

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Hartogenesis, Martine; Jones, Jennifer L; Palmer, Lee Anne; Carey, Lauren
Sent: 6/4/2018 4:58:24 PM
Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy
Attachments: 800.267-DCM-Grainfree analysis.pptx

Everyone,

I have a prepared draft for

B5

B5

Thanks,
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: Rotstein, David
Sent: Thursday, May 24, 2018 10:04 AM
To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

B5

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B5

B5

Thank you,

Dave

B4, 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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To: Queen, Jackie L
CC: Rotstein, David
Sent: 5/24/2018 2:03:36 PM
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy
Attachments: 800.267-DCM-Grainfree analysis.pptx

Jackie,

Please take a look when you get a chance:

B5

B5

Thank you,

Dave

B4, B5

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
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From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Edwards, David; Burkholder, William
Sent: 6/14/2018 8:39:00 PM
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Dave,

Thank you.

I definitely didn't expect this overnight! There is so much that we don't know and hopefully will determine as this rolls out.

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: Edwards, David
Sent: Thursday, June 14, 2018 4:37 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Dave,

We have asked Bill to dig into this some, but it might take a bit to get the review pulled together. Quite a complex and interesting topic.

Dave

From: Rotstein, David
Sent: Wednesday, June 13, 2018 8:19 AM
To: Edwards, David <David.Edwards@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: FW: 800.267-DCM and meeting with Cardiac Care for Pets

Good Morning,

We have been passing around a draft for an update about the DCM issue. I've put the link below for comment.

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[CVM Update – Canine DCM & GF Diets](#)

Thank you

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: Monday, June 11, 2018 12:06 PM

To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Good morning everyone,

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B5

Please let me know if you have feedback or comments by COB Friday (6/15).

Thank you,
Jen

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



From: Norris, Anne
Sent: Tuesday, May 22, 2018 9:24 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Thank you for explaining.

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From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 9:13 AM
To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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From: Norris, Anne
Sent: Tuesday, May 22, 2018 8:49 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

That should be fine. I apologize if we already discussed this

B5

B5

From: Palmer, Lee Anne
Sent: Tuesday, May 22, 2018 8:39 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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To: Norris, Anne <Anne.Norris@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

Anne,

Agreed.

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: Norris, Anne
Sent: Tuesday, May 22, 2018 8:34 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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From: Jones, Jennifer L
Sent: Tuesday, May 22, 2018 8:31 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

B5

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



From: Rotstein, David
Sent: Tuesday, May 22, 2018 8:25 AM
To: Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
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From: Reimschuessel, Renate
Sent: Tuesday, May 22, 2018 8:18 AM
To: Edwards, David <David.Edwards@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
Subject: RE: 800.267-DCM and meeting with Cardiac Care for Pets

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Just some food for thought... rr

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: Edwards, David

Sent: Tuesday, May 22, 2018 7:54 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

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Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David
Sent: Monday, May 21, 2018 7:49 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>; Hodges, April <April.Hodges@fda.hhs.gov>
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From: Hartogensis, Martine
Sent: Monday, May 21, 2018 7:47 AM
To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

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Jen, does CVCA know we need individual complaints for each case? We need to tell them and we may only reach a subset of the cases.

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne
Sent: Friday, May 18, 2018 2:09 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks... Jen... very interesting issue!

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I also cleaned up and
this one out!

B5

Thanks – hope we can figure

Lee Anne

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 1:54 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

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



From: Hartogensis, Martine
Sent: Friday, May 18, 2018 11:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 6:42 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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



From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 7:52 PM

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work! One question though.

B5

B5

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Date: May 17, 2018 at 2:27:35 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel,

Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:14:48 PM EDT

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan

Sent: Thursday, May 17, 2018 2:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to B6 talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 17, 2018 at 2:06:04 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi there -

B5

B5

B5

From: Hartogenesis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

Just a few questions

B5

B5

One other question

B5

B5

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Please see the PPT for the rationale/summary

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



From: Rotstein, David

Sent: Monday, May 14, 2018 10:22 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Date: May 14, 2018 at 9:09:17 AM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting.

B5

B5

Martine

From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell,

Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell,

Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic.

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell,

Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi there –

B5

B5

I'll final this up next week, have to get to other things yet today. Have a great weekend! J Lee Anne

B5

From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine

<Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>;

Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi –

B5

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 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>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with B6 @ Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it! The resident I spoke to was **B6**

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

I'm happy to share more info as needed.
Jen

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



From: Rotstein, David
Sent: Tuesday, May 08, 2018 9:45 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>
Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

Looping in Jen.

Thanks for the update!

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: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Date: May 7, 2018 at 1:03:13 PM EDT

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

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

From: Rotstein, David </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A3B17EBFCF14A6CB8E94F322906BADD-DROTSTEI>
To: Jones, Jennifer L; Palmer, Lee Anne; Hartogensis, Martine; Carey, Lauren
Sent: 6/6/2018 3:25:14 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Thanks Jen.

I'll update this for the Division's/

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, June 06, 2018 11:24 AM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Here is the updated powerpoint:

B5

B5

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



From: Palmer, Lee Anne
Sent: Tuesday, June 05, 2018 3:19 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Looks good to me! Thanks.

From: Hartogensis, Martine
Sent: Tuesday, June 5, 2018 2:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi!

I just spoke to Peter Tabor of PFI. We are tentatively going to do a call Monday 9:30-10:30. Does that work for everyone?

They will set up a Go To meeting and I will forward.

Thanks again!

Martine

From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Dave, will you hold on the powerpoint? I'd like to give you an updated version.

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



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Thank you.

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: Hartogensis, Martine

Sent: Tuesday, June 05, 2018 2:23 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>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi Dave,

Are you talking about the ORA Divisions? If so, great idea and ok with me to send.

Martine

From: Rotstein, David

Sent: Monday, June 04, 2018 12:58 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
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: Rotstein, David

Sent: Thursday, May 24, 2018 10:04 AM

To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

B5

B5

B5

Thank you,

Dave

B4, B5

B4, 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: Palmer, Lee Anne </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF7C8BD53B6C45A39318A596ACEA7C53-LPALMER>
To: Hartogensis, Martine; Jones, Jennifer L; Rotstein, David; Carey, Lauren
Sent: 6/5/2018 7:19:03 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Looks good to me! Thanks.

From: Hartogensis, Martine
Sent: Tuesday, June 5, 2018 2:51 PM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Hi!

I just spoke to Peter Tabor of PFI. We are tentatively going to do a call Monday 9:30-10:30. Does that work for everyone?

They will set up a Go To meeting and I will forward.

Thanks again!

Martine

From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Dave, will you hold on the powerpoint? I'd like to give you an updated version.

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



From: Rotstein, David
Sent: Tuesday, June 05, 2018 2:25 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Thank you.

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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Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

David Rotstein, DVM, MPVM, Dipl. ACVP
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CVM OSC/DC/CERT
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Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

B5

B5

B5

Thank you,

Dave

B4, B5

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
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From: Hartogenesis, Martine </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02DF91D554D34B948FC58433D0E42073-MHARTOGE>
To: Jones, Jennifer L; Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:31:27 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Yes, sorry Jen and good idea!

From: Jones, Jennifer L
Sent: Tuesday, June 05, 2018 2:30 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
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Jennifer Jones, DVM
Veterinary Medical Officer
Tel: 240-402-5421



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Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Thank you.

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
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Martine

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Sent: Monday, June 04, 2018 12:58 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

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

Sent: Thursday, May 24, 2018 10:04 AM

To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>

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

Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

B5

B5

B5

Thank you,

Dave

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
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To: Jones, Jennifer L; Hartogensis, Martine; Palmer, Lee Anne; Carey, Lauren
Sent: 6/5/2018 6:31:13 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Sure. Just let me know when it's ready and we will replace it with the newer version.

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
7519 Standish Place
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Tel: 240-402-5421



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Thank you.

B5

David Rotstein, DVM, MPVM, Dipl. ACVP
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Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
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Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

B5

B5

B5

Thank you,

Dave

B4, B5

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
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From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Rotstein, David; Hartogensis, Martine; Palmer, Lee Anne; Carey, Lauren
Sent: 6/4/2018 5:00:55 PM
Subject: RE: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

I received results from Covance [B5] After further investigation, the lab ran the wrong test [B5] Please stay tuned.

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



From: Rotstein, David
Sent: Monday, June 04, 2018 12:58 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: checking in-FW: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Everyone,

B5

Thanks,
dave

David Rotstein, DVM, MPVM, Dipl. ACVP
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B5

B5

B5

Thank you,

Dave

B4, B5

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To: Queen, Jackie L
Sent: 5/25/2018 12:26:42 PM
Subject: RE: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Thanks!

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
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From: Queen, Jackie L
Sent: Friday, May 25, 2018 8:24 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Thanks. Then that would be LOS-DO.
CC = Frank Lee. His Supervisor is Katherine Jacobitz, Acting DIB

Jackie

From: Rotstein, David
Sent: Friday, May 25, 2018 8:18 AM
To: Queen, Jackie L <Jackie.Queen@fda.hhs.gov>
Subject: RE: DRAFT- email to the Divisions about Dilated Cardiomyopathy

It's B5

thanks

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
CVM OSC/DC/CERT
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From: Queen, Jackie L
Sent: Friday, May 25, 2018 8:13 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: RE: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Dave,

I like it. Well said. It even helped me to better understand! J

B5

Thanks,
Jackie

From: Rotstein, David
Sent: Thursday, May 24, 2018 10:04 AM
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Cc: Rotstein, David <David.Rotstein@fda.hhs.gov>
Subject: DRAFT- email to the Divisions about Dilated Cardiomyopathy

Jackie,

Please take a look when you get a chance:

Good Morning,

B5

B5

Thank you,

Dave

B4, B5

David Rotstein, DVM, MPVM, Dipl. ACVP
CVM Vet-LIRN Liaison
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Cummings Veterinary Medical Center

AT TUFTS UNIVERSITY
Cardiology Liaison: 508-887-4696

B6

Patient ID: B6

B6 Canine

B6 years Old Female (Spayed)

Australian Shepherd Cross

Brindle BW: Weight (kg) 25.60

Cardiology Inpatient

Date B6

Weight: Weight (kg) 25.60

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

Thoracic radiographs available for review?

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

Presenting complaint:

possible pericardial effusion

Current history:

lives with one other dog, came home from vaca 7/29 and she was panting frequently, would vomit clear fluid while laying down - from 0-2 times per day, also dry coughing/hacking (O sounds like clearing her throat), V+ does not occur specifically after eating or at specific times, no lethargy, E/D normally, no C/S/D, normal U/BM, O has had her since 6 months old

Prior medical history: January had B6 no other health issues

Current medications:

no medications

Diet:

Rachel Ray Nutrish dry food (unknown protein source), given bully sticks and marrow bone treats and peanut butter

STOP - remainder of form to be filled out by Cardiology

Physical Examination

B6

Muscle condition:

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

Cardiovascular Physical Exam

Murmur Grade:

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

Murmur location/description: Left apical systolic

Jugular vein:

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

Arterial pulses:

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

Arrhythmia:

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

Gallop:

- Yes
- No
- Intermittent
- Pronounced
- Other:

Pulmonary assessments:

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

Abdominal exam:

- Normal
- Hepatomegaly
- Abdominal distension
- Mild ascites

Echocardiogram Findings:

B6

B6

Assessment and recommendations:

Echocardiogram reveals changes consistent with DCM with marked LA enlargement and frequent ventricular arrhythmia. Based on the fact that the MV does not appear to be markedly thickened and that the MR was very central, we are suspicious that the changes are DCM changes more than advanced DMVD. It could be diet related vs. primary/genetic in origin. Blood was pulled today for taurine blood levels and recommend supplementing while waiting for the results to be back. Continue with the current dose of [B6] mg IV q8-12 based on the respiratory rate and effort. There was also frequent ventricular arrhythmia and recommend starting [B6] 200 mg PO BID for the next 7 days then decrease to SID. Recheck kidney values daily while in the hospital and then 10-14 days after the start of the cardiac medications. The patient should be sent home with [B6] with instructions to start 2-3 days after going home if she is still eating with a good appetite. A recheck ECG is also recommended in 10-14 days. Full recheck echocardiogram is recommended in 3 months or sooner if the patient develops clinical signs such as increased RR/RE, cough, exercise intolerance, or syncope.

Treatment plan:

B6

Final Diagnosis:

DCM-like changes with marked LA enlargement and suspected LCHF - r/o diet related vs. genetic in

origin.

Ventricular ectopy

Heart Failure Classification Score:

ISACHC Classification:

- Ia
- Ib
- II
- IIIa
- IIIb

ACVIM CHF Classification:

- A
- B1
- B2
- C
- D

M-Mode

IVSd

LVIDd

LVPWd

IVSs

LVIDs

LVPWs

%FS

Ao Diam

LA Diam

LA/Ao

EPSS

M-Mode Normalized

IVSdN

LVIDdN

LVPWdN

IVSsN

LVIDsN

LVPWsN

Ao Diam N

LA Diam N

2D

SA LA

Ao Diam

SA LA / Ao Diam

IVSd

LVIDd

LVPWd

EDV(Teich)

IVSs

LVIDs



om

om

om

om

om

om

%

om

om

om

{0.29 - 0.52}

{1.35 - 1.73} !

{0.33 - 0.53}

{0.43 - 0.71}

{0.79 - 1.14} !

{0.53 - 0.78} !

{0.68 - 0.89} !

{0.64 - 0.90} !

om

om

om

om

om

ml

om

om

LVPWs
ESV(Teich)
EF(Teich)
%FS
SV(Teich)

Doppler

MR Vmax
MR maxPG
MVE Vel
MV DecT
MVA Vel
MVE/A Ratio
E'
A'
E/E'
PV Vmax
PV maxPG
AV Vmax
AV maxPG
TR Vmax
TR maxPG

B6

cm
ml
%
%
ml

m/s
mmHg
m/s
ms
m/s

m/s
m/s

m/s
mmHg
m/s
mmHg
m/s
mmHg

Client: **B6**
 Veterinarian: **B6**
 Patient ID: **B6**
 Visit ID: 2490582

Patient: **B6**
 Species: Canine
 Breed: Australian Shepherd Cross
 Sex: Female (Spayed)
 Age: **B6** years Old

Lab Results Report

Chem Prof - Small Animal (Cobas) **B6** 10:04:27 PM **Accession ID: B6**

Test	Results	Reference Range	Units
GLUCOSE	B6	67 - 135	mg/dL
UREA		8 - 30	mg/dL
CREATININE		0.6 - 2	mg/dL
PHOSPHORUS		2.6 - 7.2	mg/dL
CALCIUM2		9.4 - 11.3	mg/dL
MAGNESIUM 2+		1.8 - 3	mEq/L
T. PROTEIN		5.5 - 7.8	g/dL
ALBUMIN		2.8 - 4	g/dL
GLOBULINS		2.3 - 4.2	g/dL
A/G RATIO		0.7 - 1.6	
SODIUM		140 - 150	mEq/L
CHLORIDE		106 - 116	mEq/L
POTASSIUM		3.7 - 5.4	mEq/L
tCO2 (BICARB)		14 - 28	mEq/L
AGAP		8 - 19	
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
GGT		0 - 10	U/L
ALT		14 - 86	U/L
AST		9 - 54	U/L
CK		22 - 422	U/L
CHOLESTEROL		82 - 355	mg/dL
TRIGLYCERIDES		30 - 338	mg/dl
AMYLASE	409 - 1250	U/L	

Discharge Instructions

Patient

Name: B6

Species: Canine

Brindle Female (Spayed) Australian

Shepherd Cross

Birthdate: B6

Owner

Name: B6

Address: B6

Patient ID: B6

Attending Cardiologist:

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

B6

Cardiology Resident:

B6

B6

Student: B6

Cardiology Technician:

B6

Admit Date: B6 1:10:59 PM

Discharge Date: B6

Diagnoses: Dilated cardiomyopathy (DCM) with congestive heart failure

Diagnostic test results and findings:

Echocardiogram findings: All chambers of the heart are enlarged and there is a leak at the mitral valve

ECG findings: The ECG showed an occasional arrhythmia (ventricular premature complexes) that have decreased in frequency since B6 first was admitted.

Labwork findings: B6 kidney and liver values are normal. She has no evidence of systemic infection.

Case summary:

B6 presented to the Tufts Emergency Room on B6 after being seen by your regular veterinarian for panting, vomiting, and a cough. Your regular veterinarian took chest x-rays that showed an enlarged heart and fluid in the lungs so they referred B6 to Tufts for further diagnostics and treatment.

On presentation in the Emergency Room we measured B6 vitals (heart rate, respiratory rate, temperature) which were all normal aside from some occasional increased respiratory rate and effort. We then did a quick ultrasound of the chest and could see that her heart was dilated and had decreased contractility. She was then monitored overnight and transferred to our Cardiology Service in the morning.

Our Cardiology Service took over B6 case and performed an echocardiogram (ultrasound of the heart) which confirmed the finding of a large, dilated heart with decreased contractility. We also could appreciate some insufficiency with her mitral valve within her heart as well, which is likely secondary to her enlarged heart. We also performed an ECG to

assess the electrical activity within her heart and noticed that she was having occasional arrhythmias (ventricular premature complexes).

Based on our findings, B6 has been diagnosed with a primary heart muscle disease called dilated cardiomyopathy (DCM). This disease is more common in large and giant breed dogs and is characterized by thinning of the walls of the heart, reduced cardiac pump function, and enlargement of the upper chambers of the heart. Many dogs with DCM will also have significant arrhythmias which can be life-threatening and also require medical management. The heart enlargement has now progressed to the point of congestive heart failure, meaning that fluid is backing up into the lungs or belly. Unfortunately this is a progressive disease and we cannot reverse the changes to the heart muscle, however we can use cardiac medications and some changes to the diet to make your dog comfortable and have her breathing easier.

While in the hospital we have been monitoring B6 closely for increased respiratory rate/ effort and she seems to be breathing much more comfortably since she was when she first was admitted. We also have kept her on 24/7 ECG monitoring in our Intensive Care Unit to see if she has been having any arrhythmias. Since starting her cardiac medications yesterday she has had a decreased frequency of arrhythmias which is great.

Based on how she has been improving while in the hospital, and that she seems bright, alert, and comfortable, we believe that she is ready to go home for continued monitoring and care.

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.
- We recommend that you purchase an AliveCor to use at home. This is a way for you to monitor her heart for any arrhythmias at home. You can purchase one on Amazon and learn more at www.alivecor.com
- If you have any concerns, please call or have your dog evaluated by a veterinarian. Our emergency clinic is open 24 hours/day.

Recommended Medications:

B6

B6

Taurine - Give 1000 mg by mouth every 12 hours. This can be purchase in a human pharmacy.
Taurine is an amino acid that has been related to the reversal of DOM changes in some dogs with dietary deficiencies.
NEXT DOSE DUE: Tonight

Diet suggestions:

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

Your dog's usual diet may also have more sodium than recommended - we want him/her to continue to eat his/her normal diet for the first 7 to 14 days so we can make sure he is tolerating medications well, but after that time we would recommend slowly introducing one of the lower sodium diets on the HeartSmart list (25% of the new diet and 75% old diet for 2-3 days, then 50:50, etc.). Hopefully you can find a diet on the list that your dog likes to eat. Alternatively, if you are attached to the current diet you can research the amount of sodium in the diet to ensure that the sodium content is similar to those on the list.

Exercise Recommendations:

For the first 7 to 10 days after starting medications for heart failure we recommend very limited activity. Leash walking only is ideal, and short walks to start. Once the heart failure is better controlled, then slightly longer walks are acceptable. However, if you find that B6 is lagging behind or needs to stop on a walk then this was too long a walk and shorter walks are advised in the future. Repetitive or strenuous high energy activities (repetitive ball chasing, running fast off-leash, etc.) are generally not advised at this stage of heart failure.

Recheck Visits:

A recheck visit is recommended in 1-2 weeks. At that time we would like to repeat bloodwork in order to recheck her kidney values. This can be done either here or with your primary care veterinarian if more convenient.

A recheck echocardiogram is recommended in 3-4 months.

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

Sincerely,

B6

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

Prescription Refill Disclaimer:

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

Ordering Food:

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

online retailers with a prescription/veterinary approval.

Clinical Trials:

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

Case: B6

Owner: B6

Discharge Instructions

CARDIOLOGY DIET HISTORY FORM

Please answer the following questions about your pet

Pet's name: B6 Owner's name: B6 Today's date: 9/6/18

- How would you assess your pet's appetite? On a scale of 1-10 with 1 being poor and 10 being excellent: 5 or 6
- 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: Depends some days she eats good other
- Over the last few weeks, has your pet (check one)
 - Lost weight
 - Gained weight
 - Stayed about the same weight
 - Don't know
- 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 do 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 ½ cup	2x/day	Jan 2018
85% lean hamburger	microwaved	3 oz	1x/week	Jan 2015
Pupperoni original beef flavor	treat	½	1x/day	Aug 2015
Rawhide	treat	6 inch twist	1x/week	Dec 2015
Rachl Ray nutritish real beef and brown rice bar code 7119000095	Dry	2cups	2x day	Jan 2017
Bully sticks		1	Day	Jan 2012
Marrow bones frozen		1	1x week	Jan 2012
Peanut butter skippy brand		1 tablespoon	3x week	Jan 2012
Dentalix pedigree mint flavor		1	1x day	Jan 2012

***Any additional diet information can be listed at the bottom of this sheet**

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

- 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): _____

Additional diet or supplement information: _____

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

Client:
 Veterinarian:
 Patient ID:
 Visit ID: 2490582

Patient:
 Species: Canine
 Breed: Australian Shepherd Cross
 Sex: Female (Spayed)
 Age: Years Old

Lab Results Report

Taurine Panel	<input type="text" value="B6"/>	11:29:01 AM	Accession ID: <input type="text" value="B6"/>
Test	Results	Reference Range	Units
TAURINE P	<input type="text" value="B6"/>	60 - 120	nmol/mL
TAURINE WB	<input type="text" value="B6"/>	200 - 350	nmol/mL

From: PFR Event <preventcreation@fda.hhs.gov>
To: Cleary, Michael *; HQ Pet Food Report Notification; [B6]
Sent: 9/16/2018 3:44:27 PM
Subject: Taste of the Wild Prey Beef dry (will provide full diet history): Lisa Freeman - EON-365610
Attachments: 2054966-report.pdf; 2054966-attachments.zip

A PFR Report has been received and PFR Event [EON-365610] has been created in the EON System.

A "PDF" report by name "2054966-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 "2054966-attachments.zip" and is attached to this email notification.

Below is the summary of the report:

EON Key: EON-365610

ICSR #: 2054966

EON Title: PFR Event created for Taste of the Wild Prey Beef dry (will provide full diet history), 4Health beef stew canned; 2054966

AE Date	09/12/2018	Number Fed/Exposed	2
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: 2054966

Product Group: Pet Food

Product Name: Taste of the Wild Prey Beef dry (will provide full diet history), 4Health beef stew canned

Description: DCM and CHF - had been having respiratory signs for ~1 month prior to diagnosis at Tufts Littermate is [B6] already reported by owner after being diagnosed with DCM and CHF in July 2018) Owner has another Great Dane at home (~1 year of age) eating the same diet that will be screened soon

Owner approved submission of this report and talking to FDA Will send rest of medical records by email (sorry - too many to upload)

Submission Type: Initial

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

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

Number of Animals Treated With Product: 2

Number of Animals Reacted With Product: 1

Product Name	Lot Number or ID	Best By Date
Taste of the Wild Prey Beef dry (will provide full diet history)		
4Health beef stew canned		

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-365610>

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=382429>

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.

From: [Edwards, David](#)
To: [Rotstein, David](#); [Hartogensis, Martine](#); [Burkholder, William](#); [Palmer, Lee Anne](#); [Jones, Jennifer L](#); [DeLancey, Siobhan](#)
Cc: [Carey, Lauren](#); [Norris, Anne](#); [Lovell, Randall A](#); [Reimschuessel, Renate](#); [Ceric, Olgica](#); [Nemser, Sarah](#); [Conway, Charlotte](#); [Atkinson, Krisztina Z](#); [Hodges, April](#)
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets
Date: Tuesday, May 22, 2018 7:54:00 AM
Attachments: [image001.png](#)
[image007.png](#)
[image008.png](#)
[image009.png](#)
[image010.png](#)
[image012.png](#)
[image013.png](#)
[image014.png](#)
[image015.png](#)
[image021.png](#)
[image022.png](#)
[image023.png](#)

Hi everyone,

B5

Thanks,
Dave

From: Rotstein, David
Sent: Monday, May 21, 2018 7:49 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards,

David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>;
Hodges, April <April.Hodges@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

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: Hartogenesis, Martine

Sent: Monday, May 21, 2018 7:47 AM

To: Burkholder, William <William.Burkholder@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.DeLancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks Bill and your concerns are noted!

B5

B5

Jen, does CVCA know we need individual complaints for each case? We need to tell them and we may only reach a subset of the cases.

Thank you all for your help and dedication to this fascinating issue!

Martine

From: Burkholder, William

Sent: Friday, May 18, 2018 5:04 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>; Conway, Charlotte <Charlotte.Conway@fda.hhs.gov>; Edwards, David <David.Edwards@fda.hhs.gov>; Atkinson, Krisztina Z <Krisztina.Atkinson@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

B5

Bill

What Socrates is really supposed to have said: *"The only true wisdom is in knowing that you know nothing."

From: Palmer, Lee Anne

Sent: Friday, May 18, 2018 2:09 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thanks, Jen, very interesting issue!

B5

B5

I also cleaned up and
can figure this one out!

B5

Thanks – hope we

Lee Anne

From: Jones, Jennifer L

Sent: Friday, May 18, 2018 1:54 PM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren

<Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Any other ideas or suggestions?

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



From: Hartogensis, Martine
Sent: Friday, May 18, 2018 11:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Thank you Jen! Sounds good and looking forward to the meeting.

Martine

From: Jones, Jennifer L
Sent: Friday, May 18, 2018 6:42 AM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric,

Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

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



From: Hartogensis, Martine

Sent: Thursday, May 17, 2018 7:52 PM

To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Yes, excellent work!

B5

B5

Thanks in advance!

Martine

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Date: May 17, 2018 at 2:27:35 PM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Indeed! Brands mentioned included California Naturals, Rachel Ray, Ellen DeGeneres' Halo brand - esp the vegan formulation - and a few other niche brands I didn't catch.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:14:48 PM EDT
To: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hah! Perfect timing! We're all heading down the same path...

From: DeLancey, Siobhan
Sent: Thursday, May 17, 2018 2:13 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

As luck would have it, I'm at CE today listening to [B6] from [B6] talk about nutrition and cardiomyopathies. See attached slide.

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Date: May 17, 2018 at 2:06:04 PM EDT
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>, Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>, Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>, Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>
Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Hi there

[B5]

[B5]

B5

From: Hartogenesis, Martine

Sent: Thursday, May 17, 2018 11:59 AM

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

Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

Excellent work Jen!!

B5

B5

Martine

From: Jones, Jennifer L

Sent: Thursday, May 17, 2018 11:29 AM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>; Reimschuessel, Renate <Renate.Reimschuessel@fda.hhs.gov>; Ceric, Olgica <Olgica.Ceric@fda.hhs.gov>; Nemser, Sarah <Sarah.Nemser@fda.hhs.gov>

Subject: RE: 800.267-DCM and meetign with Cardiac Care for Pets

B5

Please see the PPT for the rationale/summary

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



From: Rotstein, David

Sent: Monday, May 14, 2018 10:22 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B6

Once we get a better handle on a specific cause, we can work on that.

From: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>

Date: May 14, 2018 at 9:09:17 AM EDT

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

This is very interesting.

B5

B5

Martine

From: Palmer, Lee Anne

Sent: Friday, May 11, 2018 4:30 PM

To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

B5

From: Rotstein, David

Sent: Friday, May 11, 2018 4:14 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Lee Anne,

This is fantastic.

B5

B5

B5

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 11, 2018 at 4:06:05 PM EDT

To: Rotstein, David <David.Rotstein@fda.hhs.gov>, Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>, Lovell, Randall A <Randall.Lovell@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi there –

B5

B5

B5

B5

From: Rotstein, David

Sent: Wednesday, May 9, 2018 4:13 PM

To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Sounds very intriguing!!!

From: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>

Date: May 9, 2018 at 4:09:18 PM EDT

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>, Rotstein, David <David.Rotstein@fda.hhs.gov>, Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>, Carey, Lauren <Lauren.Carey@fda.hhs.gov>, Norris, Anne <Anne.Norris@fda.hhs.gov>, DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Subject: RE: DCM and meetign with Cardiac Care for Pets

Hi -

B5

B5

From: Hartogensis, Martine
Sent: Wednesday, May 9, 2018 2:17 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>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Awesome, thank you Dave!

Martine

From: Rotstein, David
Sent: Wednesday, May 09, 2018 2:06 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Cc: Burkholder, William <William.Burkholder@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>; Norris, Anne <Anne.Norris@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>
Subject: RE: DCM and meetign with Cardiac Care for Pets

Good Afternoon,

I spoke with [B6] Cardiac Care for Pets. He is going to look into times/dates with the cardiologists there and we can set the meeting up from that point.

Just some basic information:

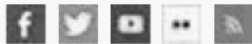
B5

As a side note, there is a facebook page dedicated to this issue:

<https://www.facebook.com/groups/1952593284998859/about/>

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: Hartogenesis, Martine
Sent: Tuesday, May 08, 2018 10:58 AM
To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Jen and Dave! Very interesting and sounds like you all are on it!
was

B6

B6

B6

Keep us posted!

