>
Subject: RE: updates

Thanks, Lisa. Please disregard my earlier email 😊

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



From: Freeman, Lisa <Lisa.Freeman@tufts.edu>
Sent: Thursday, September 13, 2018 5:14 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: updates

Hi Jen

Here are some updates:

1. We did an echo on [redacted B6] last week. Apparently, the owner submitted a report to FDA after the dog was echoed at [redacted B6] in July. WB taurine was [redacted B6] although that's from [redacted B6] so I'm suspicious. Anyway, [redacted B6] was eating Taste of the Wild and Blue Buffalo originally and changed diet to Pro Plan Sensitive Skin and Stomach salmon after diagnosis and has improved significantly on the echo.
2. Owner of [redacted B6] just sent me a sample of food if you'd like me to submit that (or I can wait until I have a few collected and then submit all at once).
3. We have a new Great Dane with DCM and CHF in the hospital (eating Taste of the Wild). Littermate also has DCM. Once I collect all the info, I'll get them submitted.
- 4.

B5

B5

Thanks
Lisa

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