Thanks again!

Martine

Hi Martine,

B5

B5

I'm happy to share more info as needed.

Jen

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



From: Rotstein, David

Sent: Tuesday, May 08, 2018 9:45 AM

To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>

Subject: RE: DCM

Martine,

Jen and I spoke with cardiologists from NCSU and a few other institutions. That's how we were able to get the information.

B5

Looping in Jen.

Thanks for the update!

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: Hartogensis, Martine
Sent: Tuesday, May 08, 2018 9:00 AM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>
Subject: RE: DCM

Thank you Dave! We did not go around yesterday because the Vet-LIRN folks came in for their routine presentation.

B5

B5

Might be a good opportunity for us to partner with some cardiology folks...

Martine

From: Rotstein, David
Sent: Monday, May 07, 2018 1:13 PM
To: Hartogensis, Martine <Martine.Hartogensis@fda.hhs.gov>
Subject: Re: DCM

Martine

B5

There's a way to go on this moving forward.

Dave

From: Hartogenesis, Martine <Martine.Hartogenesis@fda.hhs.gov>

Date: May 7, 2018 at 1:03:13 PM EDT

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

Subject: DCM

Hi Dave!

Do you have any more details on the DCM and grain free diet issue?

Martine

DOCUMENT PRODUCED IN NATIVE

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

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

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

Below is the summary of the report:

EON Key: EON-380742

ICSR #: 2063133

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

AE Date	01/15/2019	Number Fed/Exposed	6
Best By Date		Number Reacted	3
Animal Species	Dog	Outcome to Date	Stable
Breed	Bulldog		
Age	B6 Years		
District Involved	PFR-New England DO		

Product information

Individual Case Safety Report Number: 2063133

Product Group: Pet Food

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

Description: DCM and CHF diagnosed 1/15/19 Eating BEG diet. 6 dogs being fed this diet - so far, 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been

changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food

Submission Type: Initial

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

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

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 3

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6

USA

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

<https://eon.fda.gov/eon//browse/EON-380742>

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=397751>

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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-380742

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

Reported Problem:
Problem Description: DCM and CHF diagnosed 1/15/19 Eating BEG diet, 6 dogs being fed this diet - so far 3 have been diagnosed with DCM/ARVC. One other had a normal NT-proBNP and 2 others will be tested Diet has been changed to Royal Canin Early Cardiac and we will recheck in 3 months. I have sample of dry and canned food
Date Problem Started: 01/15/2019
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

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

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Bulldog
Gender: Female
Reproductive Status: Neutered
Weight: 19.8 Kilogram
Age: B6 years
Number of Animals Given the Product: 6
Number of Animals Reacted: 3
Owner Information: Owner Information provided: Yes
Contact: Name: B6
Phone: B6
Email: B6
Address: B6
United States
Healthcare Professional Information: Practice Name: B6
Contact: Name: B6
Phone: B6
Email: B6

Address:

B6

United States

Sender Information:

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

Additional Documents:

Attachment:	rpt_medical_record_preview.pdf
Description:	Med records
Type:	Medical Records

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

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

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

Below is the summary of the report:

EON Key: EON-380745

ICSR #: 2063135

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

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

Product information

Individual Case Safety Report Number: 2063135

Product Group: Pet Food

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

Description: Eating BEG diet - 2 other dogs in household diagnosed with DCM ([B6]) -

already reported) RDVM screened this dog with NT-proBNP which was elevated so we evaluated at Tufts 2/20/19 Probable ARVC/diet-associated DCM but no arrhythmia detected (enlarged right ventricle, reduced contractility) Changing diet to Royal Canin Early Cardiac and will re-evaluate in 3 months. Taurine and troponin pending

Submission Type: Initial

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

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

Number of Animals Treated With Product: 6

Number of Animals Reacted With Product: 3

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

Sender information

Lisa Freeman
200 Westboro Rd
North Grafton, MA 01536
USA

Owner information

B6 USA

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

<https://eon.fda.gov/eon//browse/EON-380745>

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=397754>

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Report Details - EON-380745

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

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

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

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

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

From: Palmer, Lee Anne </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7c8bd53b6c45a39318a596acea7c53-LPALMER>
To: Peterson, Glenn A
Sent: 2/27/2019 4:40:54 PM
Subject: DCM papers
Attachments: Adin 2019.pdf; Freeman 2018 javma.253.11.1390.pdf; Freeman_Nutrition and CM 2007 10.1007_s11897-007-0005-6.pdf; Mansilla 2019 J Anim Sci.pdf

Hi – here you go...

Thanks, Lee Anne

Lee Anne M. Palmer, VMD, MPH

Team Leader HFV-242, Supervisory VMO

Center for Veterinary Medicine
OSC, Division of Veterinary Product Safety
U.S. Food and Drug Administration
Tel: 240-402-5767
Leeanne.palmer@fda.hhs.gov





Echocardiographic phenotype of canine dilated cardiomyopathy differs based on diet type



Darcy Adin, DVM*, Teresa C. DeFrancesco, DVM ,
Bruce Keene, DVM , Sandra Tou, DVM , Kathryn Meurs, DVM,
PhD , Clarke Atkins, DVM , Brent Aona, DVM , Kari Kurtz, DVM ,
Lara Barron, DVM , Korinn Saker, DVM, PhD

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Received 30 May 2018; received in revised form 24 October 2018; accepted 6 November 2018

KEYWORDS

Nutritional;
Heart failure;
Dog;
Taurine

Abstract *Introduction:* Canine dilated cardiomyopathy (DCM) can result from numerous etiologies including genetic mutations, infections, toxins, and nutritional imbalances. This study sought to characterize differences in echocardiographic findings between dogs with DCM fed grain-free (GF) diets and grain-based (GB) diets.

Animals: Forty-eight dogs with DCM and known diet history.

Methods: This was a retrospective analysis of dogs with DCM from January 1, 2015 to May 1, 2018 with a known diet history. Dogs were grouped by diet (GF and GB), and the GF group was further divided into dogs eating the most common grain-free diet (GF-1) and other grain-free diets (GF-o). Demographics, diet history, echocardiographic parameters, taurine concentrations, and vertebral heart scale were compared between GB, all GF, GF-1, and GF-o groups at diagnosis and recheck.

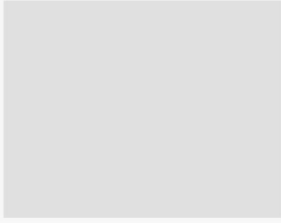
Results: Dogs eating GF-1 weighed less than GB and GF-o dogs, but age and sex were not different between groups. Left ventricular size in diastole and systole was greater, and sphericity index was less for GF-1 compared with GB dogs. Diastolic left ventricular size was greater for all GF compared with that of GB dogs. Fractional shortening, left atrial size, and vertebral heart scale were not different between groups. Taurine deficiency was not identified in GF dogs, and presence of congestive heart failure was not different between groups. Seven dogs that were

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reevaluated after diet change (6 received taurine supplementation) had clinical and echocardiographic improvement.

Conclusions: Dietary-associated DCM occurs with some GF diets and can improve with nutritional management, including diet change. The role of taurine supplementation, even without deficiency, is uncertain.

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Commentary

Diet-associated dilated cardiomyopathy in dogs: what do we know?

Lisa M. Freeman DVM, PhD

Joshua A. Stern DVM, PhD

Ryan Fries DVM

Darcy B. Adin DVM

John E. Rush DVM, MS

From the Department of Clinical Sciences, Cummings School of Veterinary Medicine, Tufts University, North Grafton, MA 01536 (Freeman, Rush); Department of Medicine and Epidemiology, School of Veterinary Medicine, University of California-Davis, Davis, CA 95616 (Stern); Department of Veterinary Clinical Medicine, College of Veterinary Medicine, University of Illinois, Urbana, IL 61802 (Fries); and Department of Clinical Sciences, College of Veterinary Medicine, North Carolina State University, Raleigh, NC 27607 (Adin).

Address correspondence to Dr. Freeman (lisa.freeman@tufts.edu).

Diet-associated DCM first came to light in cats in the late 1980s¹ and in dogs in the mid-1990s.² The association between diet and DCM in dogs has generally not been much in the news since the early 2000s, but over the past few years, an increasing number of DCM cases involving dogs appear to have been related to diet. The extent of this issue is not clear, not all cases have been confirmed to be linked to diet, and a true association has not been proven to exist. However, when one of the authors (RF) recently surveyed veterinary cardiologists about cases of possible diet-associated DCM in dogs examined in the past 2 years, information for > 240 cases was obtained, with responses received from the United States, United Kingdom, Canada, Israel, and Austria (unpublished data). Dogs for which breed was specified consisted of mixed-breed dogs (n = 134), Golden Retrievers (23), Labrador Retrievers (9), German Shepherd Dogs (8), Cocker Spaniels (7), and between 1 and 5 dogs each of 25 other breeds. Further, possible diet-associated DCM represented 16% of all cases of DCM diagnosed by the respondents during this period.

The recent announcement from the US FDA³ alerting pet owners and veterinarians about reports of DCM in dogs eating pet foods containing peas, lentils, other legume seeds, or potatoes as main ingredients has raised concerns among the pet-owning public. Therefore, we wanted to increase awareness of this issue among veterinarians, review what is currently known about the possible association between certain diets and DCM in dogs, and discuss what veterinarians can do to help identify and manage cases

ever, Pion et al¹ published a landmark paper reporting that DCM in cats was associated with taurine deficiency and could be reversed by providing supplemental taurine. On the basis of that report and substantial subsequent research, the requirement for taurine in cat foods was increased, and taurine deficiency-related DCM is now uncommon in cats. However, it can still be seen in cats eating home-prepared diets or commercial diets prepared with inadequate nutritional expertise or quality control.

In 1995, veterinary cardiologists investigating the role of taurine deficiency in dogs with DCM suggested that certain breeds (eg, Golden Retrievers and American Cocker Spaniels) may be predisposed to taurine deficiency,² and a study in Cocker Spaniels subsequently showed that supplementation with taurine and L-carnitine could partially or completely reverse the disease.⁴ Additional dog breeds potentially predisposed to taurine deficiency-associated DCM were identified, including Newfoundlands, English Setters, Saint Bernards, and Irish Wolfhounds.⁵⁻¹⁰ Later, certain types of diets, including lamb and rice, low-protein, and high-fiber diets were associated with taurine deficiency in some dogs.^{5,7,9,11-14} Research suggested that other ingredients (eg, beet pulp) may also increase the risk of taurine deficiency,¹⁵ although the exact role of these ingredients was still unclear. In addition, the apparent breed predispositions suggested that genetic factors, breed-specific metabolic abnormalities, or low metabolic rates may also have been playing a role.^{8,9,16}

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Nutrition and Cardiomyopathy: Lessons from Spontaneous Animal Models

*Lisa M. Freeman, DVM, PhD, DACVN, and
John E. Rush, DVM, MS, DACVIM (Cardiology), DACVECC*

Corresponding author

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Current Heart Failure Reports 2007, **4**:84–90
Current Medicine Group LLC ISSN 1546-9530
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Spontaneously occurring dilated cardiomyopathy in dogs and hypertrophic cardiomyopathy in cats are common diseases and are vastly underutilized as models of human cardiac disease. The goals of nutrition are no longer limited to a low-sodium diet, as research is now showing that nutrients can modulate disease and be an important adjunct to medical therapy. Deficiencies of certain nutrients can contribute to cardiomyopathies, as with taurine, but some nutrients—such as n-3 fatty acids, carnitine, and antioxidants—may have specific pharmacologic benefits. Dogs and cats with spontaneous cardiomyopathies are an exciting and promising model for studying nutritional modulation of cardiac disease.

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From: Jones, Jennifer L </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0F6CA12EAA9348959A4CBB1E829AF244-JENNIFER.JO>
To: Rotstein, David; Palmer, Lee Anne; Carey, Lauren
Sent: 5/8/2018 11:09:31 AM
Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

B4, B5

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



From: Rotstein, David
Sent: Monday, May 07, 2018 2:42 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

Lee Anne,

It was all very helpful!

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

CVM OSC/DC/CERT
7519 Standish Place
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From: Palmer, Lee Anne
Sent: Monday, May 07, 2018 2:34 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

B5

From: Palmer, Lee Anne
Sent: Monday, May 7, 2018 2:32 PM
To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

B5

From: Rotstein, David
Sent: Monday, May 7, 2018 2:19 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

Lee Anne,

B5

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To: Rotstein, David <David.Rotstein@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

B5

From: Rotstein, David
Sent: Monday, May 7, 2018 2:10 PM
To: Palmer, Lee Anne <LeeAnne.Palmer@fda.hhs.gov>; Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>
Subject: RE: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

Lee Anne,

Thank you.

B5

Dave

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From: Palmer, Lee Anne

Sent: Monday, May 07, 2018 2:08 PM

To: Jones, Jennifer L <Jennifer.Jones@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Carey, Lauren <Lauren.Carey@fda.hhs.gov>

Subject: Ingredient listing by Atypical vs Typical Breed for Canine DCM.docx

Report Details - EON-365657

ICSR: 2055027
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-09-17 20:24:06 EDT

Reported Problem:

Problem Description: Acute onset cough and respiratory distress. Physical exam and diagnostic work-up revealed dilatated cardiomyopathy, with congestive heart failure. Blood work, including taurine levels are pending.

Date Problem Started: B6

Concurrent Medical Problem: No

Outcome to Date: Died Euthanized

Date of Death: B6

Product Information:

Product Name: 4health Untamed Open Highland Recipe Lamb and Lentil Formula Dog Food

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 25 Pound

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: No

Product Use Information:

Description: 2 cups given orally daily

First Exposure Date: 09/01/2017

Last Exposure Date: B6

Time Interval between Product Use and Adverse Event: 12 Months

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

Adverse Event Abate After Product Stop: Not Applicable

Product Use Started Again: No

Perceived Relatedness to Adverse Event: Definitely related

Other Foods or Products Given to the Animal During This Time Period: No

Manufacturer /Distributor Information:

Purchase Location Information:

Name: Tractor Supply

Address: B6

B6

United States

Animal Information:

Name: **B6**

Type Of Species: Dog

Type Of Breed: Retriever - Golden

Gender: Male

Reproductive Status: Neutered

Weight: 81.5 Pound

Age: 3 Years

Assessment of Prior Health: Excellent

Number of Animals Given the Product: 3

Number of Animals Reacted: 1

Owner Information:

Owner Information provided: Yes

Contact Name: **B6**

Phone: **B6**

Address:

B6

United States

Healthcare Professional Information:

Practice Name: **B6**

Contact Name: **B6**

Phone: **B6**

Email: **B6**

Address:

B6

United States

Type of Veterinarian: Primary/regular veterinarian

Permission to Release Records to FDA: Yes

Sender Information:

Name: **B6**

Address:

B6

Contact Phone: **B6**

Email: **B6**

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Reported to Other Parties: None

Additional Documents:

Attachment:

B6

Results.pdf

Description: Complete Blood Cell Count, chemistry profile, total T4, urinalysis, whole blood and plasma taurine levels.

Type: Laboratory Report

Report Details - EON-365660		
ICSR:	2054979	
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:	B6 0:25:49 EDT	
Reported Problem:	Problem Description: Dog was diagnosed with dilated cardiomyopathy on 8-26-2018. Started on medications and abdomen drained. dog improved for a short time but has now declined to the point that euthanasia is necessary.	
	Date Problem Started: 08/26/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Euthanized	
	Date of Death: B6	
Product Information:	Product Name: Acana Heritage	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Number Purchased: 1	
	Possess Unopened Product: Yes	
	Possess Opened Product: Yes	
	Storage Conditions: in airtight Tupperware tote	
	Product Use Information:	Description: fed in bowl - twice daily
		First Exposure Date: 09/01/2014
		Last Exposure Date: B6
		Time Interval between Product Use and Adverse Event: 4 Years
		Perceived Relatedness to Adverse Event: Definitely related
Other Foods or Products Given to the Animal During This Time Period: No		
Manufacturer /Distributor Information:		
Purchase Location Information: Name: Chewy.com		
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Rottweiler	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 103 Pound	
	Age: 6 Years	
	Assessment of Prior: Excellent	

	Health:									
	Number of Animals Given the Product:	1								
	Number of Animals Reacted:	1								
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> </table>	Owner Information provided:	Yes	Contact: Name:	B6	Phone:	B6	Address:	B6
Owner Information provided:	Yes									
Contact: Name:	B6									
Phone:	B6									
Address:	B6									
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Permission to Release Records to FDA:</td> <td>Yes</td> </tr> </table>	Practice Name:	B6	Contact: Name:	B6	Phone:	B6	Permission to Release Records to FDA:	Yes
Practice Name:	B6									
Contact: Name:	B6									
Phone:	B6									
Permission to Release Records to FDA:	Yes									
Sender Information:	Name:	B6								
	Address:	B6								
	Contact: Phone:	B6								
	Email:	B6								
	Reporter Wants to Remain Anonymous:	No								
	Permission To Contact Sender:	Yes								
	Preferred Method Of Contact:	Email								
	Reported to Other Parties:	None								
Additional Documents:										

Report Details - EON-365653

ICSR: 2055020
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-09-17 17:33:45 EDT

Reported Problem:
Problem Description: B6 developed a cough and an increase in respiratory rate. He was evaluated at B6 2 weeks ago and was treated with B6 but no improvement was noted. He was reevaluated at B6 (9/11/18) and radiographs were performed which identified cardiomegaly and congestive heart failure. He was referred to the B6 on 9/12/18 for evaluation and supportive care. CVCA consult identified advanced dilated cardiomyopathy (possibly nutritional due to chronically being on a grain free diet) and nasal oxygen was placed and he was started on B6 in hospital. Samples were drawn for CVCA/FDA Trial on 9/14/18. Drawn 3 hours after feeding.
Date Problem Started: 09/11/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6 was being treated with B6 prior to echocardiogram due to a cough and increase in respiratory rate.
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Wegmans Nature - Grain Free - Turkey & Pea - Natural Dog Food
Product Type: Pet Food
Lot Number:
UPC: 077890439036
Package Type: BAG
Package Size: 4 Pound
Purchase Date: 09/13/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: Top of bag was rolled down and secured with tape
Product Use Information:
Description: Food was fed to dog in a bowl by itself
Last Exposure Date: 09/14/2018
Perceived Relatedness to Adverse Event: Possibly related
Manufacturer /Distributor Information:
Purchase Location Information:
Name: Wegmans
Address: B6
 United States

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Shepherd Dog - Australian
Gender: Male
Reproductive Status: Neutered
Weight: 29.5 Kilogram
Age: 13 Years

	Assessment of Prior Health:	Unknown		
	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		
	Contact:	Name:	B6	
		Phone:	B6	
		Email:	B6	
	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:	B6	
Permission To Contact Sender:	Yes			
Preferred Method Of Contact:	Phone			
Additional Documents:	Attachment:	B6	pdf	
	Description:	History from B6 9/14/18		
	Type:	Medical Records		
	Attachment:	B6	Report and ECG B6 pdf	
	Description:	Echocardiogram report and ECG from B6 9/12/18		
	Type:	Medical Records		
	Attachment:	Echo Data B6 pdf		
	Description:	Echocardiogram Data from 9/12/18		
	Type:	Echocardiogram		
	Attachment:	B6	pdf	
	Description:	History from primary care veterinarian		

Report Details - EON-379288

ICSR:	2062471
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-10 21:18:15 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	<p>[B6] had continual vomiting throughout the day on [B6] [B6] was taken to the veterinarian and had blood work, abdominal and thoracic x-rays, which revealed an enlarged heart. He was taken to an emergency clinic later that evening, where an ultrasound of the heart was performed. No evidence of pericardial effusion was observed. We returned to the veterinarian on January 30th, 2019 for an echo cardiogram and EKG by a board certified cardiologist. A diagnosis of dilated cardiomyopathy was received. [B6] was fed grain free Acana pork/squash alternating with grain free Acana lamb/lentil for 3 1/2 years. We then fed Fromm grain free lamb and lentil from March 30, 2018- September 7, 2018 when we changed to Holistic Select chicken. Our cardiologist recommended Purina Pro Plan. On February 10, 2019 we started feeding [B6] Purina Pro Plan Focus.</p>	
	Date Problem Started:	01/29/2019	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Unknown	

Product Information:	Product Name:	Acana Pork and Squash and Lamb and Apple - both Grain free.		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	03/01/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	sealed container		
	Product Use Information:	Description:	4 cups per day	
		First Exposure Date:	03/02/2018	
		Last Exposure Date:	03/30/2018	
		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:		No		
Manufacturer /Distributor Information:				
Purchase Location				

	Information:	Name: Address:	<div style="border: 1px dashed black; padding: 5px; text-align: center;"> <h1 style="margin: 0;">B6</h1> </div>	
		United States		
Animal Information:	Name:	<div style="border: 1px dashed black; padding: 2px;"> B6 </div>		
		Type Of Species:	Dog	
		Type Of Breed:	Retriever - Golden	
		Gender:	Male	
		Reproductive Status:	Neutered	
		Weight:	65 Pound	
		Age:	5.5 Years	
		Assessment of Prior Health:	Excellent	
		Number of Animals Given the Product:	1	
		Number of Animals Reacted:	1	
		Owner Information:		
		Healthcare Professional Information:		
Sender Information:	Name:			
		Address:	<div style="border: 1px dashed black; padding: 10px;"> <h1 style="margin: 0;">B6</h1> </div>	
		United States		
		Contact:	Phone:	
				<div style="border: 1px dashed black; padding: 2px;"> B6 </div>
		Email:		
		Permission To Contact Sender:	Yes	
		Preferred Method Of Contact:	Email	
		Reported to Other Parties:	Store/Place of Purchase	
Additional Documents:				

Report Details - EON-379247			
ICSR:	2062464		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-02-09 23:45:11 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Dog was asymptomatic but had been on a grain free diet for over 3 years. Dogs blood was tested by her local veterinarian and found to have elevated N-proBNP. Referred to cardiologist for workup. Echocardiogram revealed moderate diet mediated dilated cardiomyopathy.	
	Date Problem Started:	11/20/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	Product Name:	Castor and Pollux Pristine Grain Free Grass Fed Lamb and Lentil Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	4 Pound	
	Purchase Date:	10/01/2018	
	Number Purchased:	4	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In original bag or in a sealed plastic container.	
	Product Use Information:	Description:	Fed to my dog.
		Last Exposure Date:	11/29/2018
		Time Interval between Product Use and Adverse Event:	3 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	No
Product Use Started Again:		No	
Perceived Relatedness to Adverse Event:		Probably related	
Other Foods or Products Given to the Animal During This Time Period:		Yes	
Manufacturer /Distributor Information:			
Purchase Location	Name:	Petco	

	Information:	Address:	B6
			United States
Product Name:	Castor and Pollux Organix Grain Free Chicken and Sweet Potato Recipe Dry Dog Food		
Product Type:	Pet Food		
Lot Number:			
Package Type:	BAG		
Package Size:	4 Pound		
Purchase Date:	09/01/2015		
Number Purchased:	4		
Possess Unopened Product:	No		
Possess Opened Product:	No		
Storage Conditions:	Stored in closed bag or sealed plastic storage container.		
Product Use Information:	Description:	Dry dog food was fed daily to my dog.	
	First Exposure Date:	09/18/2015	
	Last Exposure Date:	11/20/2018	
	Time Interval between Product Use and Adverse Event:	3 Years	
	Product Use Stopped After the Onset of the Adverse Event:	Yes	
	Adverse Event Abate After Product Stop:	Unknown	
	Product Use Started Again:	No	
	Perceived Relatedness to Adverse Event:	Probably related	
	Other Foods or Products Given to the Animal During This Time Period:	Yes	
Manufacturer /Distributor Information:			
Purchase Location Information:	Name:	Petco	
	Address:	B6	
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd Dog - German	
	Gender:	Female	
	Reproductive Status:	Neutered	

	Weight: 85 Pound
	Age: 4 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
Healthcare Professional Information:	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Email: B6
	Address: B6
	United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 11/21/2018
	Permission to Release Records to FDA: Yes
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: Manufacturer	
Additional Documents:	

Report Details - EON-379227

ICSR:	2062460			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)			
Reporting Type:	Voluntary			
Report Submission Date:	2019-02-09 15:04:09 EST			
Reporter is the Animal Owner:	Yes			
Reported Problem:	Problem Description:	I started feeding my dog grain free food about a year prior to him getting sick. In May of 2018, he was diagnosed with heart disease/enlarged heart. The vet could not explain it. In July 2018, I read the NY Times article about a link between grain free food and heart problems in dogs. There was also a segment on TV (60 minutes?) at the same time. My dog, B6 is now on 3 different medications for this issue.		
	Date Problem Started:	05/23/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Worse/Declining/Deteriorating		
Product Information:	Product Name:	Heath Extension Grain Free Dog Food		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	i don't have one	
		Expiration Date:	08/06/2018	
	Package Type:	BAG		
	Package Size:	4 Pound		
	Purchase Date:	03/01/2018		
	Number Purchased:	3		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	in original bag, inside a rubbermaid container		
	Product Use Information:	Description:	1/4 cup, twice-a-day	
		First Exposure Date:	04/05/2018	
		Last Exposure Date:	07/31/2018	
		Time Interval between Product Use and Adverse Event:	15 Months	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	No	
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Definitely related		
Manufacturer /Distributor Information:				

	Purchase Location Information:	Name: Chewy.com
		Address: United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Maltese
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	10 Pound
	Age:	12 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact:	B6
	Phone:	
	Email:	
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Store/Place of Purchase Other
Additional Documents:		

Report Details - EON-379277

ICSR:	2062468
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-10 17:58:28 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	<p>B6 seemed fine but over the course of about 6 months, she started to seem less active, had bursts of energy and then tired. Cough when she laid down. Her breathing seemed erratic. I took her to the vet in November, 2018, December of 2018 and they didn't think anything was wrong. Then she was giving me a hard time to eat and they thought she might have had stomach ulcers from the meds. She took antacid type meds over the christmas holiday with no change only worse. Beginning of January they did an ultrasound of her stomach and detected fluid in her chest and an enlarged heart. We took her to a veterinary cardiologist on January 8 and he diagnosed DCM and told us to discontinue the Costco Natures Domain Salmon and sweet potato dog food and began her on heart meds. Her condition was too far gone. Her left ventricle was only working at 14% capacity. There was no chance for improvement so we put her down.</p>	
	Date Problem Started:	09/02/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Died Euthanized	
	Date of Death:	B6	

Product Information:	Product Name:	Natures Domain Salmon Meal and Sweet Potato		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	35 Pound		
	Purchase Date:	09/02/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Air tight container		
	Product Use Information:	Description:	One cup twice a day for approximately 10 years	
		First Exposure Date:	09/02/2018	
		Last Exposure Date:	01/09/2019	
Time Interval between Product Use and Adverse Event:		10 Years		
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		No		

		Product Use Started Again:	
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name: Costco Wholesale,	B6
		Address: B6	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	68 Pound	
	Age:	13 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	
		Address:	B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	01/08/2019
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		
	Address:	B6	
		United States	
	Contact: Phone:	B6	
	Email:		
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	

	Reported to Other Parties:	Store/Place of Purchase
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Additional Documents:	
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Report Details - EON-379164

ICSR:	2062435
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-08 17:19:40 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	For about a week we noticed that our Dog, B6 developed a slight cough that was only noticeable in the morning until the evening of B6 our B6 started having rapid shallow breathing with respirations over 100 per minute at times. We took him to the Vet in the morning where they immediately heard his irregular heartbeat and sent us right over to an emergency vet with a cardiologist on staff. B6 had echocardiogram, X-ray, EKG and blood work and it was determined that he has Dilated Cardiomyopathy. Our B6 now has to take 5 medications twice a day for the rest of his life. Both Vets mentioned that there is a link between the grain free dog food and DCM, you can imagine how heartbroken I am thinking that I have caused this by providing him, what I thought was a healthy choice in dog food. He has been on several types over the years but mostly Natures Recipe grain free Salmon and Pumpkin
	Date Problem Started:	02/06/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Natures Recipe Grain Free Salmon, Sweet Potatoe and Pumpkin		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Purchase Date:	02/04/2019		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Storage Conditions:	In the bag it was bought in with top rolled up		
	Product Use Information:	Description:	I provided each dog with one cup in the morning and one cup Olay dinner time.	
		Last Exposure Date:	02/07/2019	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Unknown	
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:		Yes		
Manufacturer /Distributor Information:				

	Purchase Location Information:	Name:	B6		
		Address:	United States		
Animal Information:	Name:	B6			
	Type Of Species:	Dog			
	Type Of Breed:	Shepherd (unspecified)			
	Gender:	Male			
	Reproductive Status:	Neutered			
	Weight:	67 Pound			
	Age:	11 Years			
	Assessment of Prior Health:	Excellent			
	Number of Animals Given the Product:	2			
	Number of Animals Reacted:	1			
	Owner Information:				
	Healthcare Professional Information:	Practice Name:	B6		
		Contact:	Name:	B6	
			Phone:		
Address:		B6			
		United States			
Type of Veterinarian:		Primary/regular veterinarian			
Date First Seen:		02/07/2019			
Permission to Release Records to FDA:		Yes			
Practice Name:		B6			
Contact:		Name:	B6		
		Phone:			
Address:		B6			
		United States			
Type of Veterinarian:		Referred veterinarian			
Date First Seen:	02/07/2019				
Permission to Release Records to FDA:	Yes				
Sender Information:	Name:	B6			
	Address:	B6			
		United States			
	Contact:	Phone:	B6		
Email:					
Reporter Wants to Remain Anonymous:	No				
Permission To Contact	Yes				

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

Additional Documents:

Report Details - EON-379243

ICSR: 2062463
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2019-02-09 21:10:39 EST
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: B6 consumed grain free food for 5 years. He started collapsing and was taken to the vet. Vet confirmed DCM. Health deteriorated from diagnosis date and we lost B6 to stage IV heart failure 3 months after diagnosis.
Date Problem Started: 08/09/2018
Concurrent Medical Problem: No
Outcome to Date: Died Euthanized
Date of Death: B6

Product Information:
Product Name: Pro Pac Ultimates Grain Free Dog Food. Overland Red variety.
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 40 Pound
Purchase Date: 10/08/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Stored in open area of the business. After purchase, it was stored in an air-tight container.
Product Use Information:
Description: Fed 2 cups, twice daily.
Time Interval between Product Use and Adverse Event: 5 Years
Product Use Stopped After the Onset of the Adverse Event: Yes
Adverse Event Abate After Product Stop: No
Product Use Started Again: No
Perceived Relatedness to Adverse Event: Definitely related
Other Foods or Products Given to the Animal During This Time Period: No
Manufacturer /Distributor Information:
Purchase Location Information: Name: B6

		Address: B6 United States	
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd Dog - German	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	100 Pound	
	Age:	7 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	3	
	Number of Animals Reacted:	2	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
Phone:		B6	
Address:		B6 United States	
Type of Veterinarian:		Referred veterinarian	
Date First Seen:		08/19/2018	
Permission to Release Records to FDA:		Yes	
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact: Phone:	B6	
	Email:	B6	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	Other Store/Place of Purchase		
Additional Documents:			

Report Details - EON-379283

ICSR:	2062470		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date:	2019-02-10 19:57:39 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Taste of the Wild Pacific Stream & Buffalo customer for the past 10 + years, and feeding Prey Angus Beef 8 months (due to digestive problems for about 3 years). Dec 3rd we took our dog to the vet for coughing/hacking. We live in a rural area in B6 His heart was extremely enlarged with Dilated Cardiomyopathy & Congestive Heart failure. Dr. visits plus many heart medications and 2 months later, he finally saw the traveling heart specialist for a full cardio work up. This is not a genetic disposition. With \$3000 in medical, a change of diet since Dec 3rd and heart medication/supplements his heart is beginning to heal and his digestive issues do not exist anymore.	
	Date Problem Started:	11/22/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	Product Name:	Taste of the Wild PREY Angus Beef Limited Ingredient Formula for Dogs 4/2018-12/2018 Taste of Wild Pacific Stream Canine Recipe with Smoked Salmon a grain Free Diet 05/2009-4/2018	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	in a sealed dog food bin	
	Product Use Information:	Description:	our dog received 2 cups am & pm or 1 cup 4 times daily with lukewarm water We switched from Taste of the Wild Pacific Stream to PREY Angus Beef in April 2018 and he was fed 9 bags during April-December 2018
		First Exposure Date:	05/10/2009
		Last Exposure Date:	12/10/2018
		Time Interval between Product Use and Adverse Event:	9 Years
		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:		Definitely related	

Other Foods or Products Given to the Animal During This Time Period: No

Manufacturer /Distributor Information:

Purchase Location Information:

Name:

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Other Canine/dog

Gender: Male

Reproductive Status: Neutered

Weight: 90 Pound

Age: 9 Years

Assessment of Prior Health: Fair

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional Information:

Practice Name:

B6

Contact:

Name:

Phone:

Other Phone:

Email:

B6

Address:

B6

Type of Veterinarian: Referred veterinarian

Date First Seen: 12/04/2018

Permission to Release Records to FDA: Yes

Sender Information:

Name:

Address:

B6

United States

Contact:

Phone:

Other Phone:

Email:

B6

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Reported to Other: Manufacturer

Parties:

Additional Documents:

Report Details - EON-379291

ICSR:	2062472
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-02-11 00:14:42 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	<p>B6 was eating Zignature Lamb Limited Ingredient diet because of his allergies. He died on B6 when his heart stopped without notice. Just prior to dying he went outside, then came in to eat dinner. He fell down and passed. We took him to his primary veterinary clinic, B6 in B6. B6 He was already dead. I requested an autopsy, but was told that I would have to drive him to the B6 myself to get it done. That was not possible. I have since become aware of issues that others have had with this food.</p>	
	Date Problem Started:	B6	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	<p>B6 and took B6. He did not have heart problems prior to eating this food.</p>	
	Outcome to Date:	Died Other	
	Date of Death:	B6	

Product Information:	Product Name:	Zignature Lamb Formula		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	6M05P08062N	
		Expiration Date:	06/05/2018	
		Lot Number:	8E07P15401	
		Expiration Date:	11/05/2019	
		Lot Number:	8E29P12111	
		Expiration Date:	11/27/2019	
	UPC:	8864113106		
	Package Type:	BAG		
	Package Size:	27 Pound		
	Purchase Date:	08/01/2017		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Product Use Information:			
Manufacturer /Distributor Information:	Name:	Zignature/Pets Global Inc.		
	Type(s):	Manufacturer		
	Address:	28334 Industry Dr Valencia California 91355 United States		
	Contact:	Phone:	(888) 897-7207	
		Web Address:	Zignature.com	
		Possess One or More Labels from	Yes	

		This Product:	
	Purchase Location Information:	Name:	B6
		Address:	
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Terrier - Bull	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	75 Pound	
	Age:	8 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name:
			B6
			Phone:
			Other Phone:
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	B6
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:		
			United States
	Contact:	Phone:	B6
		Other Phone:	
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Store/Place of Purchase	
Additional Documents:	Attachment:	image.jpg	
	Description:	Container label.	

Type: Photograph

Report Details - EON-379292

ICSR:	2062473
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-02-11 00:28:31 EST
Initial Report Date:	02/11/2019
Reporter is the Animal Owner:	Yes
Parent ICSR:	2062472
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	<p>B6 was eating Zignature Lamb Limited Ingredient diet because of his allergies. He died on B6 when his heart stopped without notice. Just prior to dying he went outside, then came in to eat dinner. He fell down and passed. We took him to his primary veterinary clinic, B6 in B6. B6 He was already dead. I requested an autopsy, but was told that I would have to drive him to the B6 myself to get it done. That was not possible. I have since become aware of issues that others have had with this food.</p>	
	Date Problem Started:	B6	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	<p>B6 and took B6. He did not have heart problems prior to eating this food.</p>	
	Outcome to Date:	Died Other	
	Date of Death:	B6	

Product Information:	Product Name:	Zignature Lamb Formula		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	6M05P08062N	
		Expiration Date:	06/05/2018	
		Lot Number:	8E07P15401	
		Expiration Date:	11/05/2019	
		Lot Number:	8E29P12111	
		Expiration Date:	11/27/2019	
	UPC:	8864113106		
	Package Type:	BAG		
	Package Size:	27 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
Storage Conditions:	stored inside in a sealed container.			
Product Use Information:	Description:	Fed 2 1/2 cups per day for approximately 1 year.		
	First Exposure Date:	08/01/2017		
	Last Exposure Date:	B6		
	Time Interval between Product Use and Adverse Event:	1 Years		

		Product Use Stopped After the Onset of the Adverse Event:	No	
		Perceived Relatedness to Adverse Event:	Definitely related	
Manufacturer /Distributor Information:	Name:	Zignature/Pets Global Inc.		
	Type(s):	Manufacturer		
	Address:	28334 Industry Dr Valencia California 91355 United States		
	Contact:	Phone:	(888) 897-7207	
		Web Address:	Zignature.com	
	Possess One or More Labels from This Product:	Yes		
Purchase Location Information:	Name:	B6		
	Address:			United States
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Terrier - Bull		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	75 Pound		
	Age:	8 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	2		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
Phone:				
Other Phone:				
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:	B6			
Permission to Release Records to FDA:	Yes			

Sender Information:	Name:	B6	
	Address:		
		United States	
	Contact:	Phone:	B6
		Other Phone:	
		Email:	
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Reported to Other Parties:	Store/Place of Purchase		

Additional Documents:

Report Details - EON-372099		
ICSR:	2059326	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-11-27 18:17:48 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: I tested for low taurine levels because of the discussions about it. I had switched the dog to grain free diet. Acana Freshwater fish due to sensitive stomach. Test showed low taurine level. Took to Cardiologist for Echo and showed mild DCM. No symptoms from the dog yet. Breed had done genetic testing on dog before I got him and he was cleared of DCM.	
	Date Problem Started: 09/28/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: Acana Heritage Freshwater Fish	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 26 Pound	
	Purchase Date: 09/07/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: In a plastic dog food container stored in a closet	
	Product Use Information:	Description: Dog was fed 2/3 cup twice a day
		Last Exposure Date: 11/01/2018
		Other Foods or Products Given to the Animal During This Time Period: No
Manufacturer /Distributor Information:		
Purchase Location Information:	Name: PetFlow.com	
	Address: United States	
Animal Information:	Name:	
	Type Of Species: Dog	
	Type Of Breed: Schnauzer (unspecified)	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 39 Pound	
	Age: 3.5 Years	
	Assessment of Prior Health: Excellent	
Number of Animals Given the Product: 2		

	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	Practice Name: B6
		Contact: Name: B6 Phone: B6
		Address: B6 United States
		Type of Veterinarian: Primary/regular veterinarian
Sender Information:	Name:	B6
	Address:	B6 United States
	Contact: Phone:	B6
	Email:	B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	Other
Additional Documents:		

Report Details - EON-374145

ICSR:	2060281
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-12-17 20:39:03 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	After years of eating grain-free products with peas as a main ingredient, our dog was diagnosed with a heart murmur that got progressively worse over 2-3 years and he is being euthanized B6 due to congestive heart failure. He was not born with a heart murmur and always had good, normal checkups until the heart murmur arose around age 7 or 8.
	Date Problem Started:	04/05/2016
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Purina Beyond Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	Description:	Started using this food after Purina Beneful Grain Free became unavailable in September 2018.
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	Purina Beneful Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	Product Use Information:	Description:	Given daily for multiple years
		Product Use Stopped After the Onset of the Adverse Event:	No
		Perceived Relatedness to Adverse Event:	Probably related
	Manufacturer /Distributor Information:		
	Purchase Location Information:		

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Terrier (unspecified)
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	18 Pound
	Age:	10 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals	1

	Reacted:	
	Owner Information:	
	Healthcare Professional Information:	Contact: Name: B6
		Phone: B6
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:	None
Additional Documents:		

Report Details - EON-374108

ICSR:	2060252		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2018-12-17 14:11:47 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	2 year old Labrador has been diagnosed with Dilated Cardiomyopathy after showing signs of illness. Given the unusual nature of this condition in Labs and certainly labs of this age multiple vets including cardiology specialist believe the condition was caused by his food. He has been fed Taste of the Wild grain free since he was ~6mos old.	
	Date Problem Started:	12/02/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Unknown	
Product Information:	Product Name:	Taste of the Wild Pine Forest Canine Recipe With Venison and Legumes A Grain Free Diet	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	11/22/2018	
	Number Purchased:	1	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	No	
	Storage Conditions:	In a sealed dog food storage container	
	Product Use Information:	Description:	Feed twice daily
		First Exposure Date:	11/22/2018
		Last Exposure Date:	12/03/2018
		Time Interval between Product Use and Adverse Event:	18 Months
Product Use Stopped After the Onset of the Adverse Event:		Yes	
Perceived Relatedness to Adverse Event:		Definitely related	
Manufacturer /Distributor Information:			
Purchase Location Information:	Name:	chewy.com	
	Address:	B6 United States	
Animal Information:	Name:	B6 Dog	

	Type Of Species:		
	Type Of Breed:	Retriever - Labrador	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	78 Pound	
	Age:	2 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	
		Email:	
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	12/12/2018	
Permission to Release Records to FDA:	Yes		
Sender Information:	Name:		
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email		
Reported to Other Parties:	Store/Place of Purchase Other		
Additional Documents:			

Report Details - EON-378871

ICSR:	2062231
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-06 14:49:32 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	On 3/19/18 after I received his allergy test results, the test and our vet recommended a grain free food. One of the recommendations was Canidae brand food. I ordered the Canidae Grain Free Pure Wild Boar Limited Ingredient Dry Dog food, Canidae Grain Free Pure Foundations Puppy Formula with Chicken Canned Dog Food, as well as Canidae Grain free treats from Chewy on 3/19/18 and would have begun feeding it to him immediately upon arrival a day or so later. He developed a cough mid July, which we treated as kennel cough for 2 rounds of antibiotics. Of B6 I brought B6 to the ER vet as I knew in my heart something more was wrong and he was diagnosed with heart failure. I have the chest Xrays as well as follow up echocardiograms that show this. While meds have pulled him back from heart failure, he still has Dilated Cardiomyopathy. Several vets have suggested the Canidae food was the cause.
	Date Problem Started:	07/11/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6 was having food allergies and it was recommended to put him on a grain free food due to his allergy test showing he was allergic to some proteins and grains. His allergy results came to us 3/19/18.
	Outcome to Date:	Stable

Product Information:	Product Name:	Canidae Grain Free Pure Foundations Puppy Formula with Canned Chicken		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	CAN		
	Package Size:	12		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	the cans were only opened when he was being fed and he got the entire can		
	Product Use Information:	Description:	B6	was fed the canned dog food with the same brand dry dog food
		First Exposure Date:	03/21/2018	
		Last Exposure Date:	07/31/2018	
		Time Interval between Product Use and Adverse Event:	4 Months	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
Adverse Event Abate After Product Stop:		No		
Product Use Started Again:		No		

		Perceived Relatedness to Adverse Event:	Definitely related	
		Other Foods or Products Given to the Animal During This Time Period:	No	
	Manufacturer /Distributor Information:			
	Purchase Location Information:	Name:	Chewy.com	
	Product Name:	Canidae Grain-Free Pure Wild Boar Limited Ingredient Adult Dry Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	24 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Product Use Information:	First Exposure Date:	03/21/2018	
		Last Exposure Date:	07/31/2018	
		Time Interval between Product Use and Adverse Event:	4 Months	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	No	
		Product Use Started Again:	No	
		Perceived Relatedness to Adverse Event:	Definitely related	
		Other Foods or Products Given to the Animal During This Time Period:	No	
		Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Chewy.com	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Foxhound - American		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	190 Pound		
	Age:	10 Years		
	Assessment of Prior	Good		

	Health:	
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	Name:	B6
	Address:	United States
	Contact:	Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None

Additional Documents:

Report Details - EON-378903	
ICSR:	2062253
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-02-06 18:31:22 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: Before the family left the house he was acting energetic, running and jumping as normal. After returning home three hours later, he was moving very slowly, would normally be excited to go outside and eat dinner, which he was not excited at all. Went out doors very slowly, attempted to go to the bathroom, barely made it up the 6 stairs back onto the deck and collapsed once he entered back into the house. He was still breathing, but unresponsive, no eye movement and mouth was foaming. After trying to wake him back up and shaking him, we immediately called the emergency vet hospital as this was a Sunday evening and our regular vet office was closed. The initial check out by the Dr. reported that he had a heart arrhythmia and an enlarged heart, as well as a very high heart rate. We retraced everything for the day and know that he had not ingested anything that was not given to him or would harm him. That office set him up with an IV pic line so that he was ready for treatment once we arrived at the second vet hospital. They treated him and monitored him over night and was scheduled to be seen by the cardiologist. The Dr. called the next morning to give the details she observed and asked what type of diet we feed him, as they are starting to see linked cases with these symptoms. It turns out that the GRAIN FREE dry dog food diet that we had chosen as what was best for our dogs is what has led us to this point and caused all of these health issues. He is now on two heart medications to help with his irregular heart beat and strengthen his heart and two vitamin supplements to help with both issues as well. It has been a very heart wrenching, exhausting, disappointing and upsetting week since the issue started.
	Date Problem Started: 01/27/2019
	Concurrent Medical Problem: No
	Outcome to Date: Stable
Product Information:	Product Name: Taste of the Wild Pacific Stream
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Package Size: 30 Pound
	Purchase Date: 01/22/2019
	Number Purchased: 1
	Possess Unopened Product: No
	Possess Opened Product: Yes
	Storage Conditions: Before- in unopened bag After- in medium metal pail with lid
Product Use Information:	Description: 1 1/2 cups twice per day
	First Exposure Date: 01/22/2019
	Last Exposure Date: 01/27/2019
	Time Interval between Product Use and Adverse Event: 7 Years
	Product Use Stopped After the Yes

		Onset of the Adverse Event:	
		Adverse Event Abate After Product Stop:	No
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Labrador	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	70 Pound	
	Age:	7 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	
		Address:	B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	01/27/2019
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:		
		United States	

	Contact: Phone:	B6
	Email:	
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
Reported to Other Parties:	Other	
Additional Documents:		

Report Details - EON-379071

ICSR:	2062336
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-07 18:49:52 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was diagnosed in September 2017 with DCM and end stage heart failure. Previously she did not have even a heart murmur. She died B6 from DCM and end stage heart failure. 2 months after she died our other dog B6 was diagnosed with DCM and heart failure. This was on 1/23/2018. B6 was listed as terminal a few months later. He also ate the same food for most of his adult life. B6 is 1 year older than B6 is now 8 years of age) Both dogs were completely different breeds and were not related. 12/31/2018 after about 6 months from (I believe we changed his food end of May or early June) changing B6 diet and taking him off the grain free food, he has improved. Our cardiologist and primary vet will be submitting a report as well. B6 heart has significantly decreased in size. He is now listed as "very well controlled CHF". We have images and echocardiogram results to show his decline and then improvement once his diet was changed.
	Date Problem Started:	09/17/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	California Naturals Grain Free Venison and Sweet Potato with Lentils		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	10/01/2017		
	Number Purchased:	5		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	The food was stored in it's original bag in a pantry.		
	Product Use Information:	Description:	Dogs were fed orally	
		Last Exposure Date:	B6	
		Time Interval between Product Use and Adverse Event:	6 Years	
		Product Use Stopped After the Onset of the Adverse Event:	No	
		Perceived Relatedness to Adverse Event:	Definitely related	
Other Foods or Products Given		Yes		

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Mixed (Dog)

Gender: Female

Reproductive Status: Neutered

Weight: 45 Pound

Age: 6 Years

Assessment of Prior
Health: Good

Number of Animals
Given the Product: 2

Number of Animals
Reacted: 2

Owner Information:

Healthcare Professional
Information:

Practice Name:

B6

Contact:

Name:

B6

Phone:

Address:

B6

United States

Type of
Veterinarian: Primary/regular veterinarian

Date First Seen: 11/22/2017

Permission to
Release Records
to FDA: Yes

Practice Name:

B6

Contact:

Name:

B6

Phone:

Address:

B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: 09/17/2017

Permission to
Release Records
to FDA: Yes

Sender Information:

Name:

Address:

B6

United States

	Contact:	Phone:	B6	
		Email:		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Phone		
Reported to Other Parties:	Manufacturer Other			

Additional Documents:

Attachment:	B6	krays.jpg
Description:	The photo on your right is the first image taken when diagnosed. The photo on your left is 1 year later from diagnosis and approximately 6 months after discontinuing grain free diet.	
Type:	Other	
Attachment:	B6	df
Description:	Medical Records	
Type:	Medical Records	
Attachment:	B6	df
Description:	Medical Records	
Type:	Medical Records	

Report Details - EON-379084

ICSR:	2062349		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-02-08 05:01:04 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Dog started coughing and couldnt walk. Took him to the ER and he was diagnosed with Dilated Cardiomyopathy. Almost 2 years ago, at time of removal, he had X-rays and ultrasound done and his heart was healthy. This is exactly the time I switched his food to grain-free Orijen Six Fish. B6	
	Date Problem Started:	01/07/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Worse/Declining/Deteriorating	
Product Information:	Product Name:	Orijen Six Fish	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	25 Pound	
	Storage Conditions:	Airtight dog food container	
	Product Use Information:	Description:	Fed to dog
		First Exposure Date:	05/01/2017
		Last Exposure Date:	01/07/2019
		Time Interval between Product Use and Adverse Event:	20 Months
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Not Applicable
		Product Use Started Again:	No
Perceived Relatedness to Adverse Event:		Definitely related	
Other Foods or Products Given to the Animal During This Time Period:		Unknown	
Manufacturer /Distributor Information:			
Purchase Location Information:			
Animal Information:	Name:	B6	

	Type Of Species: Dog
	Type Of Breed: Bulldog - American
	Gender: Male
	Reproductive Status: Neutered
	Weight: 95 Pound
	Age: 11 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
Healthcare Professional Information:	Contact: Name: B6
	Phone: B6
	Address: B6
	Type of Veterinarian: Referred veterinarian
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: None
Additional Documents:	

Report Details - EON-379142		Print	[-]	
ICSR:	2062420			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.RFR.V.V2			
Reporting Type:	Voluntary			
Applicable Dates:	Report Submission Date:	2019-02-08 14:35:55 EST [-]		
	Date the article of food was determined to be a Reportable Food:	07/12/2018		
	Date Notified:	07/12/2018		
Product Intentionally Adulterated:	No			
Additional Documents:	No			
Reason for this reportable food (agent):	Other [-]			
	Please describe other:	Possible cause of Dilated Cardiomyopathy		
Reported Problem:	Problem Description:	Initial FDA report linking possible cause of DCM linked to certain foods. This canine B6 was diagnosed with Dilated Cardiomyopathy on 6/12/17. She was being fed a suspect ingredient high in legume ingredients. [-]		
	How did you first learn about the Reportable Food?	Notified by Federal, state, tribal, local, or other competent authority		
	Please specify authority:	FDA Report		
	What corrective actions have been taken to prevent future occurrences?	None that I am aware of		
	Root cause:	Unknown		
	To the best of your knowledge, has all of the reportable food been removed from commerce?	No		
	Animal Information:	[-]		
			Animal Species food intended for	Lifestage of animal food intended for
	Blue Wilderness:	Dog	Adult	
Locations:	Location Information [-]			
	Type of Site:	Sender	Food Facility Site	
	FDA Districts Impacted:	B6	CIN	
	Organization Name:		Champion Petfoods Dogstar Kitchen	
	Address:		12871 Bowling Green Road	
Auburn				
Kentucky				
	42206	United States		
	United States	United States		

	Contact Name: Phone: Email: Organization Type:	<div style="border: 1px dashed black; padding: 10px; font-size: 2em; font-weight: bold;">B6</div>	Manufacturing Plant unknown unknown (270) 542-5300 customercare@championpetfoods.com Manufacturer																		
Product(s):	<table border="1" style="width: 100%;"> <tr> <td data-bbox="422 370 682 435"> P Product Name: </td> <td data-bbox="682 370 1466 435"> Blue Wilderness [-] Generate One Page Notification </td> </tr> <tr> <td data-bbox="422 435 682 478"> Product Type: </td> <td data-bbox="682 435 1466 478"> Pet Food </td> </tr> <tr> <td data-bbox="422 478 682 521"> Product Commodity: </td> <td data-bbox="682 478 1466 521"> Animal Feed/Pet Food </td> </tr> <tr> <td data-bbox="422 521 682 564"> Intended Use Code: </td> <td data-bbox="682 521 1466 564"> Animal </td> </tr> <tr> <td data-bbox="422 564 682 620"> Product Distribution Type: </td> <td data-bbox="682 564 1466 620"></td> </tr> <tr> <td data-bbox="422 620 682 664"> Reason for the Recall: </td> <td data-bbox="682 620 1466 664"> Other </td> </tr> <tr> <td data-bbox="422 664 682 728"> Was the product recalled? </td> <td data-bbox="682 664 1466 728"> No </td> </tr> <tr> <td data-bbox="422 728 682 814"> Did you receive the reportable food from an outside source? </td> <td data-bbox="682 728 1466 814"> Unknown At This Time </td> </tr> <tr> <td colspan="2" data-bbox="422 814 1466 858" style="text-align: right;"> Go to the top of the page </td></tr> </table>			P Product Name:	Blue Wilderness [-] Generate One Page Notification	Product Type:	Pet Food	Product Commodity:	Animal Feed/Pet Food	Intended Use Code:	Animal	Product Distribution Type:		Reason for the Recall:	Other	Was the product recalled?	No	Did you receive the reportable food from an outside source?	Unknown At This Time	Go to the top of the page	
P Product Name:	Blue Wilderness [-] Generate One Page Notification																				
Product Type:	Pet Food																				
Product Commodity:	Animal Feed/Pet Food																				
Intended Use Code:	Animal																				
Product Distribution Type:																					
Reason for the Recall:	Other																				
Was the product recalled?	No																				
Did you receive the reportable food from an outside source?	Unknown At This Time																				
Go to the top of the page																					
Adverse Event Data:	<table border="1" style="width: 100%;"> <tr> <td data-bbox="422 866 682 931"> Human Symptoms Present Indicator: </td> <td data-bbox="682 866 1466 931"> No [-] </td> </tr> <tr> <td data-bbox="422 931 682 996"> Animal Symptoms Present Indicator: </td> <td data-bbox="682 931 1466 996"> Yes </td> </tr> <tr> <td data-bbox="422 996 682 1246"> Description of Animal Adverse Events: </td> <td data-bbox="682 996 1466 1246"> There is severe global cardiac dilation and severe generalized hypokinesia consistent with dilated cardiomyopathy (r/o idiopathic vs. tachycardia-induced). There is mild mitral valve thickening with low velocity mitral regurgitation. Pulmonary arterial pressures appear marginally elevated. There is moderate to severe abdominal effusion and scant pleural effusion. No pericardial effusion was observed. Diagnosis: Rapid atrial fibrillation Dilated cardiomyopathy - r/o idiopathic vs. tachycardia-induced Congestive heart failure (abdominal and pleural effusion) </td> </tr> </table>			Human Symptoms Present Indicator:	No [-]	Animal Symptoms Present Indicator:	Yes	Description of Animal Adverse Events:	There is severe global cardiac dilation and severe generalized hypokinesia consistent with dilated cardiomyopathy (r/o idiopathic vs. tachycardia-induced). There is mild mitral valve thickening with low velocity mitral regurgitation. Pulmonary arterial pressures appear marginally elevated. There is moderate to severe abdominal effusion and scant pleural effusion. No pericardial effusion was observed. Diagnosis: Rapid atrial fibrillation Dilated cardiomyopathy - r/o idiopathic vs. tachycardia-induced Congestive heart failure (abdominal and pleural effusion)												
Human Symptoms Present Indicator:	No [-]																				
Animal Symptoms Present Indicator:	Yes																				
Description of Animal Adverse Events:	There is severe global cardiac dilation and severe generalized hypokinesia consistent with dilated cardiomyopathy (r/o idiopathic vs. tachycardia-induced). There is mild mitral valve thickening with low velocity mitral regurgitation. Pulmonary arterial pressures appear marginally elevated. There is moderate to severe abdominal effusion and scant pleural effusion. No pericardial effusion was observed. Diagnosis: Rapid atrial fibrillation Dilated cardiomyopathy - r/o idiopathic vs. tachycardia-induced Congestive heart failure (abdominal and pleural effusion)																				

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Report Details - EON-380036		
ICSR:	2062789	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-02-18 12:23:48 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Dog was diagnosed with mild dilated cardiomyopathy by echocardiogram on January 28, 2019. In his lifetime he's been fed: Taste of the Wild High Prairie (about 15 months) Blue Buffalo of unknown type (about 3 months) Wellness Core (original and Ocean) (about 18 year) Acana Single (mackerel or pork) mixed with either the wellness core or Orijen six fish. He is currently being treated under care of a cardiologist with taurine and L-carnitine supplementation.	
	Date Problem Started: 01/28/2019	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6	
	Outcome to Date: Stable	
Product Information:	Product Name: Acana Heritage Freshwater Fish Formula Grain Free Dry Dog Food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 25 Pound	
	Purchase Date: 12/02/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: in sealed vittles vault.	
	Product Use Information:	Description: fed, mixed as stated in previous answer.
		First Exposure Date: 12/11/2018
		Last Exposure Date: 12/25/2018
		Product Use Stopped After the Onset of the Adverse Event: Yes
Adverse Event Abate After Product Stop: Unknown		
Product Use Started Again: No		
Perceived Relatedness to Adverse Event: Probably related		
Other Foods or Products Given to the Animal During This Time Period: Yes		
Manufacturer:		

	/Distributor Information: Purchase Location Information:	Name: Address:	<div style="border: 1px dashed black; padding: 10px; text-align: center; font-size: 2em; font-weight: bold;">B6</div> United States
Animal Information:	Name: Type Of Species: Type Of Breed: Gender: Reproductive Status: Weight: Age: Assessment of Prior Health: Number of Animals Given the Product: Number of Animals Reacted: Owner Information:	<div style="border: 1px dashed black; padding: 2px; text-align: center; font-weight: bold;">B6</div> Dog Retriever - Golden Male Neutered 84 Pound 4 Years Good 2 1	Healthcare Professional Information: Practice Name: Contact: Name: Phone: Type of Veterinarian: Permission to Release Records to FDA:
Sender Information:	Name: Address:	<div style="border: 1px dashed black; padding: 10px; text-align: center; font-size: 2em; font-weight: bold;">B6</div> United States	Contact: Phone: Email: Reporter Wants to Remain Anonymous: Permission To Contact Sender: Preferred Method Of Contact: Reported to Other Parties:
Additional Documents:	Attachment: Description: Type:	<div style="border: 1px dashed black; padding: 2px; text-align: center; font-weight: bold;">B6</div> <div style="border: 1px dashed black; padding: 2px; text-align: center; font-weight: bold;">B6</div> Echocardiogram	Cardio 1-28-19.pdf cardiology report

Report Details - EON-379897

ICSR:	2062755		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-02-15 19:00:10 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	My dog collapsed. I rushed to Vet where an echocardiogram was done and dog was diagnosed with DCM.	
	Date Problem Started:	06/11/2017	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Merrick turkey and sweet potato	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	06/05/2017	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In a sealed glass canister and in the bag inside a metal container in kitchen	
	Product Use Information:	Description:	Fed to dog daily
		First Exposure Date:	06/11/2017
		Last Exposure Date:	10/02/2017
		Time Interval between Product Use and Adverse Event:	6 Months
		Product Use Stopped After the Onset of the Adverse Event:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
Manufacturer /Distributor Information:			
Purchase Location Information:	Name:	B6	
	Address:	B6	

			B6 United States
Product Name:	Acana whitefish and sweet potato		
Product Type:	Pet Food		
Lot Number:			
Package Type:	BAG		
Package Size:	25 Pound		
Purchase Date:	06/01/2017		
Possess Unopened Product:	No		
Possess Opened Product:	No		
Storage Conditions:	Stored in the bag in metal container in my kitchen and in a sealed glass canister jar.		
Product Use Information:	Description:	Food was feed to dog on daily basis.	
	First Exposure Date:	06/11/2017	
	Last Exposure Date:	06/20/2017	
	Time Interval between Product Use and Adverse Event:	6 Years	
	Product Use Stopped After the Onset of the Adverse Event:	Yes	
	Adverse Event Abate After Product Stop:	Unknown	
	Product Use Started Again:	No	
	Perceived Relatedness to Adverse Event:	Definitely related	
	Other Foods or Products Given to the Animal During This Time Period:	Yes	
	Manufacturer /Distributor Information:		
Purchase Location Information:	Name:	B6	
	Address:		
		United States	
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Labrador	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	70 Pound	
	Age:	6 Years	
	Assessment of Prior Health:	Excellent	

	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	Name:	
	Address:	B6
		United States
	Contact:	
	Phone:	B6
	Email:	
	Reporter Wants to Remain Anonymous:	No
Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Phone	
Reported to Other Parties:	None	

Additional Documents:

Report Details - EON-379857	
ICSR:	2062737
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-15 12:03:58 EST
Reported Problem:	Problem Description: [B6] a 5 Yrs. 0 Mos., Neutered Male, Schnauzer, Giant, owned by [B6] was presented through Emergency Services or [B6] for cardiac evaluation. [B6] has a history of GI upset. Today he was admitted through Dr. [B6] for vomiting, lethargy, soft stools/diarrhea. Scant abdominal effusion was noted on [B6]. An arrhythmia was noted on exam and an echocardiogram and ECG were recommended. He is fed Blue Buffalo (possibly grain-free) ECG: Atrial fibrillation with average heart rate of 140-160 bpm. There is generalized cardiac chamber enlargement and severe LV hypokinesis consistent with dilated cardiomyopathy. There is mild to moderate low velocity mitral regurgitation. There is mild tricuspid regurgitation with normal velocities. All cardiac valves appear normal. Diagnosis: Dilated cardiomyopathy, Atrial fibrillation
	Date Problem Started: [B6]
	Concurrent Medical Problem: Unknown
	Outcome to Date: Better/Improved/Recovering
Product Information:	Product Name: Blue Buffalo (owner believes was a grain free variety)
	Product Type: Pet Food
	Lot Number:
	Product Use Information:
	Manufacturer /Distributor Information:
	Purchase Location Information:
Animal Information:	Name: [B6]
	Type Of Species: Dog
	Type Of Breed: Schnauzer - Giant
	Gender: Male
	Reproductive Status: Neutered
	Weight: 50 Kilogram
	Age: 5 Years
	Assessment of Prior Health: Good
	Number of Animals Reacted: 1
	Owner Information: Owner Information provided: No
	Healthcare Professional Information:
Practice Name: [B6]	
Contact: Name: [B6]	
Phone: [B6]	
Type of Veterinarian: Primary/regular veterinarian	
Sender Information:	Name:
	Address: [B6]

		B6	
		United States	
	Contact:	Phone:	B6
		Email:	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
	Reported to Other Parties:	None	

Additional Documents:

Report Details - EON-379855

ICSR: 2062734
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-02-15 11:52:04 EST

Reported Problem:
Problem Description: B6 a 5 Yrs. 4 Mos., Male, Retriever, Labrador, owned by B6 was presented on 11/13/2018 for cardiac evaluation. B6 was presented to Emergency Services on Friday through B6 was presented for evaluation of congestive heart failure. B6 was noted to have increased respiratory effort at the end of October. He was diagnosed with congestive heart failure. He has recently had a decreased appetite, although he will eat when the owners cook for him. He is currently on B6 mg once daily and B6 mg b.i.d. He was presented today due to decreasing appetite and abdominal distention. B6 evaluate B6 and increased his B6 B6 mg PO BID and started B6 mg PO AM, 15 mg PO PM. B6 ad 5400 mL of fluid drained from his abdomen on Friday. His owners have noted a clinical improvement since his medication adjustments and abdominocentesis. B6 was previously fed Victor grain free diet for life, but was recently switched to Purina Proplan. ECG: normal sinus rhythm with frequent ventricular ectopy of RV origin including ventricular couplets and one ventricular triplet average heart rate of 160 bpm. Diagnosis: Dilated cardiomyopathy leading to a ventricular arrhythmia and congestive heart failure

Date Problem Started: 11/09/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Victor Grain Free Dog Food (unknown variety)
Product Type: Pet Food
Lot Number:
Product Use Information: Perceived Relatedness to Adverse Event: Possibly related
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Retriever - Labrador
Gender: Male
Reproductive Status: Intact
Weight: 47 Kilogram
Age: 5 Years
Assessment of Prior Health: Good
Number of Animals Reacted: 1
Owner Information: Owner Information provided: No
Healthcare Professional Information: Practice Name: B6
 Contact: Name: B6
 Phone: B6

		Type of Veterinarian: Primary/regular veterinarian
Sender Information:	Name:	B6
	Address:	
	Contact:	Phone: B6
		Email:
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
Reported to Other Parties:	None	
Additional Documents:		

Report Details - EON-380888

ICSR:	2063224
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-26 14:08:33 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	We had an X ray done on B6 on 9-10-2018 due to a mild cough that had started within weeks of the appointment, no issues with his lungs but his heart was enlarged. An echocardiogram done by a veterinary cardiologist the next day (9-11-2018) confirmed that he had severe dilated cardiomyopathy. He had been eating Earthborn Meadow Feast Grain Free dry kibble for the past 6 years, since he was transitioned off of puppy food at around 1 year old. They noted severe damage to his heart, aside from medication, he was given a diet change to Royal Canin Early Cardiac and a taurine test was done. Taurine levels from UC Davis came back within normal range. He was also given taurine supplements and L-carnitine along with B6 . We were told the prognosis was very poor. We had a follow-up echocardiogram 3 months after the diet change on 12-11-2018. B6 showed very minor improvement in the overall chamber size and wall thickness and the ability of his heart to constrict. They determined that this is dietary DCM due to the minor improvement at the 3 month echocardiogram after being taken off the grain free Earthborn Meadow Feast kibble. He is still extremely sick and we have been told that he has at the very most 6 to 18 (with a miracle) months from the time of diagnosis in September 2018.
	Date Problem Started:	09/10/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Earthborn Holistic Grain Free Meadow Feast with Lamb Meal		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	14 Pound		
	Purchase Date:	07/01/2012		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	It was stored in a sealed bag in a dry corner of the garage with smaller quantities moved into a plastic, sealed-lid dispenser in our kitchen after the bag was opened. The remaining food in the bag (once opened) was stored (resealed with the zipper) in the same dry area of the garage off the floor.		
	Product Use Information:	Description:	Dog was fed dry kibble in a bowl at mealtimes - two to three times a day. We started feeding this food to him in July of 2012 and stopped it on 9/10/2018.	
		First Exposure Date:	07/01/2012	
Last Exposure Date:		09/10/2018		
Time Interval		6 Years		

between Product Use and Adverse Event:	
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:	Definitely related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:

Purchase Location Information:

Name:	B6
Address:	
	United States

Animal Information:

Name:	B6	
Type Of Species:	Dog	
Type Of Breed:	Terrier - Welsh	
Gender:	Male	
Reproductive Status:	Neutered	
Weight:	22.4 Pound	
Age:	7.5 Years	
Assessment of Prior Health:	Excellent	
Number of Animals Given the Product:	1	
Number of Animals Reacted:	1	
Owner Information:		
Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6 Phone: B6 Email: B6
	Address:	B6
		United States
	Type of Veterinarian:	Primary/regular veterinarian
	Date First Seen:	09/10/2018
	Permission to Release Records to FDA:	Yes

Sender Information:

	Name:	B6	
	Address:		
		United States	
	Contact:	Phone:	B6
		Email:	
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Reported to Other Parties:	Other		

Additional Documents:

Report Details - EON-380879

ICSR:	2063206		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-02-26 10:07:35 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	I had B6 whole blood taurine levels checked after learning she was eating a suspect diet. Her level came bac B6 which is of concern in whippets. I scheduled echocardiograms for both her and my younger whippet. My younger whippet is fine B6 results are that she has mild to moderate enlargement of the left atrial chamber. Her cardiologist said he does not expect enlargement from her mitral valve jets which are trivial (previously diagnosed). He is concerned that the enlargement is caused by her diet. We are waiting 6 months now that she is on ProPlan and will recheck her.	
	Date Problem Started:	02/25/2019	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Stella and Chewy's Surf and Turf Patties	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	2 Pound	
	Purchase Date:	01/01/2019	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	No	
	Storage Conditions:	in original packaging	
	Product Use Information:	Description:	Used as a food topper, 1/2 patty a day.
		First Exposure Date:	01/01/2019
		Last Exposure Date:	01/16/2019
		Time Interval between Product Use and Adverse Event:	4 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:		Unknown	
Product Use Started Again:		No	
Perceived Relatedness to Adverse Event:		Possibly related	
Other Foods or Products Given		Yes	

to the Animal
During This Time
Period:

**Manufacturer
/Distributor Information:**

**Purchase Location
Information:** Name: Chewy.com

Product Name: Honest Kitchen Keen

Product Type: Pet Food

Lot Number:

Package Type: BOX

Package Size: 10 Pound

Purchase Date: 01/01/2019

Number Purchased: 1

**Possess Unopened
Product:** Yes

**Possess Opened
Product:** No

Storage Conditions: In original packaging.

**Product Use
Information:**

Description: Fed as 50% of her diet, 1/2 cup reconstituted with water in the PM.

**First Exposure
Date:** 01/01/2019

**Last Exposure
Date:** 01/16/2019

**Time Interval
between Product
Use and Adverse
Event:** 4 Years

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

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

**Product Use
Started Again:** No

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

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

**Manufacturer
/Distributor Information:**

**Purchase Location
Information:** Name: Amazon

Product Name: Fromm Duck and Sweet Potato

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 15 Pound

Purchase Date: 01/01/2019

**Possess Unopened
Product:** No

	Possess Opened Product:	No																		
	Storage Conditions:	Stored in an airtight kibble container.																		
	Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>Fed as 50% of her diet, 2/3 cup in the am.</td> </tr> <tr> <td>First Exposure Date:</td> <td>01/01/2019</td> </tr> <tr> <td>Last Exposure Date:</td> <td>01/16/2019</td> </tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>4 Years</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Yes</td> </tr> <tr> <td>Adverse Event Abate After Product Stop:</td> <td>Unknown</td> </tr> <tr> <td>Product Use Started Again:</td> <td>No</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	Fed as 50% of her diet, 2/3 cup in the am.	First Exposure Date:	01/01/2019	Last Exposure Date:	01/16/2019	Time Interval between Product Use and Adverse Event:	4 Years	Product Use Stopped After the Onset of the Adverse Event:	Yes	Adverse Event Abate After Product Stop:	Unknown	Product Use Started Again:	No	Perceived Relatedness to Adverse Event:	Probably related	Other Foods or Products Given to the Animal During This Time Period:	Yes
Description:	Fed as 50% of her diet, 2/3 cup in the am.																			
First Exposure Date:	01/01/2019																			
Last Exposure Date:	01/16/2019																			
Time Interval between Product Use and Adverse Event:	4 Years																			
Product Use Stopped After the Onset of the Adverse Event:	Yes																			
Adverse Event Abate After Product Stop:	Unknown																			
Product Use Started Again:	No																			
Perceived Relatedness to Adverse Event:	Probably related																			
Other Foods or Products Given to the Animal During This Time Period:	Yes																			
	Manufacturer /Distributor Information:																			
	Purchase Location Information:	<table border="1"> <tr> <td>Name:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Name:		Address:	B6		United States												
Name:																				
Address:	B6																			
	United States																			
Animal Information:	Name:	B6																		
	Type Of Species:	Dog																		
	Type Of Breed:	Whippet																		
	Gender:	Female																		
	Reproductive Status:	Neutered																		
	Weight:	32 Pound																		
	Age:	4 Years																		
	Assessment of Prior Health:	Excellent																		
	Number of Animals Given the Product:	2																		
	Number of Animals Reacted:	1																		
	Owner Information:																			
	Healthcare Professional Information:																			
Sender Information:	Name:																			
	Address:	B6																		

		B6
		United States
	Contact:	Phone:
		B6
		Email:
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None

Additional Documents:

Report Details - EON-380865	
ICSR:	2063199
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-02-26 08:02:25 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: First notable health issue occurred Aug 2018. Seizure event displayed rigid limbs, excessive drool, panting and labored breathing, and collapse. The symptoms worsened with violent head thrashing, foaming, and rolled eyes. Canine was rushed to vet hospital and upon arrival (approx. 15mins later) all symptoms had ceased. Canine was given a full evaluation and no further testing was requested by owner. In Feb 2019 coughing returned and persisted. Canine was seen by regular vet. No fluid in lungs so it was thought to be bronchitis and prescribed cough syrup and B6. Coughing did not improve after 1 week and returned to vet. Chest film showed fluid surrounding heart and it was recommended to see a cardio specialist. 4 days after canine was in severe labored breathing, distress, and displaying worsened signs of weakness. Canine was taken to vet ER hospital and admitted for cardiac and respiratory failure condition. Treatment of oxygen, meds, and preliminary EKG indicated condition worsened to fluid around heart and in lungs. Drainage of 1 liter of fluid. Full evaluation include echocardiogram and lab analysis. Officially diagnosed with DCM. Discussed with owner and determined likely cause was grain free diet recommended from breeder and the only diet for canine since birth.
	Date Problem Started: 08/01/2018
	Date of Recovery: 02/26/2019
	Concurrent Medical Problem: No
	Outcome to Date: Better/Improved/Recovering
Product Information:	Product Name: Wellness CORE Grain Free Wild Game Duck, Turkey, Boar & Rabbit Recipe Dry Dog Food, 26-lb bag
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Package Size: 26 Pound
	Possess Unopened Product: No
	Possess Opened Product: Yes
	Storage Conditions: Stored in original package in a sealed Tupperware container.
	Product Use Information:
	Description: Given per recommendations on package label for dog weight, mixed with approx. 0.5cup of water. Also offered dry.
Time Interval between Product Use and Adverse Event: 1 Days	
Product Use Stopped After the Onset of the Adverse Event: Yes	
Adverse Event Abate After Product Stop: No	
Product Use Started Again: Yes	
ReIntroduction: 2 Days	

	<p>Waiting Period:</p> <p>Adverse Event Reappear After Reintroduction: Yes</p> <p>Perceived Relatedness to Adverse Event: Definitely related</p> <p>Other Foods or Products Given to the Animal During This Time Period: Yes</p>
	<p>Manufacturer /Distributor Information:</p> <p>Purchase Location Information: Name: Chewy.com Address: United States</p>
Animal Information:	<p>Name: B6</p> <p>Type Of Species: Dog</p> <p>Type Of Breed: Weimaraner</p> <p>Gender: Male</p> <p>Reproductive Status: Neutered</p> <p>Weight: 98 Pound</p> <p>Age: 4.5 Years</p> <p>Assessment of Prior Health: Excellent</p> <p>Number of Animals Given the Product: 1</p> <p>Number of Animals Reacted: 1</p> <p>Owner Information:</p> <p>Healthcare Professional Information: Practice Name: B6 Contact: Name: B6 Phone: B6 Address: B6 United States Type of Veterinarian: Referred veterinarian Date First Seen: 02/25/2019 Permission to Release Records to FDA: Yes</p>
Sender Information:	<p>Name:</p> <p>Address: B6 United States</p> <p>Contact:</p> <p>Reporter Wants to Remain Anonymous: Yes</p> <p>Reported to Other Parties: None</p>
Additional Documents:	

Report Details - EON-380882

ICSR:	2063213
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-26 11:55:43 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	In April 2016 (easter weekend) he started coughing periodically. At first I thought he had kennel cough. by Sunday night he could barely breathe. we brought him to the ER where he was diagnosed with late stage DCM. Being Great Danes are predisposed to DCM our regular vet suggested we speak with our breeder. In our breeders 20+ years of breeding she has never lost a Dane to DCM. In fact all of B6 brothers and sisters are still alive at 8 years old. The vet had mentioned this could be Diet related and suggested we see a Cardiologist. Unfortunately B6 passed away in our arms on B6 before he was able to see a cardiologist. He was on B6 of medications during the last 6 weeks of his life.
	Date Problem Started:	04/12/2016
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Died Other
	Date of Death:	B6

Product Information:	Product Name:	Zignature Trout and Salmon Meal	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	27 Pound	
	Purchase Date:	04/01/2016	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	The product was stored on the shelf at the store. Once home with the product we put it in a plastic container to keep it fresh. He went through 27lb every two-ish weeks. Will not allow me to enter the correct dates. My great dane was feed this product over 4 years. It can take years for DCM to develop. Entered wrong dates but here are the correct dates. Last purchase date: 04/29/2016 Date product was first given: 11/10/2012 Date last feed was: B6	
	Product Use Information:	Description:	He ate 6 cups of dry dog food a day out of his elevated food bowl.
		First Exposure Date:	04/05/2016
		Last Exposure Date:	B6
Time Interval between Product Use and Adverse Event:		4 Years	
Product Use Stopped After the Onset of the Adverse Event:		No	

		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Great Dane	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	145 Pound	
	Age:	5 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	3	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	B6
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	04/12/2016
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:		
			United States
	Contact: Phone:	B6	
	Email:		
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	

	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other

Additional Documents:

Report Details - EON-382577

ICSR:	2064141
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-03-17 09:55:28 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I took my 9 month old English Bulldog into our local veterinary clinic to discuss getting him neutered. Doctor listened to his heart to make sure he was good for the surgery and said he heard different breathing. Stated that his breathing was strong when he was in for his puppy vaccines a few months ago. Took an X-ray of his chest and said he has an enlarged heart (12.2 to be exact). Referred to me to see a cardiologist to get an echo done on him. I contacted the breeders which have zero heart reports. A member of the AKC registered Bulldog page that Im friends with on FB informed me about the Blue Buffalo grain free puppy food causing heart disease. This is the food Ive fed my pup since I took him home at 12 wks.
	Date Problem Started:	03/13/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Blue Buffalo puppy grain free		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	35 Pound		
	Purchase Date:	08/01/2018		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	In a large Rubbermaid.		
	Product Use Information:	Description:	Given as per food daily	
		First Exposure Date:	08/01/2018	
		Last Exposure Date:	03/17/2019	
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:	No			
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	Pet smart		
	Address:	<div style="border: 1px dashed black; padding: 5px; display: inline-block;"> B6 United States </div>		

Animal Information:	Name:	B6
	Type Of Species:	Dog

	Type Of Breed: Bulldog
	Gender: Male
	Reproductive Status: Intact
	Weight: 35 Pound
	Age: 9 Months
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
Healthcare Professional Information:	Practice Name: B6
	Contact: Name: B6 Phone: B6
	Address: B6 United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 03/13/2019
	Permission to Release Records to FDA: Yes
	Sender Information:
	Name: B6 Address:
Contact: Email: B6	
Reporter Wants to Remain Anonymous: No	
Permission To Contact Sender: Yes	
Preferred Method Of Contact: Email	
Reported to Other Parties: Unknown	

Additional Documents:

Report Details - EON-382566	
ICSR:	2064140
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-03-17 00:43:35 EDT
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: Our dog was a healthy almost 8 year lab with never any health problems who went into congestive heart failure. Took her to ER and diagnosed her with dilated cardiomyopathy. She is on lots of medications now and very sick. Up until her diagnosis we have only fed her a grain-free diet.
	Date Problem Started: 10/25/2018
	Concurrent Medical Problem: No
	Outcome to Date: Worse/Declining/Deteriorating
Product Information:	Product Name: Don't remember names of food but always boutique, grain-free food
	Product Type: Pet Food
	Lot Number:
	Product Use Information: Description: She only ate high-end boutique grain-free food. NEVER any people food.
	Manufacturer /Distributor Information:
	Purchase Location Information:
Animal Information:	Name: B6
	Type Of Species: Dog
	Type Of Breed: Retriever - Labrador
	Gender: Female
	Reproductive Status: Neutered
	Weight: 75 Pound
	Age: 8 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
	Healthcare Professional Information:
Sender Information:	Name: B6
	Address: B6
	United States
	Contact: Phone: B6
	Email: B6
	Reporter Wants to Remain Anonymous: No
Permission To Contact Sender: Yes	

	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None

Additional Documents:

Report Details - EON-382580

ICSR: 2064142
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-03-17 10:46:04 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: We found an enlarged heart on Radiographs. Echo confirmed large left ventricle and mitral valve insufficiency. Taurine results of Plasma [B6] and Whole Blood: [B6]
Date Problem Started: 01/25/2019
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Earthborn Coastal Catch
Product Type: Pet Food
Lot Number:
Package Type: BAG
Purchase Date: 02/01/2015
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Product kept in bag.
Product Use Information:
Description: Dog was fed Earthborn Coastal Catch twice a day for the first three years of his life.
First Exposure Date: 02/01/2015
Last Exposure Date: 02/01/2018
Time Interval between Product Use and Adverse Event: 3 Years
Product Use Stopped After the Onset of the Adverse Event: Yes
Perceived Relatedness to Adverse Event: Probably related
Other Foods or Products Given to the Animal During This Time Period: No
Manufacturer /Distributor Information:
Purchase Location Information: Address: [B6] United States

Animal Information:
Name: [B6]
Type Of Species: Dog
Type Of Breed: Retriever - Golden

	Gender: Male
	Reproductive Status: Intact
	Weight: 75 Pound
	Age: 3 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
Healthcare Professional Information:	Practice Name: B6
	Contact: Name:
	Phone: B6
	Address: B6
	United States
	Type of Veterinarian: Referred veterinarian
	Date First Seen: 02/05/2019
	Permission to Release Records to FDA: No
Sender Information:	Name:
	Address: B6
	United States
	Contact: Phone: B6
	Email:
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Phone
	Reported to Other Parties: None
Additional Documents:	

Report Details - EON-382503

ICSR:	2064075
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-03-15 16:46:13 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dog is diagnosed with early Nutritional Dilated Cardiomyopathy. B6 was given an echocardiogram at a health clinic and the Veterinary Cardiologist saw mild systolic dysfunction. We then went to a veterinary specialty cardiologist for a full work up. She was given another echocardiogram, and blood work was done to test for Taurine and also Thyroid. Her whole blood Taurine was low B6 and her plasma Taurine was marginal B6. Several other possibilities were ruled out and the final diagnosis was early Nutritional Dilated Cardiomyopathy. B6 has been on grain free diets ever since puppyhood. The last three years she was eating either air-dried raw beef (ZiwiPeak) or freeze-dried raw beef (Stella & Chewy's).
	Date Problem Started:	12/06/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Stella & Chewy's Freeze-Dried Raw Super Beef Dinner Patties		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	180625PRO006046	
		Expiration Date:	08/25/2019	
	UPC:	8601100045		
	Package Type:	BAG		
	Package Size:	25 Ounce		
	Purchase Date:	11/01/2018		
	Number Purchased:	3		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	Yes		
	Storage Conditions:	The product was stored on the counter in it's original zip lock plastic bag.		
	Product Use Information:	Description:	At meal times, twice a day, I would break up 6 of the patties into small pieces and add water to cover the pieces and let it soak for 5 minutes. When all the pieces were softened, I would feed it to my dog.	
		First Exposure Date:	11/01/2018	
Last Exposure Date:		12/06/2018		
Time Interval between Product Use and Adverse Event:		6 Months		
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		Unknown		

		Product Use Started Again:	No	
		Perceived Relatedness to Adverse Event:	Probably related	
		Other Foods or Products Given to the Animal During This Time Period:	Yes	
	Manufacturer /Distributor Information:	Name:	Stella & Chewy's	
		Type(s):	Manufacturer	
		Address:	111 West Oakview Parkway Oak Creek Wisconsin 53154 United States	
		Contact:	Phone:	(888) 477-8977
			Web Address:	www.StellaAndChewys.com
		Possess One or More Labels from This Product:	Yes	
	Purchase Location Information:	Name:	B6	
		Address:		United States
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Portuguese Water Dog		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	44 Pound		
	Age:	5.5 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
Address:		B6		
		United States		
Type of Veterinarian:		Referred veterinarian		
Date First Seen:	12/06/2018			
Permission to Release Records	Yes			

		to FDA:	
		Practice Name:	B6
		Contact:	Name: B6 Phone: B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	11/28/2018
		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	DCM Vet Report.pdf
	Description:	This is the report from the veterinary cardiologist.	
	Type:	Medical Records	
	Attachment:	B6	urine Results.pdf
	Description:	Lab report with taurine relsts.	
	Type:	Laboratory Report	

Report Details - EON-368405

ICSR:	2056029
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-10-15 11:47:22 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Adopted B6 at 18 months old. I noticed through the summer that she did not tolerate exercise well. When we adopted her, she was eating Farmina N&D pumpkin for onemeal and raw for the other. We transitioned her to Kirkland Nature's Domain Salmon and Sweet Potato. She was quite itchy on this, so we put her on Kirkland Organic Chicken and Pea. Her exercise intolerance became increasingly apparent. A ECG was run and came back as tall R waves. Radiographs came back with mildly enlarged heart. At this time, I began supplementing with 250mg taurine supplement BID. An echocardiogram was scheduled, the results of which was moderate to marked left ventricular dilation with mild mitral regurgitation and mild right ventricular dilation with no tricuspid regurgitation. No taurine testing was done as she had been receiving taurine supplementation.
	Date Problem Started:	05/16/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	Kirkland Organic Chicken and Pea		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	08/30/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in bag inside an airtight plastic container		
	Product Use Information:	Description:	One cup in stainless steel bowl BID	
		Last Exposure Date:	09/24/2018	
		Product Use Stopped After the Onset of the Adverse Event:	Unknown	
		Perceived Relatedness to Adverse Event:	Possibly related	
Other Foods or Products Given to the Animal During This Time Period:		Yes		
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	Costco		
	Address:	B6		

B6

United States

Product Name:	Kirkland Natures Domain Salmon and Sweet Potato	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Package Size:	35 Pound	
Purchase Date:	04/16/2018	
Number Purchased:	1	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Storage Conditions:	Kept in bag inside an airtight plastic container	
Product Use Information:	Description:	B6 was given 1 cup am and pm, dry in a stainless steel bowl
	Product Use Stopped After the Onset of the Adverse Event:	Unknown
	Perceived Relatedness to Adverse Event:	Possibly related
	Other Foods or Products Given to the Animal During This Time Period:	No
Manufacturer /Distributor Information:		
Purchase Location Information:	Name:	Costco
	Address:	B6 United States

Product Name:	Farmina N&D Pumpkin Formula Medium and Maxi	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Package Size:	26.4 Pound	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Storage Conditions:	Product was stored in bag inside and airtight plastic container.	
Product Use Information:	Description:	One cup of kibble in warm water in the morning, raw ground meat in warm water in the evening
	Last Exposure Date:	06/01/2018
	Product Use Stopped After the Onset of the Adverse Event:	Unknown
	Perceived Relatedness to Adverse Event:	Possibly related
	Other Foods or	Yes

		Products Given to the Animal During This Time Period:		
	Manufacturer /Distributor Information:			
	Purchase Location Information:	Address:	United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Shepherd Dog - Australian		
	Gender:	Female		
	Reproductive Status:	Intact		
	Pregnancy Status:	Not Pregnant		
	Lactation Status:	Not lactating		
	Age:	20 Months		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
Phone:				
Email:				
Address:		B6		
		United States		
Type of Veterinarian:		Referred veterinarian		
Date First Seen:	09/24/2018			
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:	None			
Additional Documents:	Attachment:	B6 Initial Cardiology Report.pdf		
	Description:	Initial Cardiology Report		

Report Details - EON-368453

ICSR:	2056048
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-10-15 17:01:25 EDT

Reported Problem:	Problem Description:	B6 has been fed a grain free diet since he was a puppy. He has been a happy, healthy dog until recently, when after a trip to B6 he started showing signs of exercise intolerance and cough and a diagnostic workup revealed an enlarged heart on radiographs. He was referred for an echocardiogram. He takes Heartgard monthly, Nexguard if needed.
	Date Problem Started:	09/03/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Not Applicable

Product Information:	Product Name:	Merrick Chunky Carver's Delight Dinner Grain Free Recipe		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	2280828297		
	Package Type:	CAN		
	Package Size:	12.7 Ounce		
	Purchase Date:	09/01/2018		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	No		
	Storage Conditions:	unknown		
	Product Use Information:	Description:	Fed as supplement to dry food	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Unknown	
		Product Use Started Again:	No	
		Perceived Relatedness to Adverse Event:	Possibly related	
Other Foods or Products Given to the Animal During This Time Period:		Yes		
Manufacturer /Distributor Information:				
Purchase Location Information:				
Product Name:	Taste of the Wild Prey Trout Limited Ingredient Formula			
Product Type:	Pet Food			
Lot Number:				
Package Type:	BAG			
Possess Unopened	No			

	Product:																			
	Possess Opened Product:	Yes																		
	Storage Conditions:	Unknown																		
	Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>Fed 2 cups in AM, 1 & 1/2 cup in PM</td> </tr> <tr> <td>First Exposure Date:</td> <td>09/29/2014</td> </tr> <tr> <td>Last Exposure Date:</td> <td>09/27/2018</td> </tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>4 Years</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Yes</td> </tr> <tr> <td>Adverse Event Abate After Product Stop:</td> <td>Unknown</td> </tr> <tr> <td>Product Use Started Again:</td> <td>No</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Definitely related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	Fed 2 cups in AM, 1 & 1/2 cup in PM	First Exposure Date:	09/29/2014	Last Exposure Date:	09/27/2018	Time Interval between Product Use and Adverse Event:	4 Years	Product Use Stopped After the Onset of the Adverse Event:	Yes	Adverse Event Abate After Product Stop:	Unknown	Product Use Started Again:	No	Perceived Relatedness to Adverse Event:	Definitely related	Other Foods or Products Given to the Animal During This Time Period:	Yes
Description:	Fed 2 cups in AM, 1 & 1/2 cup in PM																			
First Exposure Date:	09/29/2014																			
Last Exposure Date:	09/27/2018																			
Time Interval between Product Use and Adverse Event:	4 Years																			
Product Use Stopped After the Onset of the Adverse Event:	Yes																			
Adverse Event Abate After Product Stop:	Unknown																			
Product Use Started Again:	No																			
Perceived Relatedness to Adverse Event:	Definitely related																			
Other Foods or Products Given to the Animal During This Time Period:	Yes																			
	Manufacturer /Distributor Information:																			
	Purchase Location Information:																			
Animal Information:	Name:	B6																		
	Type Of Species:	Dog																		
	Type Of Breed:	Retriever - Golden																		
	Gender:	Male																		
	Reproductive Status:	Neutered																		
	Weight:	38.6 Kilogram																		
	Age:	4 Years																		
	Assessment of Prior Health:	Excellent																		
	Number of Animals Given the Product:	1																		
	Number of Animals Reacted:	1																		
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td> <table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	Owner Information provided:	Yes	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States						
Owner Information provided:	Yes																			
Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:																
Name:	B6																			
Phone:																				
Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States																	
B6																				
United States																				

Healthcare Professional Information:	Practice Name:	B6				
	Contact:	Name:	B6			
		Phone:	B6			
		Email:	B6			
	Address:	B6				
		United States				
	Type of Veterinarian:	Referred veterinarian				
Date First Seen:	09/25/2018					
Permission to Release Records to FDA:	Yes					
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:	None					
Additional Documents:	Attachment:	Echo report and data	B6	2018-09-25.pdf		
	Description:	Echo report				
	Type:	Echocardiogram				
	Attachment:	Rads	B6	2018-09-24.jpg		
	Description:	VD Radiograph				
	Type:	Radiographs				
	Attachment:	Rads (RLatThora)	B6	2018-09-24.jpg		
	Description:	Right lateral radiograph				
	Type:	Radiographs				
	Attachment:	openGeneratedFile.php.pdf				
	Description:	Initial cardiac appointment summary				
	Type:	Medical Records				
	Attachment:	Hx	B6	2018-09-25 to 2018-09-13;	B6	1).pdf
	Description:	primary care vet history medical records				
	Type:	Medical Records				

Report Details - EON-370347

ICSR: 2058477
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-06 10:44:43 EST

Reported Problem:

Problem Description: B6 presented in December 2015 following multiple episodes of collapse, suspected to be syncope. He was diagnosed with dilated cardiomyopathy, and he was started on Taurine supplementation. A Holter monitor showed an occasional arrhythmia, and he was also started on B6. In April 2017, he was diagnosed with B6.

Date Problem Started: 12/08/2015
Date of Recovery: 05/02/2016
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:

Product Name: Merrick Back Country
Product Type: Pet Food
Lot Number:

Product Use Information:

Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	Unknown
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Possibly related
Other Foods or Products Given to the Animal During This Time Period:	No

Manufacturer /Distributor Information:
Purchase Location Information:

Product Name: Fromme Grain-Free
Product Type: Pet Food
Lot Number:

Product Use Information:

Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	No
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Probably related

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

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Bullmastiff

Gender: Male

Reproductive Status: Neutered

Weight: 52.4 Kilogram

Age: 9 Years

Assessment of Prior Health: Good

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information:

Owner Information provided: Yes

Contact:

Name: B6

Phone:

Email:

Address: B6

United States

Healthcare Professional Information:

Practice Name: B6

Contact:

Name: B6

Phone:

Email:

Address: B6

United States

Sender Information:

Name:

Address: B6

United States

Contact:

Phone:

Email: B6

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Reported to Other: None

Parties:

Additional Documents:

Attachment:

B6

Medical Records.pdf

Description:

B6

SOAPs, communications, labwork, echo reports, and Holter monitors

Type:

Medical Records

Report Details - EON-370249

ICSR: 2058418
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-05 12:37:19 EST

Reported Problem:

Problem Description: I do not have the previous 7 year medical record. The Pet presented to me for a second opinion. The Pet was taking **B6**. **B6** The Pet had a grade 3/6 systolic murmur, referring radiographs showed abdominal and plural effusion. The Pet was referred for an echocardiogram that showed the Pet had Dilated Cardiomyopathy. Upon questioning, the Pet has eaten a grain free diet it's entire life- Kirkland signature Nature's Domain Salmon meal and sweet potato- grain free all life stages.

Date Problem Started: 10/31/2018

Concurrent Medical Problem: No

Outcome to Date: Stable

Product Information:

Product Name: Kirkland Signature Nature's Domain Salmon meal and sweet potato - Grain free all life stages

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 18 Pound

Purchase Date: 09/01/2018

Number Purchased: 1

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Storage Conditions: unknown

Product Use Information:

Description: The pet has been eating this food it's entire life

Last Exposure Date: 11/01/2018

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

Adverse Event Abate After Product Stop: Unknown

Product Use Started Again: No

Perceived Relatedness to Adverse Event: Possibly related

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

Manufacturer /Distributor Information:

Purchase Location Information:

Name: Costco

Address: **B6**

		United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Bulldog
	Reproductive Status:	Neutered
	Weight:	60 Pound
	Age:	7 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: No
	Healthcare Professional Information:	Practice Name:
Contact:		Name: B6 Phone:
Type of Veterinarian:		Referred veterinarian
Date First Seen:		11/01/2018
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact:	Phone: B6 Email:
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
Reported to Other Parties:	Other	
Additional Documents:	Attachment:	B6 .pdf
	Description:	Ultrasound Report
	Type:	Echocardiogram

Report Details - EON-371308

ICSR:	2058977
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-11-16 18:55:34 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Attended a health clinic on 11/3/18 and did an echo cardiogram. Per the cardiologist: B6 is equivocal for DCM. She has been on a suspect (grain-free) diet. Taurine level report showed: B6 (plasma). Transitioning her off grain-free at the recommendation of the cardiologist and will redo the echo in 4-6 months.
	Date Problem Started:	11/03/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Unknown

Product Information:	Product Name:	Earthborn Holistic Great Mountain Feast w/Bison Meal
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	28 Pound
	Purchase Date:	04/30/2018
	Number Purchased:	4
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Stored in original bag inside covered plastic trash can in the basement.

Product Use Information:	Description:	Fed twice daily
	First Exposure Date:	05/01/2018
	Last Exposure Date:	11/03/2018
	Product Use Stopped After the Onset of the Adverse Event:	Yes
	Adverse Event Abate After Product Stop:	Unknown
	Product Use Started Again:	No
	Perceived Relatedness to Adverse Event:	Probably related
	Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:	
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	Purchase Location Information:	Name: Address:	<div style="border: 1px dashed black; padding: 10px; text-align: center;"> <h1>B6</h1> </div>	
		United States		
Animal Information:	Name:	<div style="border: 1px dashed black; padding: 5px;"> <h2>B6</h2> </div>		
		Type Of Species: Dog		
		Type Of Breed: Shepherd Dog - Belgian Tervueren		
		Gender: Female		
		Reproductive Status: Neutered		
		Weight: 48 Pound		
		Age: 3 Years		
		Assessment of Prior Health: Good		
		Number of Animals Given the Product: 1		
		Number of Animals Reacted: 1		
		Owner Information:		
		Healthcare Professional Information:	Practice Name:	<div style="border: 1px dashed black; padding: 5px;"> <h2>B6</h2> </div>
				Contact: Name:
				<div style="border: 1px dashed black; padding: 5px;"> <h2>B6</h2> </div>
				Phone:
				Address:
				<div style="border: 1px dashed black; padding: 10px;"> <h1>B6</h1> </div>
		United States		
		Type of Veterinarian: Primary/regular veterinarian		
		Date First Seen: 11/05/2018		
		Permission to Release Records to FDA: Yes		
		Practice Name:	<div style="border: 1px dashed black; padding: 5px;"> <h2>B6</h2> </div>	
				Contact: Name:
				<div style="border: 1px dashed black; padding: 10px;"> <h1>B6</h1> </div>
				Phone:
				Email:
				Address:
				<div style="border: 1px dashed black; padding: 10px;"> <h1>B6</h1> </div>
		United States		
		Type of Veterinarian: Referred veterinarian		
		Date First Seen: 11/03/2018		
		Permission to Release Records to FDA: Yes		
Sender Information:	Name:	<div style="border: 1px dashed black; padding: 10px;"> <h1>B6</h1> </div>		
		Address:	<div style="border: 1px dashed black; padding: 10px;"> <h1>B6</h1> </div>	
		United States		

	Contact:	Phone:	B6
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
	Reported to Other Parties:	Other	
Additional Documents:			

Report Details - EON-371311

ICSR:	2058978
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-11-16 20:08:17 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dog has received a low taurine blood test result. We will be conducting further diagnostic testing to determine the extent of the heart problems associated with this low test result.
	Date Problem Started:	10/21/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	Fromm Chicken a la veg and Fromm Duck and Sweet Potato		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	09/15/2018		
	Number Purchased:	2		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	No		
	Storage Conditions:	The dog food was stored in the bag in a closet.		
	Product Use Information:	Description:	The food was given to my dog twice per day.	
		First Exposure Date:	09/30/2018	
		Last Exposure Date:	10/15/2018	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
Adverse Event Abate After Product Stop:		Unknown		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:		Yes		

Manufacturer /Distributor Information:		
Purchase Location Information:	Name:	B6
	Address:	

			B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Corgi - Welsh Cardigan		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	25 Pound		
	Age:	5 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	3		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
Phone:				
Address:		B6		
		United States		
Type of Veterinarian:	Primary/regular veterinarian			
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6		
	Address:	B6		
		United States		
	Contact:	Phone:	B6	
		Email:	B6	
	Reporter Wants to Remain Anonymous:	No		
	Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email			
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-371365			
ICSR:	2058985		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2018-11-18 00:20:54 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Diagnosed with congestive heart failure after I took her to the vet following a day of continual coughing. Tests revealed CHV. She had previously been very healthy except for a slight heart murmur.	
	Date Problem Started:	09/13/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Worse/Declining/Deteriorating	
Product Information:	Product Name:	Orijen Senior Biologically Appropriate Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	6 kilogram	
	Purchase Date:	04/01/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in the original bag with a zip top closure	
	Product Use Information:	Description:	Free fed in a glass dish at home.
		First Exposure Date:	04/01/2018
		Last Exposure Date:	09/01/2018
		Time Interval between Product Use and Adverse Event:	2 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:		No	
Product Use Started Again:		No	
Perceived Relatedness to Adverse Event:		Probably related	
Other Foods or Products Given to the Animal During This Time Period:		Yes	
Manufacturer /Distributor Information:			

	Purchase Location Information:	Name: Address:	<div style="border: 1px dashed black; padding: 5px; text-align: center; font-size: 2em; font-weight: bold;">B6</div> <p>United States</p>
Animal Information:	Name: Type Of Species: Type Of Breed: Gender: Reproductive Status: Weight: Age: Assessment of Prior Health: Number of Animals Given the Product: Number of Animals Reacted: Owner Information: Healthcare Professional Information:	Name: B6 Dog Havanese Female Neutered 12 Pound 12 Years Good 1 1 Practice Name: B6 Contact: Name: unknown name Phone: B6 Address: <div style="border: 1px dashed black; padding: 5px; text-align: center; font-size: 2em; font-weight: bold;">B6</div> <p>United States</p> Type of Veterinarian: Primary/regular veterinarian Date First Seen: 08/24/2018 Permission to Release Records to FDA: Yes	
Sender Information:	Name: Address: Contact: Reporter Wants to Remain Anonymous: Permission To Contact Sender: Preferred Method Of Contact: Reported to Other Parties:	Name: B6 Address: United States Phone: Email: B6 No Yes Email None	
Additional Documents:	Attachment:	B6 food ingredients.jpg Description: list of ingredients in the Orijen Senior food, indicating the presence of assorted legumes Type: Product Label	

Report Details - EON-371371

ICSR: 2058989
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-18 08:46:49 EST

Reported Problem:

Problem Description: Was initially referred to **B6** or **B6** for lethargy and coughing. Was diagnosed with congestive heart failure secondary to severe dilated cardiomyopathy (DCM). Paired plasma and whole blood taurine levels were measured and were severely decreased (results attached). Was hospitalized for heart failure therapy and was discharged on **B6** with oral heart failure therapy and taurine supplementation. Returned to the hospital on **B6** for lethargy, anorexia, and intermittent increase in respiratory rate and effort. Was diagnosed with recurrent left-sided congestive heart failure and right sided heart failure at that time. In the hospital, was treated aggressively for heart failure therapy but continued to decline. Humane euthanasia was elected. The patient had been fed V-dog commercial diet for approximately 1 year. For the past 2 years or so, has been receiving a combination of Halo vegan commercial diet combined with home cooked peas/lentils.

Date Problem Started: **B6**

Concurrent Medical Problem: No

Outcome to Date: Died Euthanized

Date of Death: **B6**

Product Information:

Product Name: Halo Holistic Garden of Vegan Adult Dry Dog Food
Product Type: Pet Food
Lot Number:
Package Type: BAG

Product Use Information:

Description:	The owner has been feeding this product for the past 2 years (in addition to home-cooked lentils and peas)
Perceived Relatedness to Adverse Event:	Probably related

Manufacturer /Distributor Information:
Purchase Location Information:

Product Name: V-dog kinder kibble vegan adult dry dog food
Product Type: Pet Food
Lot Number:
Package Type: BAG

Product Use Information:

Description:	Fed to the pet for approximately 1 year (3 years ago), before switching to another vegan diet
Perceived Relatedness to Adverse Event:	Probably related

Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:

Name: **B6**

Type Of Species: Dog
Type Of Breed: Coton de Tuléar
Gender: Male

	Reproductive Status: Neutered
	Weight: 6 Kilogram
	Age: 5 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: [Redacted] B6
	Phone: [Redacted] B6
	Email: [Redacted] B6
	Address: [Redacted] B6
	United States
	Healthcare Professional Information:
	Practice Name: [Redacted] B6
	Contact: Name: [Redacted] B6
	Phone: [Redacted] B6
	Email: [Redacted] B6
	Address: [Redacted] B6
	United States
Sender Information:	Name: [Redacted] B6
	Address: [Redacted] B6
	United States
	Contact: Phone: [Redacted] B6
	Email: [Redacted] B6
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
	Reported to Other Parties: None
Additional Documents:	Attachment: [Redacted] B6 Discharge 2.pdf
	Description: Discharge summary from second hospitalization
	Type: Medical Records
	Attachment: [Redacted] B6 taurine level.pdf
	Description: Paired taurine levels
	Type: Laboratory Report
	Attachment: [Redacted] B6 Discharge 1.pdf
	Description: Discharge summary from first hospitalization
	Type: Medical Records

Attachment:	B6	radiology report 2 .pdf
Description:	Chest x-ray report from 2nd hospitalization, prior to euthanasia	
Type:	Medical Records	
Attachment:	B6	echo report.pdf
Description:	Echo report	
Type:	Echocardiogram	

Report Details - EON-371395			
ICSR:	2058997		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2018-11-18 21:39:23 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Was diagnosed on Nov. 16, 2018 by veterinary cardiologist with canine DCM believed to be caused by grain free food with kangaroo as protein source and legumes as large portion of the diet.	
	Date Problem Started:	10/22/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Zignature Kangaroo Limited Ingredient Formula Grain-Free Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	27 Pound	
	Purchase Date:	11/08/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Stored in unopened bag until needed. In the original bag in a metal can once opened. I'm not filling in the rest as this issue does not seem to be from a single use of a contaminated product.	
	Product Use Information:	Description:	Fed this product 2 times daily for a number of years (3?) as it helped with food sensitivity to chicken. Canine Dilated Cardiomyopathy diagnosed after a number of years on this product.
		Time Interval between Product Use and Adverse Event:	3 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Not Applicable
Product Use Started Again:		No	
Perceived Relatedness to Adverse Event:		Definitely related	
Other Foods or Products Given to the Animal During This Time Period:		No	
Manufacturer /Distributor Information:		Name: Pets Global, Inc	

		Type(s):	Manufacturer
		Contact:	
		Possess One or More Labels from This Product:	Yes
	Purchase Location Information:	Name:	Chewy.com
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Chesapeake Bay	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	83 Pound	
	Age:	7.5 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	B6
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	11/13/2018
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact: Name:	B6
		Phone:	B6
		Address:	B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	11/16/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6	
	Contact:	Email:	B6

	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None

Additional Documents:	Attachment:	B6 DCM diagnosis.pdf
	Description:	.pdf of notes from B6 DVM the veterinary cardiologist
	Type:	Medical Records

Report Details - EON-368875			
ICSR:	2056503		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2018-10-19 16:34:18 EDT		
Reported Problem:	Problem Description: No history of heart murmur or cardiac clinical signs. Presented for right cranial cruciate ligament rupture surgery - took thoracic radiographs as usual as pre-surgical requirement. Surprisingly, cardiomegaly noted on rads - VHS: B6 Echocardiogram reveals dilated left ventricle: LV diameter (d): B6 (normal <4.0 cm) LV diameter (s): B6 cm (normal <2.49 cm) O reports has given her grain-free Acana Light & Fit Kibble her whole life and still has no audible murmur. Given FDA warnings about grain-free food and DCM in breeds not predisposed to it - wanted to report this case in.		
	Date Problem Started: 10/11/2018		
	Concurrent Medical Problem: No		
	Outcome to Date: Stable		
Product Information:	Product Name: Acana Light & Fit Formula dog kibble 60% premium animal ingredients 40% vegetables, fruits, botanicals 0% grain, potato, glutens		
	Product Type: Pet Food		
	Lot Number:		
	Package Type: BAG		
	Product Use Information:		
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name: B6		
	Type Of Species: Dog		
	Type Of Breed: Retriever - Golden		
	Gender: Female		
	Reproductive Status: Neutered		
	Weight: 27.5 Kilogram		
	Assessment of Prior Health: Good		
	Number of Animals Given the Product: 1		
	Number of Animals Reacted: 1		
	Owner Information: <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td>Owner Information provided:</td> <td>No</td> </tr> </table>	Owner Information provided:	No
	Owner Information provided:	No	
Healthcare Professional Information:			
Sender Information:	Name:		
	Address: B6 Canada		
	Contact:		
	Reporter Wants to Remain Anonymous: Yes		
Reported to Other: Other			

Parties:

Additional Documents:

Report Details - EON-369738

ICSR:	2058222
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-10-30 13:27:20 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 started exhibiting difficulty breathing about a year ago, mostly after climbing stairs or walks. Recently he has been breathing heavily more often, now sometimes while lying still. He has also started coughing and has had a few fainting spells. We brought these concerns up to our vet who at first thought he might have Cushing's Disease. Blood tests and urine tests did not show the normal indications for that disease, plus B6 was not exhibiting some of the usual physical signs. An x-ray of his chest revealed a slightly enlarged heart. Along with his symptoms the vet suggested it might be DCM caused by his grain-free diet. He has been on a grain free diet since he was about a year old. Previously to feeding him Halo brand he was being fed Natural Balance Venison and Potato. We will be having a Taurine blood test done on him before we change anything to capture his current levels. We then plan on switching to a food with whole grains, adding a taurine supplement, and a heart medication.
	Date Problem Started:	09/01/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Halo Holistic Turkey, Turkey Liver & Duck Recipe Grain-Free Healthy Weight Adult Dry Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	745158390145		
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	10/22/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	Immediately upon receiving from Chewy.com the bag is opened and placed into a plastic tub with a cover.		
	Product Use Information:	Description:	Fed:	B6 2/3 cup 2 times a day
		Last Exposure Date:	10/30/2018	
		Time Interval between Product Use and Adverse Event:	3 Years	
Product Use Stopped After the Onset of the Adverse Event:		No		
Perceived Relatedness to Adverse Event:		Possibly related		
Other Foods or Products Given		Yes		

to the Animal
During This Time
Period:

**Manufacturer
/Distributor Information:**

Name: Halo, Purely for pets, inc.

Type(s): Manufacturer

Address: 12400 race track road
Tampa
Florida
33626
United States

Contact:

**Possess One or
More Labels from
This Product:** Yes

**Purchase Location
Information:**

Name: Chewy.com

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Terrier - Boston

Gender: Male

Reproductive Status: Neutered

Weight: 40 Pound

Age: 11 Years

**Assessment of Prior
Health:** Excellent

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

**Number of Animals
Reacted:** 1

Owner Information:

**Healthcare Professional
Information:**

Practice Name: B6

Contact: **Name:** B6
Phone: B6

Address: B6
United States

**Type of
Veterinarian:** Primary/regular veterinarian

Date First Seen: 09/15/2018

**Permission to
Release Records
to FDA:** Yes

Sender Information:

Name:
Address: B6

United States

Contact: **Email:** B6

**Reporter Wants to
Remain Anonymous:** No

**Permission To Contact
Sender:** Yes

	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other
Additional Documents:		

Report Details - EON-369793		
ICSR:	2058247	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-10-30 22:03:16 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: My dog was diagnosed with DCM (heart failure), I have been feeding my dog Taste of the Wild - Venicin and Legumes for 3+ years. Aussies do not typically get DCM in their early years, due to her age and size we thin the grain-free diet could be the culprit as discussed with a Cardio Vet.	
	Date Problem Started: 10/20/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Unknown	
Product Information:	Product Name: Pine Forest Canine Recipe with Venison & Legumes - Taste of the Wild Pet Food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 30 Pound	
	Purchase Date: 10/18/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: I store it in an air tight container in my home	
	Product Use Information:	Description: I would feed 3-4 cups of food per day, only the food no additives - I have been feeding this food to my dog for about 40 months
		First Exposure Date: 10/18/2018
		Last Exposure Date: 10/26/2018
		Time Interval between Product Use and Adverse Event: 3 Years
Product Use Stopped After the Onset of the Adverse Event: Yes		
Adverse Event Abate After Product Stop: Unknown		
Product Use Started Again: No		
Perceived Relatedness to Adverse Event: Probably related		
Other Foods or Products Given No		

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name:

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Shepherd Dog - Australian

Gender: Female

Reproductive Status: Neutered

Weight: 53 Pound

Age: 4.5 Years

Assessment of Prior
Health: Excellent

Number of Animals
Given the Product: 1

Number of Animals
Reacted: 1

Owner Information:

Healthcare Professional
Information:

Practice Name:

B6

Contact:

Name:

Phone:

Email:

B6

Address:

B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: 10/22/2018

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: Phone

Reported to Other
Parties: Store/Place of Purchase

Additional Documents:

Report Details - EON-371274

ICSR:	2058966
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-11-16 14:42:20 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	In the year before her death, she wasn't playing as actively with other dogs, and she was shortening her walks significantly. Because of her age, we never suspected heart issues, but I think that is what ultimately caused her death. Because we did not have an autopsy, and knew nothing about taurine at the time, I know our information is not scientifically significant, but I would like to help prevent anyone else from making the same mistake in choosing dogfood.
	Date Problem Started:	B6
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6 developed a high fever suddenly, and was taken to an after hours veterinary clinic on B6 . She was treated and I was told to return to my vet in the morning. She was worse in the morning, so I took her to B6 where she was seen by an internist and dxed with immune-mediated polyarthritis after spending the night and having tests at the clinic. She was prescribed a 30mg of B6 every 12 hours. The following week, she was seen on Monday, and the doctor thought he heard a heart murmur, but she was panting, so he wasn't sure. By Thursday, she appeared to be in congestive heart failure, but the echo did not confirm that, but showed a valve issue. I believe she had an undiagnosed heart problem, which was exacerbated by the use of the steroids. She spent Thursday night in an oxygen supported bed with no improvement in the morning, and we chose to have her euthanized after talking to two doctors. Her diet for the last 4 years of her life began with a grain free Orijen product for about 2 years, and then was switched to Acana Meadowlands until she died. After reading about the current taurine study and DCM, I believe that she probably had a valve problem that went undiagnosed.
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Acana Meadowland	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Product Use Information:	Description:	Dogfood
		Time Interval between Product Use and Adverse Event:	3 Years
		Product Use Stopped After the Onset of the Adverse Event:	No
		Perceived Relatedness to Adverse Event:	Probably related
Manufacturer /Distributor Information:			

	Purchase Location Information:	Name:	B6	
		Address:		
			United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	70 Pound		
	Age:	5.5 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
			Email:	
Address:		B6		
		United States		
Type of Veterinarian:		Referred veterinarian		
Date First Seen:		B6		
Permission to Release Records to FDA:		Yes		
Practice Name:		B6		
Contact:		Name:	B6	
		Phone:		
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:	B6			
Permission to Release Records to FDA:	Yes			
Practice Name:	B6			
Contact:	Name:	B6		
	Phone:			
Address:	B6			

			B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	B6
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	None		
Additional Documents:			

Report Details - EON-371201

ICSR:	2058925
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-11-15 17:07:25 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I have been feeding my Basenji, B6 Earthborn Dog Food for 4-5 years. On the evening of Tuesday, B6 she began exhibiting extremely concerning symptoms such as heavy and labored breathing, mental disorientation, weakness to the point of not being able to stand, and refused all treats/dry food/wet food. After monitor these symptoms for approximately 1 hour I took her to a local emergency vet (as it was 8pm and my regular vet was closed). Upon arrival I was told that my dog was hypothermic and xrays were performed. The vet performed a physical exam and found that my dog had a new heart murmur, this murmur is believed to be new onset as it has never been heard previously and my dog had her yearly check up 5 months ago. Xrays showed an enlarged heart. The vet said that a normal heart can get to 10.7, my dog was at 11.5. The vet also diagnosed her with pulmonary edema and possible pleural effusion. She was placed on 2 heart medications and B6 Before I took her home that night they gave her a large shot of B6 to start getting the fluid off of her. When I went to my regular vet first thing the next morning, they called in a cardiac specialist who performed an ECHO of her heart. As a result of the findings on this test, the vet diagnosed my dog with Dilated Cardiomyopathy. After discussing my dog's health history and diet, the cardiac vet determined that the DCM was caused by the grain free diet I have fed my dogs for 4-5 years. The vet reported that this condition usually only effects large breed dogs and especially is rare for Basenjis. We immediately switched my dog's diet and also pulled a Taurine lab because we are concerned that her levels may be too low due to her diet. The vet also stated that my dog's new heart murmur has been caused by the DCM, so it is also due to the food she has been on. I would love to be contacted if there is any additional information I can provide that would assist in helping inform the public that this dog food can be life threatening. My dog has never had any major health issues in her life and I almost lost her the other day due to a food that was promoted to be healthy. I will submit the cardiology report that confirms my account.
	Date Problem Started:	B6
	Date of Recovery:	11/15/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Earthborn Holistic, Meadow Feast, with Lamb Meal, Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	40 Pound	
	Purchase Date:	10/22/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Product stored in home, temperature controlled environment, in original bag that has a Ziploc type closure	
Product Use Information:	Description:	1 cup food per day, fed in ceramic dog bowl	
	First Exposure Date:	10/22/2018	
	Last Exposure	B6	

		Date:	
		Time Interval between Product Use and Adverse Event:	1 Days
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Unknown
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Basenji	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	17 Pound	
	Age:	11 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	B6
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact: Name:	B6

		Phone:	B6
		Address:	United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	B6
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact: Name:	B6
		Phone:	
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	B6
		Permission to Release Records to FDA:	Yes

Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact: Phone:	B6	
		Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
Reported to Other Parties:	Manufacturer		

Additional Documents:	Attachment:	B6	pdf
	Description:	Report from ECHO results	
	Type:	Echocardiogram	

Report Details - EON-371192	
ICSR:	2058914
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-11-15 15:51:50 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: Two unrelated golden retriever poodle mixed dogs, fed kibble for 4 years with the following main ingredients: Dried Peas, Pea Protein, Brown Rice, Oatmeal, Potato Protein, Sorghum. Both dogs were diagnosed with DCM. Both dogs improved slightly when kibble was changed to a brand without the above ingredients, but most of the heart damage was already permanent. Both dogs have also been on heart meds for the past two years. One recently died of heart failure at the age of 9. The other is stable on current heart meds at the age of 8.
	Date Problem Started: 06/01/2014
	Concurrent Medical Problem: No
	Outcome to Date: Worse/Declining/Deteriorating
Product Information:	Product Name: V-dog kibble
	Product Type: Pet Food
	Lot Number:
	Possess Unopened Product: No
	Possess Opened Product: No
	Product Use Information:
	Description: kibble for all meals
	First Exposure Date: 01/01/2012
	Last Exposure Date: 01/01/2016
	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: No	
Manufacturer /Distributor Information:	
Purchase Location Information:	
Animal Information:	Name:
	Type Of Species: Dog
	Type Of Breed: Mixed (Dog)

	Gender: Male					
	Reproductive Status: Neutered					
	Weight: 80 Pound					
	Age: 7 Years					
	Assessment of Prior Health: Excellent					
	Number of Animals Given the Product: 2					
	Number of Animals Reacted: 2					
	Owner Information:					
	Healthcare Professional Information:	<table border="1"> <tr> <td>Contact:</td> <td>Name: B6</td> </tr> <tr> <td></td> <td>Phone:</td> </tr> </table>	Contact:	Name: B6		Phone:
Contact:	Name: B6					
	Phone:					
Sender Information:	Name: B6					
	Contact:	Email: B6				
	Reporter Wants to Remain Anonymous: No					
	Permission To Contact Sender: Yes					
	Preferred Method Of Contact: Email					
	Reported to Other Parties: Manufacturer Other					
Additional Documents:						

Report Details - EON-377713		
ICSR:	2061812	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2019-01-28 09:55:42 EST	
Reported Problem:	Problem Description: Patient eating Crave grain free diet. Developed dilated cardiomyopathy and congestive heart failure. Patient came for recheck evaluation one week later, still in CHF> Patient suffered respiratory arrest, ventricular fibrillation and ultimately died.	
	Date Problem Started: 12/24/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Naturally	
	Date of Death: B6	
Product Information:	Product Name: Crave Premium dog food with proetin from Salmon and ocean fish 22 lbs	
	Product Type: Pet Food	
	Lot Number:	
	UPC: 2310012330	
	Package Type: BAG	
	Package Size: 22 Pound	
	Purchase Date: 11/01/2018	
	Number Purchased: 1	
	Possess Unopened Product: Unknown	
	Possess Opened Product: Unknown	
	Product Use Information:	Description: Meal Fed
		Product Use Stopped After the Onset of the Adverse Event: Yes
		Perceived Relatedness to Adverse Event: Probably related
Manufacturer /Distributor Information:		
Purchase Location Information:		
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Terrier - Jack Russell	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 30 Pound	
	Age: 7 Years	
	Assessment of Prior Health: Good	
	Number of Animals Given the Product: 2	
	Number of Animals Reacted: 1	

	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6
			Phone: B6
			Email: B6
		Address:	B6
			United States
	Healthcare Professional Information:		
Sender Information:	Name:		B6
	Address:		B6
			United States
	Contact:	Phone:	B6
		Email:	B6
	Reporter Wants to Remain Anonymous:		No
	Permission To Contact Sender:		Yes
Preferred Method Of Contact:		Email	
Reported to Other Parties:		None	
Additional Documents:			

Report Details - EON-377884

ICSR: 2061858
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2019-01-29 08:37:46 EST
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Our golden retriever was diagnosed with DCM linked specifically to his diet.
Date Problem Started: 01/22/2019
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Earthborn Holistic Grain Free
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Reproductive Status: Neutered
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information:
Healthcare Professional Information:

Sender Information:
Name:
Address: [Redacted with B6]
United States
Contact: **Phone:** [Redacted with B6] **Email:** [Redacted with B6]
Permission To Contact Sender: Yes
Preferred Method Of Contact: Email

Additional Documents:

Report Details - EON-377846

ICSR: 2061845
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Product Problem (an observed or detected product issue or defect that has the potential to cause harm)
Reporting Type: Voluntary
Report Submission Date: 2019-01-28 17:20:13 EST
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Blood taurine level drawn 9/17 results **B6** slightly below range for a golden. Was feeding Nutrisource Woodlands select. Had been adding toopers of cooked liver and sardine. Food changed to Natures Logic 8/18, retested 12/3 results **B6**. Echocardiogram done 1/11/19 normal. food being transitioned to purina pro plan and supplement being given since lab o **B6** reported. Taurine retesting 2/4/19
Date Problem Started: 09/28/2017

Product Information:
Product Name: Nutrisource Woodlands select & Natures logic beef
Product Type: Pet Food
Lot Number:
UPC: do not have
Package Type: BAG
Package Size: 28 Pound
Purchase Date: 12/01/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information: Name: Address: **B6**
United States

Animal Information:
Name:
Owner Information:
Healthcare Professional Information:

Sender Information:
Name: Address: **B6**
United States
Contact: Phone: Email: **B6**
Reporter Wants to Remain Anonymous: No
Permission To Contact Sender: Yes

	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other

Additional Documents:

Report Details - EON-37775

ICSR:	2061833		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)		
Reporting Type:	Voluntary		
Report Submission Date:	2019-01-28 14:18:05 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Medium-sized hound mix was given boutique, vegan dog food for five years. Brand: v-dog. On 1/10/2019, labored breathing and swollen abdomen was noticed in dog. Emergency vet diagnosed her with severe dilated cardiomyopathy (DCM), ascites, and pleural effusion. On 1/11/2019, dog was taken to vet cardiologist and given diagnosis of diet-induced DCM (left ventricular ejection fraction 10%). Treatment plan: switch dog food, take cardiovascular medications, taurine supplementation, l-carnitine supplementation. Follow-up echo will occur in 2-3 weeks.	
	Date Problem Started:	01/10/2019	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	v-dog kinder kibble	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	05/22/2018	
	Number Purchased:	3	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	Yes	
	Storage Conditions:	Product was kept in the bag with bag in a large plastic air-tight container with lid that opens.	
	Product Use Information:	Description:	Product was given twice a day, one cup of kibble each feeding, to medium-sized hound mix for approximately five years. First started this product in September after first purchase date of September 3, 2013. Last purchase date was May 22, 2018 and last fed date was 1/10/2019. Note that in the questions "Date the product was first given to animal" that the computer would not let me put 09/03/2013, rather I had to put after the last purchase date.
		First Exposure Date:	05/23/2018
		Last Exposure Date:	01/10/2019
Time Interval between Product Use and Adverse Event:		5 Years	
Product Use Stopped After the Onset of the Adverse Event:		Yes	
Adverse Event Abate After Product Stop:		Unknown	

		Product Use Started Again:	No	
		Perceived Relatedness to Adverse Event:	Definitely related	
		Other Foods or Products Given to the Animal During This Time Period:	Yes	
	Manufacturer /Distributor Information:	Name:	V-dog	
		Type(s):	Manufacturer	
		Contact:		
		Possess One or More Labels from This Product:	Yes	
	Purchase Location Information:	Name:	V-dog online	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Mixed (Dog)		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	50 Pound		
	Age:	8 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
		Address:	B6	
			United States	
		Type of Veterinarian:	Referred veterinarian	
Date First Seen:		01/10/2019		
Permission to Release Records to FDA:		Yes		
Practice Name:		B6		
		Contact:	Name:	B6
	Phone:			
	Address:	B6		
		United States		
Type of Veterinarian:	Referred veterinarian			

Date First Seen: 01/11/2019

Permission to Release Records to FDA: Yes

Sender Information:

Name: B6

Contact:

Phone:

Email:

B6

Reporter Wants to Remain Anonymous: No

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Reported to Other Parties: None

Additional Documents:

Report Details - EON-377840											
ICSR:	2061843										
Type Of Submission:	Initial										
Report Version:	FPSR.FDA.PETF.V.V1										
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)										
Reporting Type:	Voluntary										
Report Submission Date:	2019-01-28 16:25:19 EST										
Reported Problem:	Problem Description: Patient presented for dyspnea and was diagnosed with dilated cardiomyopathy and secondary heart failure. Taurine level from Idexx was reported as B6 nmol/ml (reference range 60-120)										
	Date Problem Started: 10/26/2018										
	Concurrent Medical Problem: Yes										
	Pre Existing Conditions: B6										
	Outcome to Date: Better/Improved/Recovering										
Product Information:	Product Name: Zignature Kangaroo Formula Limited Ingredient Formula										
	Product Type: Pet Food										
	Lot Number:										
	Package Type: BAG										
	Possess Unopened Product: No										
	Possess Opened Product: No										
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>Patient was fed this food twice daily for many years</td> </tr> <tr> <td>Last Exposure Date:</td> <td>10/26/2018</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Unknown</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	Patient was fed this food twice daily for many years	Last Exposure Date:	10/26/2018	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
	Description:	Patient was fed this food twice daily for many years									
	Last Exposure Date:	10/26/2018									
	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: B6											
Animal Information:	Type Of Species: Dog										
	Type Of Breed: Retriever - Labrador										
	Gender: Male										
	Reproductive Status: Neutered										
	Weight: 95 Pound										
	Age: 9 Months										
	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	
	Healthcare Professional Information:	Practice Name: B6	
		Contact: Name: B6 Phone: B6	
		Type of Veterinarian: Referred veterinarian	
		Date First Seen: 10/28/2018	
		Permission to Release Records to FDA: No	
	Sender Information:	Name: B6 Address: B6	
		United States	
		Contact: Phone: B6 Email: B6	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
	Additional Documents:		

Report Details - EON-377827

ICSR:	2061837
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-01-28 15:27:51 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 had an episode in January 2018 (age 5 1/2) where he had chronic coughing, lethargy and lack of interest in food. I took him to my primary vet, who took an x-ray and noticed an enlarged heart and that his oxygen intake was poor. They referred me to the emergency room where it was confirmed that he had congestive heart failure. After staying overnight, the veterinary cardiologist examined him and noted that his heart condition was unusual for his breed (pomeranian) and age and that there were studies about dogs on alternative meat diets developing conditions due to taurine deficiency. B6 was advised to change his food and received prescriptions for B6 . B6 was also instructed to take a taurine supplement. After six months, B6 echocardiogram showed improvement, and now after one year, his heart has normalized and he is in the process of being weaned off his medications. The veterinarian advised that this was evidence that his heart condition was definitely dietary related.
	Date Problem Started:	01/15/2018
	Date of Recovery:	01/24/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Recovered Completely

Product Information:	Product Name:	Zignature Kangaroo Limited Ingredient Formula Grain-Free Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	4 Pound	
	Purchase Date:	12/15/2017	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	This product was stored in its bag with a sealing clip. The bag was kept in an additional container.	
	Product Use Information:	Description:	B6 ate this food 1/4 cup twice a day.
		Last Exposure Date:	01/15/2018
		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:		Definitely related	
Other Foods or		Yes	

Products Given to the Animal During This Time Period:

Manufacturer /Distributor Information:

Purchase Location Information:

Name:

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Other Canine/dog

Gender: Male

Reproductive Status: Neutered

Weight: 5 Pound

Age: 6 Years

Assessment of Prior Health: Excellent

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional Information:

Practice Name:

B6

Contact:

Name:

Phone:

Email:

B6

Address:

B6

United States

Type of Veterinarian:

Primary/regular veterinarian

Date First Seen: 01/15/2018

Permission to Release Records to FDA: Yes

Practice Name:

B6

Contact:

Name:

Phone:

Email:

B6

Address:

B6

United States

Type of Veterinarian:

Referred veterinarian

Date First Seen: 01/16/2018

Permission to Release Records to FDA: Yes

Sender Information:

Name:

Address:

B6

		B6	
		United States	
	Contact:	Phone:	B6
		Email:	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	

Additional Documents:	Attachment:	B6	cardio Report 012019.pdf
	Description:	B6	cardiology report from one year following start of diet change and treatment.
	Type:	Other	
	Attachment:	B6	cardio Report 012018.pdf
	Description:	B6	cardiology report from his initial examination with Dr. B6
	Type:	Other	

Report Details - EON-378106

ICSR:	2061939
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-01-30 14:52:46 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	3 year old healthy/fit golden retriever collapsed on [B6] and suffered sudden death. [B6] was fed Canidae brand grain free dry dog food (Pure Land & Pure Sea) and Kirkland brand grain free canned dog food his entire life. The autopsy revealed an enlarged heart, foam in lungs, and a "floppy atrium" consistent with Dilated Cardiomyopathy (DCM). This scenario matches other similar cases of young, otherwise healthy dogs suffering from DCM. [B6] presented no signs or symptoms of illness prior to collapsing and sudden death. He was alive one minute and dead the next. It is a stunning and devastating situation.
	Date Problem Started:	[B6]
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Naturally
	Date of Death:	[B6]

Product Information:	Product Name:	Kirkland grain free canned dog food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	CAN	
	Possess Unopened Product:	Yes	
	Storage Conditions:	in can	
	Product Use Information:	Description:	[B6] was fed 1/2 can in the evening
		Last Exposure Date:	[B6]
		Time Interval between Product Use and Adverse Event:	1 Hours
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Not Applicable
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
Manufacturer /Distributor Information:			
Purchase Location Name:	costco		

	Information:	Address: United States
	Product Name:	canidae pure land
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	24 Pound
	Purchase Date:	01/06/2019
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	Yes
	Storage Conditions:	kept in a plastic tote
	Product Use Information:	Description: B6 received 1 cup of food each morning and evening Last Exposure Date: B6 Time Interval between Product Use and Adverse Event: 1 Hours Product Use Stopped After the Onset of the Adverse Event: Yes Adverse Event Abate After Product Stop: Not Applicable Product Use Started Again: No Perceived Relatedness to Adverse Event: Definitely related Other Foods or Products Given to the Animal During This Time Period: Yes
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	75 Pound
	Age:	B6 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Practice Name:	B6

Information:	Contact:	Name:	B6
		Phone:	
		Other Phone:	
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
Date First Seen:	B6		
Permission to Release Records to FDA:	Yes		
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Other Phone:	
		Email:	
	Reporter Wants to Remain Anonymous:	No	
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Reported to Other Parties:	Other		
Additional Documents:	Attachment:	B6 necropsy.jpeg	
	Description:	Necropsy findings, Sorry its a photo of the report.	
	Type:	Photograph	

Report Details - EON-378153						
ICSR:	2061967					
Type Of Submission:	Initial					
Report Version:	FPSR.FDA.PETF.V.V1					
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)					
Reporting Type:	Voluntary					
Report Submission Date:	2019-01-31 01:06:01 EST					
Reporter is the Animal Owner:	Yes					
Reported Problem:	Problem Description: We feed B6 Zignature dog food, trout. It is grain free. January 2019 he was diagnosed with a heart murmur so an x-ray was ordered. He was found to have a rounded heart, enlarged. He is now on two heart pills a day.					
	Date Problem Started: 01/19/2019					
	Concurrent Medical Problem: No					
	Outcome to Date: Stable					
Product Information:	Product Name: Zignature Trout & Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food					
	Product Type: Pet Food					
	Lot Number:					
	Package Type: BAG					
	Purchase Date: 01/01/2019					
	Number Purchased: 1					
	Possess Unopened Product: No					
	Possess Opened Product: No					
	Storage Conditions: Product is stored in a airtight plastic container.					
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>We feed both dogs twice a day.</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>No</td> </tr> </table>	Description:	We feed both dogs twice a day.	Perceived Relatedness to Adverse Event:	Probably related	Other Foods or Products Given to the Animal During This Time Period:
Description:	We feed both dogs twice a day.					
Perceived Relatedness to Adverse Event:	Probably related					
Other Foods or Products Given to the Animal During This Time Period:	No					
Manufacturer /Distributor Information: <table border="1"> <tr> <td>Purchase Location Information:</td> <td>Name: Chewy</td> </tr> </table>	Purchase Location Information:	Name: Chewy				
Purchase Location Information:	Name: Chewy					
Animal Information:	Name: B6					
	Type Of Species: Dog					
	Type Of Breed: Schnauzer - Miniature					
	Gender: Male					
	Reproductive Status: Neutered					
	Weight: 25 Pound					
	Age: 7 Years					
	Assessment of Prior Health: Good					
	Number of Animals Given the Product: 2					
	Number of Animals Reacted: 1					

Owner Information: Healthcare Professional Information:	Practice Name:	B6		
	Contact:	Name:	B6	
		Phone:	B6	
	Address:	B6		
		United States		
	Type of Veterinarian:	Primary/regular veterinarian		
	Date First Seen:	01/26/2019		
	Permission to Release Records to FDA:	Yes		
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:	None			
Additional Documents:				

Report Details - EON-379407

ICSR:	2062509
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-11 17:27:22 EST

Reported Problem:	Problem Description:	Due to recent discovery of diet-associated dilated cardiomyopathy (DCM) in dogs, and especially since [B6] is a golden retriever (this breed seems to be more predisposed to this), the owner had his whole blood taurine level measured. It was low [B6] for a golden retriever (ref. reported to be >250). The patient had no symptoms of DCM. An echocardiogram was performed on 10/10/18 to screen for the presence of DCM. Mild DCM was diagnosed. The patient was switched from Nutro grain-free chicken, lentil, and sweet potato dry food onto Fromm's gold adult dry food. Also, taurine supplementation (1000 mg by mouth every 12 hours) was started. A recheck taurine level in January '19 was normal [B6]. A recheck echocardiogram on 1/31/19 revealed that the DCM had resolved.
	Date Problem Started:	10/10/2018
	Date of Recovery:	01/31/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Recovered Completely

Product Information:	Product Name:	Nutro, grain free, adult dry dog food, farm-raised chicken, lentils, and sweet potato recipe.		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Possess Unopened Product:	Unknown		
	Possess Opened Product:	Unknown		
	Product Use Information:	Description:	Fed 1.5 cups twice daily.	
		First Exposure Date:	01/01/2018	
		Last Exposure Date:	10/10/2018	
		Time Interval between Product Use and Adverse Event:	9 Months	
		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:	
	Purchase Location Information:	
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	30.6 Kilogram
	Age:	6 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: No
	Healthcare Professional Information:	
Sender Information:	Name:	B6
	Address:	B6
	Contact:	Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other
Additional Documents:	Attachment:	B6 diet form 10.10.18.pdf
	Description:	Diet form filled out by owner after the patient was diagnosed with DCM.
	Type:	Other

Report Details - EON-379388	
ICSR:	2062490
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-11 15:31:09 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: Goldendoodle. Veterinarian told owner about FDA report about GF foods and DCM. The owner discontinued the TotW. Started on Chewy brand American Journey - not grain free. 2 weeks later (12/24/18) he was taken to the vet. He had started "honking like a goose" when someone would come to the door over the weekend. The issue worsened through the day and he started vomiting. He went to the vet and was diagnosed with cardiomegaly, heart failure, and a stage 3-4 heart murmur. He was started on [B6] and heart Rx. The BNP came back as over [B6] (normal 900.) The only other prior clinical sign was that he was panting more. In hindsight he had a decreased energy level over the last 6 months. On check up the heart failure/fluid was improved. The murmur was measured as a 2. Bloodwork was normal (normal previously), no BNP done. He'll see the cardiologist in April 2019. Other 2 dogs not on grain free, on 4Health Weight Maintenance. Now all dogs on Royal Canin products.
	Date Problem Started: 12/22/2018
	Concurrent Medical Problem: No
	Outcome to Date: Better/Improved/Recovering
Product Information:	Product Name: Taste of the Wild Pacific Stream Adult Food
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Possess Unopened Product: No
	Possess Opened Product: No
	Product Use Information:
	First Exposure Date: 10/22/2017
	Last Exposure Date: 10/22/2018
	Perceived Relatedness to Adverse Event: Possibly related
Manufacturer /Distributor Information:	
Purchase Location Information:	
Name: Chewy	
Animal Information:	Name: B6
	Type Of Species: Dog
	Type Of Breed: Mixed (Dog)
	Gender: Male
	Reproductive Status: Neutered
	Weight: 75 Pound
	Age: 9 Years
	Assessment of Prior Health: Good
Number of Animals Given the Product: 1	

	Number of Animals Reacted:	1
	Owner Information:	
Healthcare Professional Information:	Practice Name:	B6
	Contact: Name:	B6
	Phone:	B6
	Email:	B6
	Address:	B6 United States
	Type of Veterinarian:	Primary/regular veterinarian
	Date First Seen:	12/24/2018
Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	B6
	Address:	B6 United States
	Contact: Phone:	B6
	Email:	B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
Preferred Method Of Contact:	Phone	
Additional Documents:		

Report Details - EON-379433					
ICSR:	2062524				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)				
Reporting Type:	Voluntary				
Report Submission Date:	2019-02-12 07:36:56 EST				
Reported Problem:	Problem Description: Initially reported as RFR EON-379401. CVM resubmitting as PFR. Initial FDA report linking possible cause of DCM linked to certain foods. This canine, B6 was diagnosed with Dilated Cardiomyopathy on 8/2/2018. He was being fed a suspect food high in legume ingredients. Whole blood taurine levels were run (6/18/18) and were low at B6 μmol/mL (normal range 200-350). Diagnosis: Dilated cardiomyopathy with a recent taurine-deficiency (potentially associated with prior grain-free diet)				
	Date Problem Started: 08/02/2018				
	Outcome to Date: Unknown				
Product Information:	Product Name: Zignature Kangaroo Limited Ingredient				
	Product Type: Pet Food				
	Lot Number:				
	Product Use Information:				
	Manufacturer /Distributor Information:				
	Purchase Location Information:				
Animal Information:	Name:				
	Type Of Species: Dog				
	Type Of Breed: Unknown				
	Gender: Male				
	Reproductive Status: Unknown				
	Assessment of Prior Health: Unknown				
	Number of Animals Reacted: 1				
	Owner Information: <table border="1" style="margin-left: 20px;"> <tr> <td>Owner Information provided:</td> <td>No</td> </tr> </table>	Owner Information provided:	No		
	Owner Information provided:	No			
Healthcare Professional Information:					
Sender Information:	Name: B6				
	Address: <table border="1" style="margin-left: 20px;"> <tr> <td style="text-align: center; vertical-align: middle;">B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States		
	B6				
	United States				
	Contact: <table border="1" style="margin-left: 20px;"> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td>B6</td> </tr> </table>	Phone:	B6	Email:	B6
	Phone:	B6			
	Email:	B6			
Reporter Wants to Remain Anonymous: No					
Permission To Contact Sender: Yes					
Preferred Method Of Contact: Email					

Reported to Other Parties: Unknown

Additional Documents:

Report Details - EON-380293		
ICSR:	2062985	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-02-20 18:52:06 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Due to overweight and then weight maintenance, the dog (a now lean, 43lbs pointer-type, intact male mixed breed) was consuming Acana Light & Fit (grain-free, high legumes-content kibble) on a daily basis since December 2017, and has now (Feb. 2019) been diagnosed with DCM (detected by chance in a thorax x-ray made for a suspected bronchitis; DCM without evident clinical symptoms yet). Although we are not in the US, this information adds a case to the current investigation in the link between DCM and grain-free diet.	
	Date Problem Started: 02/15/2019	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: ACANA Light & Fit	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 11.4 kilogram	
	Purchase Date: 12/13/2017	
	Number Purchased: 2	
	Possess Unopened Product: Yes	
	Possess Opened Product: Yes	
	Storage Conditions: Dry and cool, in the original bag, closed	
	Product Use Information:	Description: It was fed daily (with water) since December 2017 until February 2019 (when he was diagnosed with DCM), following the feeding recommendations on the package.
		First Exposure Date: 12/13/2017
		Last Exposure Date: 02/15/2019
		Time Interval between Product Use and Adverse Event: 1 Years
Product Use Stopped After the Onset of the Adverse Event: Yes		
Adverse Event Abate After Product Stop: Unknown		
Product Use Started Again: No		
Perceived Relatedness to Adverse Event: Probably related		
Other Foods or Yes		

		Products Given to the Animal During This Time Period:
	Manufacturer /Distributor Information:	
	Purchase Location Information:	Name: www.zooplus.es Address: Spain
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Mixed (Dog)
	Gender:	Male
	Reproductive Status:	Intact
	Weight:	19.5 Kilogram
	Age:	10 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	Practice Name: B6
		Contact: Name: B6 Phone: B6
		Address: B6 Spain
		Type of Veterinarian: Primary/regular veterinarian
		Date First Seen: 02/15/2019
		Permission to Release Records to FDA: Yes
Sender Information:	Name:	B6
	Address:	B6 Spain
	Contact:	Phone: B6 Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
Additional Documents:		

Report Details - EON-380237	
ICSR:	2062949
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-20 12:14:31 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: My dog had an echocardiogram was diagnosed with diet related dilated cardiomyopathy in October of 2018. Prior to the diagnosis I noticed some indication of exercise intolerance. I sent some bloodwork to UC Davis and it reported a taurine level of B6 . A second echocardiogram was performed in January 2019 and it concurred with the first diagnosis and showed minimal improvement, the left ventricular size is high normal to mildly enlarged in diastole and there is moderate global hypokinesis of LV contractility.
	Date Problem Started: 06/01/2018
	Concurrent Medical Problem: No
	Outcome to Date: Stable
Product Information:	Product Name: Earthborn Holistic Coastal Catch Grain-Free Natural Dry Dog Food from 10/2014-5/2018. Natural Balance L.I.D. Limited Ingredient Diets Sweet Potato & Fish Formula Grain-Free Dry Dog Food.
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Package Size: 28 Pound
	Number Purchased: 1
	Possess Unopened Product: No
	Possess Opened Product: No
	Storage Conditions: Stored in a plastic container.
	Product Use Information:
	First Exposure Date: 10/01/2014
	Last Exposure Date: 05/31/2018
	Time Interval between Product Use and Adverse Event: 4 Years
	Product Use Stopped After the Onset of the Adverse Event: Yes
	Adverse Event Abate After Product Stop: No
	Product Use Started Again: No

		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	chewy.com
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	82 Pound	
	Age:	5 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:		
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:	None	
Additional Documents:			

Report Details - EON-380278

ICSR: 2062976
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2019-02-20 16:37:30 EST
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: My dog was fed Fromm Heartland Gold large breed adult (grain free) for her entire adult life. I became aware of a potential link between grain free dog food and low taurine/DCM. Since my dog was eating a grain free food, I decided to have her taurine level tested in June 2018. Her taurine results were low at [B6]. I followed up with a veterinary cardiologist and who performed an echo to rule out DCM. Thankfully, her heart was fine. The cardiologist advised me to change her food and give her a taurine supplement for three months. I changed her food to Royal Canin Golden Retriever. Six months later, December 2018, I did a recheck of her taurine level and it came back in the normal range at [B6]. I waited the extra time to recheck her taurine so the results would not be influenced by the taurine supplement. The food she was consuming definitely had an impact on her health.

Date Problem Started: 06/14/2018
Date of Recovery: 12/12/2018
Concurrent Medical Problem: No
Outcome to Date: Recovered Completely

Product Information:

Product Name: Fromm Heartland Gold Large Breed Adult
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 26 Pound
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Kept in its original bag and bag was stored in an air tight bin.

Product Use Information:

Description:	Fed twice a day.
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:	Definitely related

Manufacturer /Distributor Information:

Purchase Location Information:

Name:
Address: [B6]

B6
United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Retriever - Golden

Gender: Female

Reproductive Status: Neutered

Weight: 62 Pound

Age: 3 Years

Assessment of Prior Health: Excellent

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional Information:

Practice Name:

B6

Contact:

Name:

B6

Phone:

Address:

B6

United States

Type of Veterinarian:

Primary/regular veterinarian

Date First Seen: 06/14/2018

Permission to Release Records to FDA: Yes

Practice Name:

B6

Contact:

Name:

B6

Phone:

Address:

B6

United States

Type of Veterinarian:

Referred veterinarian

Date First Seen: 06/29/2018

Permission to Release Records to FDA: Yes

Sender Information:

Name:

Address:

B6

United States

Contact:

Phone:

B6

Email:

Permission To Contact Sender: Yes

Preferred Method Of Contact:	Email
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Reported to Other Parties:	None
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Additional Documents:	
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Report Details - EON-380236

ICSR: 2062944
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-02-20 11:55:26 EST

Reported Problem:
Problem Description: Pet presented asymptomatic for an echocardiogram for Cardiac OFA certification. Grade 1 murmur noted on auscultation. Mild systolic dysfunction and mild left ventricle enlargement. rule out early DCM
Date Problem Started: 11/03/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Unknown

Product Information:
Product Name: Halo Natural Dry Dog Food
Product Type: Pet Food
Lot Number:
Product Use Information: **Last Exposure Date:** 08/01/2018
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Honest Kitchen Grain Free Turkey Recipe
Product Type: Pet Food
Lot Number:
Product Use Information: **First Exposure Date:** 08/01/2018
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Collie - Border
Gender: Male
Reproductive Status: Neutered
Weight: 15.9 Kilogram
Age: 3 Years
Assessment of Prior Health: Unknown
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** No
Healthcare Professional Information:

Sender Information:
Name:
Address: B6

		B6
		United States
	Contact:	Phone:
		B6
		Email:
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	None

Additional Documents:

Report Details - EON-380254

ICSR: 2062960
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2019-02-20 14:12:32 EST

Reported Problem: **Problem Description:** B6 a 8 Yrs. 0 Mos., Neutered Male, Pinscher, Doberman, owned by B6 B6 was presented on 1/7/2019 for cardiac evaluation following transfer from our ER services for suspect congestive heart failure. He initially presented for not defecating for a few days, not eating as much, abdomen being distended, breathing heavier and hacking some. He is on B6 B6 ECG: Rapid atrial fibrillation with a right bundle branch block and QRS alternans; average heart rate of 220 bpm A mild residual volume of pleural effusion was noted on exam. Mild pericardial effusion was also noted as well as moderate peritoneal effusion. No overt cardiac tumors or masses were observed. A liver lobe was visualized within the pericardial space consistent with a pericardial peritoneodiaphragmatic hernia. Diagnosis: Rapid atrial fibrillation, Congestive heart failure, Myxomatous mitral valve disease, Systolic dysfunction - r/o tachycardia-induced vs. diet-related vs. early DCM, Peritoneopericardial diaphragmatic hernia

Date Problem Started: 01/09/2019
Outcome to Date: Stable

Product Information:
Product Name: Nature's Select Grain Free (unknown variety)
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Doberman Pinscher
Gender: Male
Reproductive Status: Neutered
Weight: 50 Kilogram
Age: 8 Years
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** No
Healthcare Professional Information: **Practice Name:** B6
Contact: **Name:** B6 **Phone:**
Type of Veterinarian: Primary/regular veterinarian

Sender Information:
Name:
Address: B6
United States

	Contact:	Phone:	B6	
		Email:		
	Reporter Wants to Remain Anonymous:	No		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Phone		

Additional Documents:

Report Details - EON-380321		
ICSR:	2062988	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-02-20 21:37:20 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: [B6] was eating Taste of the Wild since he was a puppy. The formulas were: High Prairie Puppy from when I got him in May 2016 until March 2017 Pine Forest from March 2017 to May 2018 Pacific Stream from May 2018 to August 2018 He had a few episodes of collapsing. I took him to the vet and he multiple tests were performed and all came back negative. When I heard about taurine deficiency in dogs eating grain free food, I had his taurine levels checked. His whole blood level came back in the [B6] and plasma in the [B6] He went to a cardiologist and his heart was marginally enlarged. He food was changed and he was put on a taurine supplement.	
	Date Problem Started: 08/01/2018	
	Date of Recovery: 02/18/2019	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: [B6]	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: Taste of the Wild Pacific Stream	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 27 Pound	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: The product was transferred to a plastic container after opening.	
	Product Use Information:	Description: [B6] was fed this food for his meal 2 times per day.
		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: Definitely related
		Manufacturer /Distributor Information:
Purchase Location Information:	Name: Tractor Supply	
	Address: [B6] United States	
Product Name: Taste of the Wild Pine Forest		
Product Type: Pet Food		
Lot Number:		

	Package Type:	BAG						
	Package Size:	27 Pound						
	Purchase Date:	05/01/2018						
	Possess Unopened Product:	No						
	Possess Opened Product:	No						
	Storage Conditions:	The product was transferred to a plastic container after storage.						
	Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>B6 was eating this food for his meals 2 times per day.</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Definitely related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>No</td> </tr> </table>	Description:	B6 was eating this food for his meals 2 times per day.	Perceived Relatedness to Adverse Event:	Definitely related	Other Foods or Products Given to the Animal During This Time Period:	No
Description:	B6 was eating this food for his meals 2 times per day.							
Perceived Relatedness to Adverse Event:	Definitely related							
Other Foods or Products Given to the Animal During This Time Period:	No							
	Manufacturer /Distributor Information:							
	Purchase Location Information:	<table border="1"> <tr> <td>Name:</td> <td>Tractor Supply</td> </tr> <tr> <td>Address:</td> <td>B6 United States</td> </tr> </table>	Name:	Tractor Supply	Address:	B6 United States		
Name:	Tractor Supply							
Address:	B6 United States							
	Product Name:	Taste of the Wild High Prairie Puppy Recipe						
	Product Type:	Pet Food						
	Lot Number:							
	Package Type:	BAG						
	Package Size:	27 Pound						
	Purchase Date:	03/01/2017						
	Possess Unopened Product:	No						
	Possess Opened Product:	No						
	Storage Conditions:	Product was transferred into a plastic container after opening.						
	Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>B6 was eating this food for his meals 2-3 times per day.</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Definitely related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>No</td> </tr> </table>	Description:	B6 was eating this food for his meals 2-3 times per day.	Perceived Relatedness to Adverse Event:	Definitely related	Other Foods or Products Given to the Animal During This Time Period:	No
Description:	B6 was eating this food for his meals 2-3 times per day.							
Perceived Relatedness to Adverse Event:	Definitely related							
Other Foods or Products Given to the Animal During This Time Period:	No							
	Manufacturer /Distributor Information:							
	Purchase Location Information:	<table border="1"> <tr> <td>Name:</td> <td>Tractor Supply</td> </tr> <tr> <td>Address:</td> <td>B6 United States</td> </tr> </table>	Name:	Tractor Supply	Address:	B6 United States		
Name:	Tractor Supply							
Address:	B6 United States							
Animal Information:	Name:	B6						
	Type Of Species:	Dog						
	Type Of Breed:	Retriever - Labrador						
	Gender:	Male						
	Reproductive Status:	Neutered						
	Weight:	87 Pound						
	Age:	3 Years						

	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	Practice Name: B6
		Contact: Name: B6
		Phone: B6
		Address: B6
		United States
		Type of Veterinarian: Primary/regular veterinarian
		Permission to Release Records to FDA: Yes
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:	None
Additional Documents:		

Report Details - EON-380245	
ICSR:	2062958
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-20 13:23:13 EST
Reported Problem:	<p>Problem Description: B6 a 7 Yrs. 3 Mos., Spayed Female, Bulldog, English, owned by B6 B6 was presented on 12/5/2018 for cardiac evaluation following presentation on an ER basis for further work up of bicavitary effusion (pericardial and peritoneal). Her owner has noticed lethargy and abdominal distension over the past couple days. She had some loose stool last night. Decreased appetite. CXR and AXR- suspect pericardial and visible peritoneal effusion A pericardiocentesis was performed prior to presentation with B6 mL of non-clotting serous fluid removed. CBC/Chem - ALT B6 There is mild residual pericardial effusion with minimal diastolic right atrial collapse. A mixed echogenic heart base mass was visualized on exam measuring B6. Mild peritoneal effusion was present on exam near the liver and urinary bladder. Diagnosis: Heart base mass - suspect chemodectoma, Dilated cardiomyopathy, Bicavitary effusion (pleural and peritoneal effusion)</p> <p>Date Problem Started: 12/05/2018</p> <p>Concurrent Medical Problem: Unknown</p> <p>Outcome to Date: Unknown</p>
Product Information:	<p>Product Name: Zignature Grain Free (unknown variety)</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Product Use Information:</p> <p>Manufacturer /Distributor Information:</p> <p>Purchase Location Information:</p>
Animal Information:	<p>Name: B6</p> <p>Type Of Species: Dog</p> <p>Type Of Breed: Bulldog</p> <p>Gender: Female</p> <p>Reproductive Status: Neutered</p> <p>Weight: 36.54 Kilogram</p> <p>Age: 7 Years</p> <p>Number of Animals Reacted: 1</p> <p>Owner Information: Owner Information provided: No</p> <p>Healthcare Professional Information: Practice Name: B6</p> <p>Contact: Name: B6 Phone: B6</p> <p>Address: B6 United States</p> <p>Type of Veterinarian: Primary/regular veterinarian</p>

Sender Information:	Name:	B6		
	Address:			
		United States		
	Contact:	Phone:	B6	
		Email:		
	Reporter Wants to Remain Anonymous:	No		
	Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Phone			
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-380250	
ICSR:	2062959
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-20 13:46:03 EST
Reported Problem:	<p>Problem Description: B6 a 12 Yrs. 0 Mos., Spayed Female, Retriever, Golden Mix, owned by B6 was presented on 1/16/2019 for cardiac evaluation. She presented to our ER service on B6 for suspect syncopal episodes. About 3 weeks prior, B6 had an event where she became stiff and collapsed but would become more aware after a min or so. She had another event about a week ago and then once last night which took her longer to recover from. The owner stated that the events happen on a walk or going upstairs or after excitement or exercise. Left ventricle: Chamber size: moderately to severely increased end-diastolic dimensions; severely increased end-systolic dimensions. Diagnosis: Dilated cardiomyopathy leading to congestive heart failure - r/o diet-related DCM vs. idiopathic, Episodes of collapse- suspect syncope Diagnosis: Dilated cardiomyopathy leading to congestive heart failure - r/o diet-related DCM vs. idiopathic, Episodes of collapse- suspect syncope</p> <p>Date Problem Started: 01/16/2019</p> <p>Outcome to Date: Unknown</p>
Product Information:	<p>Product Name: Zignature Salmon Limited Ingredient Formula Grain-Free Dry Dog Food</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Product Use Information:</p> <p>Manufacturer /Distributor Information:</p> <p>Purchase Location Information:</p>
Animal Information:	<p>Name: B6</p> <p>Type Of Species: Dog</p> <p>Type Of Breed: Mixed (Dog)</p> <p>Gender: Female</p> <p>Reproductive Status: Neutered</p> <p>Weight: 40.2 Kilogram</p> <p>Age: 12 Years</p> <p>Number of Animals Reacted: 1</p> <p>Owner Information: Owner Information provided: No</p> <p>Healthcare Professional Information: Practice Name: B6</p> <p>Contact: Name: multiple vets unknown</p> <p>Phone: B6</p> <p>Address: B6</p> <p>United States</p> <p>Type of Veterinarian: Primary/regular veterinarian</p>
Sender Information:	Name: B6

	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	
	Reporter Wants to Remain Anonymous:	No	
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Phone		

Additional Documents:

Report Details - EON-380225

ICSR: 2062940
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2019-02-20 11:10:07 EST

Reported Problem:

Problem Description:	Patient was diagnosed with dilated cardiomyopathy (DCM) and congestive heart failure (CHF) by myself (veterinary cardiologist) in May 2017. Whole blood taurine levels were submitted to UC Davis and were normal. Owner was feeding a grain free diet, but did not recall the brand. Owners changed diet to a different grain-free diet on their own. This patient's heart disease resolved after the diet was changed. I am submitting this case because DCM does not resolve and I suspect it was related to diet. Unfortunately, we don't know what diet it was. The current diet (and the diet he has been on since November 2017) is called ZiwiPeak Air dried lamb dog food.
Date Problem Started:	05/02/2017
Date of Recovery:	03/14/2018
Concurrent Medical Problem:	No
Outcome to Date:	Recovered Completely

Product Information:

Product Name:	ZiwiPeak Air Dried Lamb
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Possess Unopened Product:	Unknown
Possess Opened Product:	Unknown
Product Use Information:	
Manufacturer /Distributor Information:	
Purchase Location Information:	

Animal Information:

Name:											
Type Of Species:	Dog										
Type Of Breed:	Spaniel - Cocker American										
Gender:	Male										
Reproductive Status:	Neutered										
Weight:	26 Pound										
Age:	10 Years										
Assessment of Prior Health:	Good										
Number of Animals Reacted:	1										
Owner Information:	<table border="1"><tr><td>Owner Information provided:</td><td>Yes</td></tr><tr><td>Contact:</td><td><table border="1"><tr><td>Name:</td><td>B6</td></tr><tr><td>Phone:</td><td>B6</td></tr></table></td></tr><tr><td>Address:</td><td>B6</td></tr></table>	Owner Information provided:	Yes	Contact:	<table border="1"><tr><td>Name:</td><td>B6</td></tr><tr><td>Phone:</td><td>B6</td></tr></table>	Name:	B6	Phone:	B6	Address:	B6
Owner Information provided:	Yes										
Contact:	<table border="1"><tr><td>Name:</td><td>B6</td></tr><tr><td>Phone:</td><td>B6</td></tr></table>	Name:	B6	Phone:	B6						
Name:	B6										
Phone:	B6										
Address:	B6										

			B6	
		United States		
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:	None			
Additional Documents:				

Report Details - EON-380347	
ICSR:	2062998
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-21 08:42:29 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: Reporting a confirmed DCM diagnosis when B6 was 6.5 years old. He is currently 7.5 years old. Previous routine echos showed no DCM. Fed a single grain free diet of 4Health beef and potato for at least 4-5 years. Second routine echocardiogram diagnosed DCM in August 2016. We have taurine tested at UC Davis. We continue to treat the DCM. I do realize that there is probably a genetic component to my danes DCM. I am reporting for a couple reasons. I've been doing a cardiac workup and echocardiogram every 4 months since diagnosis. We taurine tested but did not see a taurine deficiency, so we did not change his diet or supplement with taurine. With the new study that recently came out that showed that even dogs with normal taurine, their DCM improved with changing from a grain free diet and supplementing with taurine. We've done 6 echocardiograms and 24 hour holter on our dog, 5 of them since diagnosis. I'm going to change his food and add a supplement and in June, I'm going to do another echocardiogram. While I think it's pretty good to assume it's probably genetic based because he is a great dane, we will soon see if the changes from grain free will improve his condition. Due to the expense, I doubt there are a lot of DCM dogs on grain free diets, have had as much testing and extensive workups. I'm happy to provide all medical records from diagnosis, and into the future.
	Date Problem Started: 08/28/2016
	Concurrent Medical Problem: Yes
	Pre Existing Conditions: B6
	Outcome to Date: Worse/Declining/Deteriorating
Product Information:	Product Name: 4Health Grain Free Beef and Potato
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Package Size: 30 Pound
	Storage Conditions: Product was removed from package and stored in an air tight container
	Product Use Information: Description: Same product has been fed to our dog for the past 4-5 years
	Manufacturer /Distributor Information:
Purchase Location Information: Name: Tractor Supply	
Animal Information:	Name: B6
	Type Of Species: Dog
	Type Of Breed: Great Dane
	Gender: Male
	Reproductive Status: Neutered
	Weight: 200 Pound
	Age: 7 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 2
Number of Animals 1	

	Reacted:		
	Owner Information:		
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	B6
		Email:	
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	08/28/2016	
	Permission to Release Records to FDA:	Yes	
	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	B6
		Email:	
Address:	B6		
	United States		
Type of Veterinarian:	Primary/regular veterinarian		
Date First Seen:	08/28/2016		
Permission to Release Records to FDA:	Yes		
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	B6
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Additional Documents:			

Report Details - EON-380432

ICSR: 2063024
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2019-02-21 15:58:03 EST
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: B6 was raised on Purina Pro Plan Focus Puppy, transitioned February 2016 to ACANA (rotating proteins). A brief stint with Farmina (2 bags) and Sport Dog Food (1 bag) before being transitioned back to Pro Plan Sport 30/20 May 2018. During B6's time on ACANA I saw a 3 month false pregnancy that only ended with spay. This was confirmed by my vet and likely due to the phytoestrogens in this food. When I changed back to PPS30/20 I removed all suspect ingredients from their diets in both main food as well as treats. No legumes, no potatoes, no soy, no phytoestrogens (including flax). B6 born B6 Results listed with a * are during the period of feeding ACANA. B6 Holter 07/14/2016 PVC Summary : 0 singles, 0 pairs and 0 runs 08/10/2017 PVC Summary : 1 single, 0 pairs and 0 runs* 01/28/2018 PVC Summary : 1 single, 1 pair and 0 runs* ProBNP 12/27/2017 IDEXX B6 10/23/2018 IDEXX B6 Echo 09/02/2016 - Normal / FS B6 07/16/2018 Normal / FS B6 Taurine - whole blood 10/23/2018 UC Davis B6 During B6's time on ACANA she was slow and sluggish, experienced many false pregnancies, did not lactate with her litter of puppies and was very close to suspect DCM based on ProBNP. 8 months after food change her holter, probnp and SDMA results are much better and she is back to having normal energy levels without any sluggishness.

Date Problem Started: 01/01/2017
Date of Recovery: 10/28/2018
Concurrent Medical Problem: No
Outcome to Date: Recovered Completely

Product Information:

Product Name: ACANA - multiple proteins and formulas fed on rotation.
Product Type: Pet Food
Lot Number:
Package Type: BAG
Storage Conditions: rolled and clipped inside the bag and stored in an air tight container

Product Use Information:

Description:	Fed in accordance of the label instructions
First Exposure Date:	02/01/2016
Time Interval between Product Use and Adverse Event:	2 Years
Product Use Stopped After the Onset of the Adverse Event:	No
Perceived Relatedness to Adverse Event:	Definitely related
Other Foods or Products Given to the Animal During This Time Period:	No

Manufacturer /Distributor Information:

	Purchase Location Information:	Name:	B6	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Doberman Pinscher		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	68 Pound		
	Age:	4 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	2		
	Number of Animals Reacted:	2		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
Type of Veterinarian:		Referred veterinarian		
Permission to Release Records to FDA:		Yes		
Practice Name:		B6		
Contact:		Name:	B6	
		Phone:		
Type of Veterinarian:	Primary/regular 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:	Manufacturer			
	Other			
Additional Documents:				

Report Details - EON-380434

ICSR: 2063025
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2019-02-21 16:04:25 EST
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: B6 was raised on Purina Pro Plan Focus Puppy, transitioned September 2017 to ACANA (same rotating proteins as B6). A brief stint with Farmina (2 bags) and Sport Dog Food (1 bag) before being transitioned back to Pro Plan Sport 30/20 May 2018. During B6 time on ACANA she cycled every 4 months (abnormal for her familiar history, all of my bitches cycle every 7 months on the dot), she had horrific false pregnancies and super dry skin. After switching back to Pro Plan Sport 30/20 her heat cycles are back to expected every 7 month rotation. When I changed back to PPS30/20 I removed all suspect ingredients from their diets in both main food as well as treats. No legumes, no potatoes, no soy, no phytoestrogens (including flax), B6 born B6. Results listed with a * are during the period of feeding ACANA. B6 Holter 05/02/2018 PVC Summary: 1 single, 0 pairs and 0 runs. ProBNP 12/27/2017 IDEXX B6 10/23/2018 IDEXX B6 Echo 05/09/2018 - Normal FS B6 Slightly increased flow velocity across the aortic valve identified as the cause of the murmur. Murmur diagnosed as innocent. Taurine - whole blood 10/23/2018 UC Davis B6 Murmur identified at ~9 months by auscultation, confirmed by echo as "innocent" and past the growth period that she would grow out of it per my cardiologist. Unable to be heard as of 10/23/2018. I will confirm that it is gone with the next echo.

Date Problem Started: 09/01/2017
Date of Recovery: 10/01/2018
Concurrent Medical Problem: No
Outcome to Date: Recovered Completely

Product Information:

Product Name: ACANA - rotating proteins
Product Type: Pet Food
Lot Number:
Package Type: BAG
Storage Conditions: kept in original bag, clipped closed and stored in an air tight container

Product Use Information:

Description:	fed following the guidelines on the bag
First Exposure Date:	09/01/2017
Last Exposure Date:	05/01/2018
Perceived Relatedness to Adverse Event:	Definitely related
Other Foods or Products Given to the Animal During This Time Period:	No

Manufacturer /Distributor Information:

Purchase Location Information: Name: B6

Animal Information:

Name: B6
Type Of Species: Dog
Type Of Breed: Doberman Pinscher

	Gender: Female
	Reproductive Status: Intact
	Pregnancy Status: Not pregnant
	Lactation Status: Not lactating
	Weight: 55 Pound
	Age: 1.5 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 2
	Number of Animals Reacted: 2
	Owner Information:
Healthcare Professional Information:	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Permission to Release Records to FDA: Yes
	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Permission to Release Records to FDA: Yes
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: Manufacturer	
Additional Documents:	

Report Details - EON-380450

ICSR:	2063038
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-21 17:45:21 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was breathing heavy and coughing. He was diagnosed with Dilated Cardiomyopathy and Congestive Heart Failure. He tested low in taurine. He was taken off the grain free food and given numerous medications, include taurine supplements
	Date Problem Started:	08/15/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Acana Prairie (also fed Acana Ranchlands and Acana Grasslands all from the Regionals line)		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	00062201153850		
	Package Type:	BAG		
	Package Size:	11.4 kilogram		
	Purchase Date:	08/10/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	food dumped from original bag into a plastic air-tight pet food container		
	Product Use Information:	Description:	fed dry food 2 cups per day	
		First Exposure Date:	08/15/2018	
		Last Exposure Date:	09/15/2018	
Time Interval between Product Use and Adverse Event:		2 Years		
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		Unknown		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Probably related		
Other Foods or Products Given	Yes			

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name:

Address:

B6

Canada

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Retriever - Golden

Gender: Male

Reproductive Status: Neutered

Weight: 86 Pound

Age: 6 Years

Assessment of Prior
Health: Excellent

Number of Animals
Given the Product: 2

Number of Animals
Reacted: 1

Owner Information:

Healthcare Professional
Information:

Practice Name:

B6

Contact: Name:

B6

Phone

B6

Address:

B6

Canada

Date First Seen: 11/26/2018

Permission to
Release Records
to FDA: Yes

Sender Information:

Name:

Address:

B6

Canada

Contact: Phone:

B6

Email:

B6

Permission To Contact
Sender: Yes

Preferred Method Of
Contact: Email

Reported to Other
Parties: Store/Place of Purchase

Additional Documents:

Report Details - EON-381208

ICSR: 2063398
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2019-03-01 11:18:20 EST

Reported Problem:
Problem Description: OFA certification exam. measured equivocal for early DCM.
Date Problem Started: 11/03/2018
Outcome to Date: Died Euthanized
Date of Death: **B6**

Product Information:
Product Name: Earthborn Holistic Venture Duck Meal & Pumpkin formula Limited Ingredient
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Earthborn Holistic Grain Free Great Plains Feast
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: Shepherd Dog - Belgian Tervueren
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Unknown
Lactation Status: Unknown
Age: 3 Years
Number of Animals Reacted: 1
Owner Information: Owner Information provided: No
Healthcare Professional Information:

Sender Information:
Name: **B6**
Address: **B6**
United States
Contact: Phone: **B6**
Email: **B6**

**Reporter Wants to
Remain Anonymous:** No

**Permission To Contact
Sender:** Yes

**Preferred Method Of
Contact:** Phone

Additional Documents:

Report Details - EON-381204

ICSR: 2063397
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-03-01 11:04:33 EST

Reported Problem: **Problem Description:** HISTORY: **B6** a 12 Yrs. 1 Mos., Neutered Male, Pitbull, was presented on 2/25 /2019 for cardiac evaluation. The owner's adopted Igor about 4 months ago from KCPP. The owners note that he was there for about 2 years prior to adoption. He was heartworm positive in the past and was treated. The owner notes that the coughing started shortly after adoption. **B6** will cough intermittently with play /excitement. There are times where he seems to be winded sometimes after exercise, however there are other times where he plays extensively and seems fine. The owner reports that an arrhythmia was noted on exam. No unusual sneezing, vomiting or diarrhea. No polyuria/polydypsia. Appetite and activity level normal. **B6** is fed Nutro Senior formula (grain-free). Current Medications: **B6** PO SID: Fish Oil PO SID Physical Exam HR: 140; RR: Pant Weight: 79.3 lb/33.5 kg Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, no murmur, regular rhythm with fairly frequent single extrasystolic beats, lungs clear, pulses good with occasional deficits. Skin- multiple dermal masses. Normal peripheral lymph nodes Diagnostics Doppler Blood Pressure: 114 mm Hg; # 5 cuff LF ECG: normal sinus rhythm with fairly frequent single monomorphic ventricular premature complexes of RV origin (~30 VPC's/minute); average heart rate of 100 bpm. Echocardiogram: IVSd: **B6**

B6

B6 Left ventricle: - Chamber size: moderately to severely increased end-diastolic dimensions; moderately increased end-systolic dimensions - Free wall thickness: mildly increased - IVS thickness: normal - Shortening fraction: mildly depressed - Global wall movement: normal - E point to septal separation: severely increased Left atrial size: normal Right ventricle: - Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: mildly thickened Tricuspid valve leaflets: mildly thickened Aortic valve leaflets: normal Pulmonic valve leaflets: normal Aortic root: normal Aortic root motion: normal Main pulmonary artery: normal No evidence of pericardial or pleural effusion. CFD/PWD /CWD: - Mitral regurgitation: mild with normal velocities - Tricuspid regurgitation: mild with normal velocities, reflective of normal pulmonary arterial pressures - LVOT: normal flow pattern and velocities. - Aortic insufficiency: none - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none Diagnosis: Moderate to severe left ventricular dilation, mild systolic dysfunction, and ventricular arrhythmia -suspect occult dilated cardiomyopathy (potentially diet-associated DCM vs. idiopathic) Mild myxomatous mitral and tricuspid valve disease Treatment/Medications: **B6** Pharmacy given recent manufacturer's backorder). Discussed 24 hour Holter monitor placement vs. starting **B6** therapy and rechecking an ECG +/- Holter monitor in 1-2 weeks. Owner elected to hold on Holter monitor placement and would like to start **B6** therapy. Discussed whole blood and plasma Taurine levels at UC Davis- owner declined at this time. Plan to start **B6** 80 mg tabs- 1/2 tab PO BID. Recommended transitioning off the grain-free diet to either Royal Canin, Science Diet, Purina or Iams Start Taurine - 1,000 mg PO BID Start L-carnitine- 1,500 mg PO TID with food. continue fish oil supplementation. Recheck ECG in 1-2 weeks +/- place a 24 hour Holter monitor. Recheck echocardiogram and ECG in 3-6 months.

Date Problem Started: 02/25/2019

Outcome to Date: Unknown

Product Information: **Product Name:** Nutro Grain Free Senior Dry Dog Food Farm-Raised Chicken, Lentils and Sweet Potato Recipe
Product Type: Pet Food
Lot Number:
Product Use Information:

	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Pit Bull
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	33.5 Kilogram
	Age:	12 Years
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: No
	Healthcare Professional Information:	Practice Name: B6
		Contact: Name: B6
		Phone: B6
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact: Phone:	B6
	Email:	B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
Additional Documents:		

Report Details - EON-381200

ICSR: 2063391
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2019-03-01 10:24:10 EST

Reported Problem:
Problem Description: HISTORY: B6 a 9 Yrs. 0 Mos., Neutered Male, Terrier, Jack Russell, owned by B6 was presented on B6 for cardiac evaluation. B6 had an event under anesthesia during a dental cleaning in October 2018. He went in to cardiac arrest and was revived. The rDVM records indicate that B6 recovered uneventfully after that. The owner notes that in January B6 had a slip and fall on the ice. He was seen at the rDVM and radiographs looking for back or neck injury. A heart murmur was noted at that time and cardiomegaly was seen on radiographs taken 1/28/19. The owner notes that B6 was subsequently diagnosed with diabetes and started on insulin. B6 has been doing well since then. The owner notes no other concerns. No unusual coughing, sneezing, vomiting or diarrhea. No polyuria/polydypsia. Appetite and activity level normal. B6 is fed Nutro Ultra Small Breed. He has never been a good eater, but his appetite has dramatically improved since starting insulin. He was previously mostly eating peanut butter treats and chicken chews mixed with a small amount of Nutro. He would previously go up to 3 days at a time without eating. He is now consistently eating Nutro small breed wellwith salmon jerky from trader joe's and carrots as snacks. He is current on vaccines and heartworm prevention. Current Medications: B6 Physical Exam HR: 120; RR: 28 Weight: 22.4 lb/10.18 kg Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, grade II/VI left apical systolic murmur, no arrhythmias, lungs clear, pulses good. Skin normal. Musculoskeletal system normal. Normal peripheral lymph nodes Diagnostics ECG: normal sinus rhythm on lead II ECG during echocardiogram. Doppler Blood Pressure: 136 mm Hg. # 3 cuff J.E. Echocardiogram: B6
B6
B6 Left ventricle: - Chamber size: mildly increased end-diastolic and end-systolic dimensions - Free wall thickness: normal - IVS thickness: normal - Shortening fraction: mildly decreased - Global wall movement: normal Left atrial size: normal Right ventricle: - Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: normal; no thickening or prolapse Tricuspid valve leaflets: normal Aortic valve leaflets: normal Pulmonic valve leaflets: normal Aortic root: normal Aortic root motion: normal Main pulmonary artery: normal No evidence of pericardial or pleural effusion. CFD/PWD/CWD: - Mitral regurgitation: mild with normal velocities - Mitral inflows: normal - Mitral annulus motion (TDI): normal - Tricuspid regurgitation: none - LVOT: normal flow pattern and velocities. - Aortic insufficiency: none - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none Diagnosis: Mild systolic dysfunction and mild left ventricular enlargement - rule out early dilated cardiomyopathy (potentially diet-associated vs. idiopathic)
Date Problem Started: 02/26/2019
Outcome to Date: Unknown

Product Information:
Product Name: Nutro Ultra small breed (unknown protein source)
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog

	Type Of Breed:	Terrier - Jack Russell
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	10.18 Kilogram
	Age:	9 Years
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: No
	Healthcare Professional Information:	Practice Name: B6 Contact: Name: B6 Phone: B6
Sender Information:	Name:	B6
	Address:	B6 United States
	Contact:	Phone: B6 Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone

Additional Documents:

Report Details - EON-381209

ICSR:	2063401
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-03-01 11:27:25 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My mixed breed dog who has previously had no health issues since I adopted him in August of 2016 started coughing and had an increased respiratory rate around mid-January 2019. The veterinarian diagnosed him with heart disease and congestive heart failure and placed him on [REDACTED] [REDACTED] [REDACTED] also changed his diet from Taste of the Wild Pacific Stream Grain-free food--which he had been on since I adopted him--to Purina Pro Plan Sensitive Skin and Stomach Salmon and rice dog food because my primary vet stated that his heart problems could be related to a grain-free diet. I was able to take him to [REDACTED] [REDACTED] on 02/26/19 where Dr. [REDACTED] diagnosed him with Degenerative Valvular Disease with Congestive Heart Failure. Dr. [REDACTED] stated "...since he had been switched from a grain free diet, it is difficult to know whether he had poor contractility at the start of this disease although this would not have changed the appearance of his valve." Dr. [REDACTED] started him also on [REDACTED] [REDACTED] and stated that my dog's prognosis is that he likely won't live more than 9-12 months. Perhaps if he hadn't been on Taste of the Wild food that could have caused loss of contractility of his heart, my dog's heart valve wouldn't have started such a downward spiral. They need to take this food and other grain-free foods off the market because it is killing dogs. Now I have to have my other 6 dogs tested for possible cardiomyopathy related to a grain-free diet.
	Date Problem Started:	01/18/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Taste of the Wild Pacific Stream Canine Recipe with Smoked Salmon A Grain-Free Diet		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	12/15/2018		
	Number Purchased:	2		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in closet in bag before opening. After opening, stored in air-tight plastic pet food container.		
	Product Use Information:	Description:	Fed to 7 dogs dry twice daily.	
		First Exposure Date:	12/16/2018	
		Last Exposure Date:	01/20/2019	
Time Interval between Product Use and Adverse Event:		1 Months		
Product Use Stopped After the Onset of the		Yes		

Adverse Event:	
Adverse Event Abate After Product Stop:	Unknown
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Definitely related
Other Foods or Products Given to the Animal During This Time Period:	No

Manufacturer /Distributor Information:					
Purchase Location Information:	<table border="1"> <tr> <td>Name:</td> <td>Amazon</td> </tr> <tr> <td>Address:</td> <td>United States</td> </tr> </table>	Name:	Amazon	Address:	United States
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Address:	United States				

Animal Information:	Name:	B6																																	
	Type Of Species:	Dog																																	
	Type Of Breed:	Other Canine/dog																																	
	Gender:	Male																																	
	Reproductive Status:	Neutered																																	
	Weight:	23 Pound																																	
	Age:	7 Years																																	
	Assessment of Prior Health:	Excellent																																	
	Number of Animals Given the Product:	7																																	
	Number of Animals Reacted:	1																																	
	Owner Information:																																		
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Other Phone:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td> <table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> <tr> <td>Type of Veterinarian:</td> <td>Primary/regular veterinarian</td> </tr> <tr> <td>Date First Seen:</td> <td>01/18/2019</td> </tr> <tr> <td>Permission to Release Records to FDA:</td> <td>Yes</td> </tr> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Other Phone:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td> <table border="1"> <tr> <td>B6</td> </tr> </table> </td> </tr> </table>	Practice Name:	B6	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Other Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:	B6	Other Phone:		Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States	Type of Veterinarian:	Primary/regular veterinarian	Date First Seen:	01/18/2019	Permission to Release Records to FDA:	Yes	Practice Name:	B6	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Other Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:	B6	Other Phone:		Address:	<table border="1"> <tr> <td>B6</td> </tr> </table>	B6
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Permission to Release Records to FDA:	Yes																																		
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			B6
		United States	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	01/28/2019	
	Permission to Release Records to FDA:	Yes	
	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	B6
		Other Phone:	
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	02/26/2019	
	Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Other Phone:	B6
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Manufacturer	

Additional Documents:

Report Details - EON-382083

ICSR: 2063822
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2019-03-11 14:58:55 EDT

Reported Problem:

Problem Description: B6 was brought into our clinic on an emergency basis d B6 is breathing was labored and was very lethargic. During exam, a grade 4/6 heart murmur was noted. On radio-graphs lateral and VD of thorax, heart appears enlarged with left atrial enlargement and round appearance. Appearance on VD radio graph, lungs have increased in opacity, suggestive of edema. B6 was given B6 B6 tab PO BID x30. 60ct B6 had a follow up appointment on 2-4-19. murmur was stable from previous descriptions, lungs clear, Chronic Heart Failure was stable at this time. Continue on same medications as first appointment. On 2-11-19 B6 was seen from vomiting and diarrhea. NSF, was given B6 B6 PO BID x10, 20 ct. B6 was also placed on a GI diet and continued current medications. On 2-22-19 B6 had a echocardiogram with a specialist. The echocardiogram report noted no masses or effusions. Severe dilation of the left ventricle causing mitral valve insufficiency, which are consistent with dilate cardiomyopathy. On 3-5-19 echocardiogram findings were discussed with the owner.

Date Problem Started: 01/28/2019
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:

Product Name: Earthborn Holistic Meadow Feast Grain Free
Product Type: Pet Food
Lot Number:
UPC: 034846719123
Package Type: BAG
Package Size: 28 Pound
Purchase Date: 01/07/2019
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: Owner left food in a bag in a galvanized trash can with a tight lid.

Product Use Information:

Description:	Was given in the morning and "free feed." Approximately 2-3 cups per day.
First Exposure Date:	01/07/2019
Last Exposure Date:	01/26/2019
Time Interval between Product Use and Adverse Event:	19 Days
Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	No

Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Probably related
Other Foods or Products Given to the Animal During This Time Period:	No

Manufacturer /Distributor Information:

Purchase Location Information:	Name:	B6
	Address:	
		United States

Animal Information:

Name:	B6	
Type Of Species:	Dog	
Type Of Breed:	Setter - Gordon	
Gender:	Male	
Reproductive Status:	Intact	
Weight:	63.8 Pound	
Age:	7 Years	
Assessment of Prior Health:	Good	
Number of Animals Given the Product:	1	
Number of Animals Reacted:	1	
Owner Information:	Owner Information provided:	Yes
	Contact: Name:	B6
	Phone:	B6
Address:	B6	
	United States	
Healthcare Professional Information:	Practice Name:	B6
	Contact: Name:	B6
	Phone:	B6
Address:	B6	
	United States	

Sender Information:

Name:	B6	
Address:	B6	
		United States

	Contact:	Phone:	B6
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
	Reported to Other Parties:	None	
Additional Documents:	Attachment:	B6	echo.pdf
	Description:		echocardiogram results
	Type:	Echocardiogram	
	Attachment:	B6	pt chart.pdf
	Description:		chart information
	Type:	Medical Records	

Report Details - EON-382084

ICSR: 2063823
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Both
Reporting Type: Voluntary
Report Submission Date: 2019-03-11 14:59:57 EDT

Reported Problem:
Problem Description: B6 was transferred to B6 from B6 for further diagnostics and treatment for congestive heart failure. She was presented to B6 for cardiomegaly and suspected heart failure diagnosed by her regular vet. She had a one week duration of progressive anorexia, labored breathing, coughing, and tachycardia. She was started on B6. B6 Since starting medications her appetite and energy level has greatly improved.
Date Problem Started: 02/25/2019
Date of Recovery: 03/04/2019
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Fromm adult gold with grain
Product Type: Pet Food
Lot Number:
Product Use Information: **First Exposure Date:** 02/18/2019
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Nu10 grain-free lamb
Product Type: Pet Food
Lot Number:
Product Use Information: **Last Exposure Date:** 02/18/2019
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Weimaraner
Gender: Female
Reproductive Status: Neutered
Weight: 32 Kilogram
Age: 6 Years
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** Yes
Contact: **Name:** B6
Phone: B6
Address: B6

		B6	
		United States	
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	
		Phone:	B6
		Other Phone:	
Email:			
Address:	B6		
		United States	
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Other Phone:	
		Email:	
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Additional Documents:			

Report Details - EON-382300

ICSR:	2063944
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-03-13 15:01:11 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dog has been eating Halo brand Senior Dog kibble for the last two years. She was healthy when I started giving her the food. She has since developed canine dilated cardiomyopathy (DCM) and her heart was nearly twice as large as it should be. After being diagnosed last Thursday 3/7/19, she was prescribed three different heart medications. I was doing some research and saw that the FDA issued an alert for grain-free pet food with top ingredients of lentils, potatoes and peas causing DCM and saw that the ingredients you listed were in my dog's food which I have been purchasing from Whole Foods and Chewy. Here are the main ingredients as taken from their website: Turkey dried chickpeas dried lentil dried peas dried egg product turkey liver dried sweet potato duck pea fiber.... The reason I brought my dog to the vet was to have her teeth cleaned but then this was discovered and I thought I should let you know.
	Date Problem Started:	03/07/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	Halo Grain Free Senior Dog Holistic Turkey, Turkey Liver & Duck		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	21518 AC24 1735	
		Expiration Date:	02/02/2020	
	UPC:	45158 37061		
	Package Type:	BAG		
	Package Size:	10 Pound		
	Purchase Date:	01/23/2019		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	in a cool dry place		
	Product Use Information:	Description:	poured into dog's food bowl as recommended approx 1 cup per day	
		First Exposure Date:	01/25/2019	
	Last Exposure Date:	03/09/2019		
	Time Interval between Product Use and Adverse Event:	2 Weeks		
	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: Name: Chewy.com

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Mixed (Dog)

Gender: Female

Reproductive Status: Neutered

Weight: 12 Pound

Age: 10 Years

Assessment of Prior Health: Good

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional Information: Practice Name: B6

Contact: Name:

Phone: B6

Email: B6

Address: B6

United States

Type of Veterinarian: Primary/regular veterinarian

Date First Seen: 03/07/2019

Permission to Release Records to FDA: No

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: Distributor, Store/Place of Purchase, Manufacturer, Other

Additional Documents:

Report Details - EON-382274	
ICSR:	2063936
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-03-13 12:42:13 EDT
Reported Problem:	<p>Problem Description: Dilated cardiomyopathy diagnosed; B6 Congestive heart failure. Euthanized B6 for V-tach and VPC while in intensive care at B6 B6 Board certified Cardiologist, Dr. B6 report stated: "Echocardiogram: The LV is dilated secondary to poor systolic function. There is marked left atrial enlargement. FS=18% Color Flow: No evidence of valvular insufficiency. B6 heart was radiographically normal August 17, 2017. Owner feeding grain free food (Kirkland Nature's Domain Salmon Meal and Sweet Potato) since June 2018. Previous diet: Royal Canin Pure Elite Lamb.</p> <p>Date Problem Started: B6</p> <p>Concurrent Medical Problem: Yes</p> <p>Pre Existing Conditions: B6</p> <p>Outcome to Date: Died Euthanized</p> <p>Date of Death: B6</p>
Product Information:	<p>Product Name: Kirkland Nature's Domain Salmon and Sweet Potato</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Package Type: BAG</p> <p>Possess Unopened Product: Unknown</p> <p>Possess Opened Product: Yes</p> <p>Product Use Information:</p> <p>First Exposure Date: 06/01/2018</p> <p>Last Exposure Date: B6</p> <p>Product Use Stopped After the Onset of the Adverse Event: Yes</p> <p>Adverse Event Abate After Product Stop: Not Applicable</p> <p>Product Use Started Again: No</p> <p>Perceived Relatedness to Adverse Event: Probably related</p> <p>Manufacturer /Distributor Information:</p> <p>Purchase Location Information:</p>
Animal Information:	<p>Name: B6</p> <p>Type Of Species: Dog</p> <p>Type Of Breed: Bulldog - American</p> <p>Gender: Male</p> <p>Reproductive Status: Intact</p>

	Weight:	82 Pound														
	Age:	7 Years														
	Assessment of Prior Health:	Good														
	Number of Animals Given the Product:	1														
	Number of Animals Reacted:	1														
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td> <table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	Owner Information provided:	Yes	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States		
Owner Information provided:	Yes															
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Phone:	B6															
Email:																
	Permission To Contact Sender:	Yes														
	Preferred Method Of Contact:	Email														
	Reported to Other Parties:	None														

Additional Documents:

Report Details - EON-382285		
ICSR:	2063940	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-03-13 13:36:43 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: With physical exam B6 found to have a heart murmur and x-rays noted heart enlargement. Echocardiogram results indicated dilated cardiomyopathy. The cardiologist reported the cardiomyopathy was probably diet-related due to B6 diet history. X-rays from July 2018 note heart normal size.	
	Date Problem Started: 03/04/2019	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6 and taking replacement medication.	
	Outcome to Date: Stable	
Product Information:	Product Name: Zignature Turkey Formula Limited Ingredient (Grain-Free Turkey and Chickpea)	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 27 Pound	
	Purchase Date: 11/24/2017	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Dog food was kept in original package before using. After opening the, dog food was kept in a metal container with a lid. I last purchased a bag of Zignature Turkey on 1/20/2019 from chewy.com.	
	Product Use Information:	Description: B6 was fed Zignature dry dog food 2 cups twice a day.
		First Exposure Date: 11/29/2017
		Last Exposure Date: 03/07/2019
Time Interval between Product Use and Adverse Event: 15 Months		
Product Use Stopped After the Onset of the Adverse Event: Yes		
Adverse Event Abate After Product Stop: Unknown		
Product Use Started Again: No		
Perceived Relatedness to Adverse Event: Probably related		
Other Foods or Products Given to the Animal: Yes		

During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name:

Chewy.com

Address:

3251 Hollywood Blvd
Hollywood
Florida
33021
United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Shepherd Dog - German

Gender: Female

Reproductive Status: Neutered

Weight: 26 Kilogram

Age: 11.5 Years

Assessment of Prior
Health: Good

Number of Animals
Given the Product: 2

Number of Animals
Reacted: 1

Owner Information:

Healthcare Professional
Information:

Practice Name:

B6

Contact:

Name:

Phone:

Other Phone:

Email:

B6

Address:

B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: 03/04/2019

Permission to
Release Records
to FDA: Yes

Sender Information:

Name:

Address:

B6

United States

Contact:

Phone:

Other Phone:

Email:

B6

Reporter Wants to
Remain Anonymous: No

Permission To Contact
Sender: Yes

Preferred Method Of
Contact: Email

	Reported to Other Parties:	Other
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Additional Documents:	
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Report Details - EON-360076

ICSR:	2052589
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-07-23 12:45:00 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	After reading your article about DCM from grain-free dog food and dogs developing DCM, I became very concerned that a this is what happened to my 3 dogs. On [B6] I had to put my 2 twin boxers to sleep and on [B6] another one of our dogs. All 3 had the exact symptoms listed in your arctic length with enlarged hears, coughing, fluid retention, pneumonia. Medicine did not help with these conditions, they only worsened.
	Date Problem Started:	05/01/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Taste of the Wild Prey Turkey Taste of the Wild Prey Salmon Taste of The Wild Bison Taste of the Wild Turkey	
	Product Type:	Pet Food	
	Lot Number:	Lot Number: POT1006-17 TEG 01:33 Expiration Date: 10/14/2018	
	UPC:	7419861364	
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	06/13/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	In the bag in a sealed plastic container	
	Product Use Information:	Description:	One cup twice per day with water added. The dogs are monitored while eating.
		Last Exposure Date:	[B6]
		Time Interval between Product Use and Adverse Event:	5 Years
		Product Use Stopped After the Onset of the Adverse Event:	No
Perceived Relatedness to Adverse Event:		Definitely related	
Other Foods or Products Given to the Animal During This Time Period:		Yes	

	Manufacturer /Distributor Information:	
	Purchase Location Information:	Name: [Redacted] Address: [Redacted] United States
Animal Information:	Name:	[Redacted]
	Type Of Species:	Dog
	Type Of Breed:	Boxer (German Boxer)
	Gender:	Mixed Population of Female and Male
	Reproductive Status:	Neutered
	Weight:	60 Pound
	Age:	10 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	6
	Number of Animals Reacted:	3
	Owner Information:	
	Healthcare Professional Information:	Practice Name: [Redacted] Contact: Name: [Redacted] Phone: [Redacted] Address: [Redacted] United States Type of Veterinarian: Primary/regular veterinarian Date First Seen: 05/01/2018 Permission to Release Records to FDA: Yes
Sender Information:	Name:	[Redacted]
	Address:	[Redacted] United States
	Contact:	Phone: [Redacted] Email: [Redacted]
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other Manufacturer Store/Place of Purchase
Additional Documents:		

Report Details - EON-360095

ICSR:	2052602
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:	2018-07-23 14:57:29 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	As of 2 1/2 years ago, my dog was diagnosed with the beginning stages of congested heart failure
	Date Problem Started:	10/01/2016
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	As a puppy he was allergic to grains. That is why we chose a grain free food
	Outcome to Date:	Stable

Product Information:	Product Name:	Taste of the Wild Sierra Mountain Canine Recipe
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	in a plastic sealed container

Product Use Information:	Description:	It was given to my dog for breakfast and dinner in his bowl since he was a puppy
	Last Exposure Date:	07/23/2018
	Time Interval between Product Use and Adverse Event:	9 Years
	Product Use Stopped After the Onset of the Adverse Event:	No
	Perceived Relatedness to Adverse Event:	Definitely related
	Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:	

Purchase Location Information:	Name:	
	Address:	B6 United States

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Schnauzer - Miniature

	Gender: Male
	Reproductive Status: Neutered
	Weight: 20 Pound
	Age: 9 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
	Healthcare Professional Information:
Sender Information:	Name: [Redacted]
	Address: [Redacted]
	United States
	Contact: [Redacted]
	Email: [Redacted]
	Reporter Wants to Remain Anonymous: No
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
Reported to Other Parties: Store/Place of Purchase	

Additional Documents:

Report Details - EON-360243

ICSR: 2052690
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-07-24 21:19:56 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: He's been eating grain-free food since 2015 (Orijen and Acana), but I switched him to Zignature brand whitefish limited ingredient diet in June of 2017. In August of 2017, his veterinarian heard a heart murmur, which got progressively worse. He's been lethargic and slow lately, panting often, and restless at night. We didn't connect the murmur and his lethargy to a possible food issue until a month ago, when I read a report about grain-free and boutique diets being linked to dilated cardiomyopathy, so had a consult with a cardiologist on July 24, 2018, and he confirmed that **B6** does indeed have mild DCM which he believes to be diet related. He is starting on heart medication, and will also start taurine supplementation once the bloodwork comes back with his taurine levels.

Date Problem Started: 06/22/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: **B6** level is normal on his current dosage.

Outcome to Date: Stable

Product Information:

Product Name: Zignature Whitefish Limited Ingredient Formula Grain-Free Dry Dog Food

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 27 Pound

Purchase Date: 05/26/2018

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: Yes

Storage Conditions: In bag in a sealed storage bin in kitchen

Product Use Information:

Description: Fed twice daily

First Exposure Date: 05/26/2018

Last Exposure Date: 06/26/2018

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: Chewy.com

Address: United States

Animal Information: Name: **B6**

	Type Of Species: Dog
	Type Of Breed: Mixed (Dog)
	Gender: Male
	Reproductive Status: Neutered
	Weight: 50 Pound
	Age: 9 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
Healthcare Professional Information:	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Email: B6
	Address: B6
	United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 06/22/2018
	Permission to Release Records to FDA: Yes
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: None	
Additional Documents:	

Report Details - EON-373343

ICSR: 2059868
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-12-09 11:56:53 EST
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: Dog began displaying signs of lethargy. Very active dog became less active fairly rapidly. Breathing became labored one evening. The dog was hospitalized for a few days and was diagnosed with DCM by cardiologist. Dog is currently begin treated for environmentally caused DCM. Dog was previously on grain free diet for all 11 years of life.

Date Problem Started: 12/01/2018

Concurrent Medical Problem: No

Outcome to Date: Stable

Product Information:

Product Name: Blue Buffalo Wilderness Grain Free

Product Type: Pet Food

Lot Number:

Package Type: BAG

Purchase Date: 12/01/2015

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: Airtight plastic container.

Product Use Information:

Description: Fed daily.

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: No

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Taste of the Wild Grain Free

Product Type: Pet Food

Lot Number:

Package Type: BAG

Purchase Date: 09/01/2017

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: Airtight plastic container.

Product Use Information:	Description:	Fed daily.
	Product Use Stopped After the Onset of the Adverse Event:	No
	Perceived Relatedness to Adverse Event:	Possibly related
Manufacturer /Distributor Information:		
Purchase Location Information:		
Product Name:	American Journey Grain Free	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Purchase Date:	07/01/2018	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Product Use Information:	Description:	Fed daily.
	Product Use Stopped After the Onset of the Adverse Event:	No
	Perceived Relatedness to Adverse Event:	Possibly related
Manufacturer /Distributor Information:		
Purchase Location Information:		
Product Name:	Merrick Grain Free Senior	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Purchase Date:	11/01/2018	
Number Purchased:	2	
Possess Unopened Product:	No	
Possess Opened Product:	Yes	
Storage Conditions:	Airtight plastic container.	
Product Use Information:	Description:	Fed to dog daily.
	Time Interval between Product Use and Adverse Event:	6 Months
	Product Use Stopped After the Onset of the Adverse Event:	Yes
	Perceived Relatedness to Adverse Event:	Possibly related
	Other Foods or	No

Products Given to the Animal During This Time Period:

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Pointing Dog - German Short-haired

Gender: Male

Reproductive Status: Neutered

Weight: 80 Pound

Age: 11 Years

Assessment of Prior Health: Excellent

Number of Animals Given the Product: 2

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional Information:

Practice Name:

B6

Contact:

Name:

B6

Phone:

Date First Seen: 12/01/2018

Permission to Release Records to FDA: No

Sender Information:

Name:

Address:

B6

United States

Contact:

Phone:

B6

Email:

Reporter Wants to Remain Anonymous: No

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Additional Documents:

Report Details - EON-373233

ICSR:	2059844
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-12-07 17:27:15 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Diagnosed with dilated cardiomyopathy after fainting spells
	Date Problem Started:	01/01/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Natural Balance Fat Dogs Dry Food	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	numerous	
	Package Type:	BAG	
	Package Size:	15 Pound	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	in a sealed container	
	Product Use Information:	Description:	Given as main source of food over 6 years
		First Exposure Date:	06/02/2012
		Last Exposure Date:	06/01/2018
		Time Interval between Product Use and Adverse Event:	5 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:		No	
Product Use Started Again:		No	
Perceived Relatedness to Adverse Event:		Definitely related	
Other Foods or Products Given to the Animal During This Time Period:		Yes	
Manufacturer /Distributor Information:			
Purchase Location	Name:	Petco	

	Information:	Address:	B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Schnauzer - Miniature		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	21 Pound		
	Age:	13 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	B6
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		05/15/2018		
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6		
	Address:	B6		
		United States		
	Contact:	Phone:	B6	
Email:		B6		
Reporter Wants to Remain Anonymous:	No			
Permission To Contact Sender:	Yes			
Preferred Method Of Contact:	Email			
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-373364		
ICSR:	2059874	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-12-09 18:09:10 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description:	On Monday 12/3/18 my dog started having diarrhea for several days and wouldn't eat or drink much water and was very lethargic. I took her to our vet Wednesday afternoon to have her checked. She had a 104 fever and we found out she was anemic. They took a blood sample to run all labs which we would get the next day. We went back the next day to find out her lab work was horrible, low white blood cells and not making new red blood cells. All labs either too high or too low. They did an X-ray and ultrasound and thought she could be bleeding internally. When her liver and spleen and lungs looked fine, they thought had a infection of some kind or possibly thought it could be autoimmune disease in her bones or bone cancer if not an infection because her labs were so bad. Her temperature was now 105. She started antibiotics that day. We took her in the next day to get another temperature check and this time it was down to 98 which is bad because too low for a dog. The low temperature can be indicative of a heart issue. He noticed from the X-ray that her heart was slightly enlarged and felt that her infection could be sepsis because her heart rate was so low and also irregular and that the blood wasn't moving through her body fast enough so could be causing the infection. He started her on heart meds in addition to the antibiotics. She is slowly eating and drinking again and starting to get some energy back. I also called the ER vet the next day because she was so lethargic that morning. Both vets had asked me what her food was. B6 had been on a grain free diet the past 1.5 years containing lentils, sweet potatoes and chickpeas. All of which I am now finding out could be linked to an enlarged heart. She is taking baby steps each day but is still low energy and only eating and drinking some. I feel her dog food caused her to have the enlarged heart and the heart issues. Our vet had diagnosed her with DCM after hearing her very low heart rate and looking at her Xray of the enlarged heart. She now has to take these pills for life. We still plan to have an echo cardiogram done once she is feeling better but that requires going to the ER vet and spending another \$700-\$1000. She was a very healthy dog prior to Monday. We are happy she is alive but feel this food should be recalled as more cases are sure to come out about how the grain free food is hurting dogs.
	Date Problem Started:	12/03/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable
Product Information:	Product Name:	Nutri Source Super Premium Pet Foods, Pure Vita Holistic Pet Foods. Flavors used: salmon& pea, Duck & green lentils, Turkey & Sweet potatoes, Beef & Red Lentils, Venison& red Lentils
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	15 Pound
	Purchase Date:	11/20/2018
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	In the original bag inside a plastic container with a lid.
Product Use Information:	Description:	Feed 1 scoopful daily for past 1.5 years.
	Last Exposure	12/01/2018

		Date:	
		Time Interval between Product Use and Adverse Event:	1 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	No
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	
		Address:	B6
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Terrier - Tibetan	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	26 Pound	
	Age:	9 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:		
Sender Information:	Name:	B6	
	Address:	B6	
			United States
	Contact:	Phone:	
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other	Store/Place of Purchase	

Parties:

Additional Documents:

Report Details - EON-373297

ICSR:	2059859
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-12-08 11:16:43 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Dog diagnosed with dilated cardiomyopathy after eating grain free dog food.
	Date Problem Started:	11/19/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Taste Of The Wild Grain Free High Protein Dry Dog Food High Prairie Adult - Venison & Bison		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Purchase Date:	10/01/2018		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	As soon as it was opened, it was poured into buckets with screw on lids.		
	Product Use Information:	Description:	This was my dogs only dog food for slightly over a year. Prior to that she ate the same brand in a puppy version, also grain free.	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	No	
		Product Use Started Again:	No	
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:		No		
Manufacturer /Distributor Information:				
Purchase Location Information:				

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	50 Pound

	Age:	2 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	
		Phone:	B6
		Email:	
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	11/19/2018	
Permission to Release Records to FDA:	Yes		
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email		
Reported to Other Parties:	Other		
Additional Documents:			

Report Details - EON-373440

ICSR: 2059945
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-12-10 16:47:43 EST

Reported Problem:
Problem Description: B6 began coughing primarily during the night time. He also started to become lethargic and inappetent. Radiographs were completed and B6 has a VHS score of B6
Date Problem Started: 12/07/2018
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: ACANA Grain Free Diets Rotate flavours each time, have fed Free Run Duck, Pork, & Lamb.
Product Type: Pet Food
Lot Number:
Package Type: BAG
Purchase Date: 12/01/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: Stored in plastic container
Product Use Information:
Description: B6 gets fed 3 cups per day
Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:
Purchase Location Information: Name: B6
Address: Canada

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Pointer - German Longhaired
Gender: Male
Reproductive Status: Neutered
Weight: 31.9 Kilogram
Age: 3 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
	Contact: Phone:	B6
	Address:	B6 Canada
Healthcare Professional Information:	Practice Name:	B6
	Contact: Name:	B6
	Contact: Phone:	
	Contact: Other Phone:	
Contact: Email:		
Address:	B6 Canada	
Sender Information:	Name:	B6
	Address:	
		Canada
	Contact: Phone:	B6
	Contact: Other Phone:	
Contact: Email:		
Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email	

Additional Documents:

Report Details - EON-373450

ICSR: 2059957
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-12-10 18:02:56 EST
Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: My 8 year old dog started to lose her hair on her flanks, so I thought she might have an allergy to something she was eating. I switched her to a Limited Ingredient Diet and her hair improved but she started gaining weight too quickly without changing her activity level. After consulting with my vet we changed her to Blue Buffalo Grain free food for a year without much weight loss. We then changed her to Blue Buffalo Freedom Grain Free Senior dog food. After being on that for 2 years she developed Dilated Cardiomyopathy (DCM) at the age of 10. She is now stable while taking **B6** under a veterinary cardiologists care.

Date Problem Started: 11/01/2016
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: Blue Buffalo Freedom Grain Free Senior
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:

Name:
Type Of Species: Dog
Type Of Breed: Boxer (German Boxer)
Gender: Female
Reproductive Status: Neutered
Weight: 65 Pound
Age: 10 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information:
Healthcare Professional Information: **Contact:** **Name:** **B6** **Phone:**

Sender Information:

Name:
Address: **B6**
United States
Contact:
Reporter Wants to Remain Anonymous: Yes
Reported to Other: None

Parties:

Additional Documents:

Report Details - EON-373433

ICSR: 2059941
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-12-10 15:49:41 EST

Reported Problem:

Problem Description: Patient was being fed primarily California Naturals Lamb and Rice diet, owner would occasionally alternate to fish or duck diets also from California naturals, and developed nutritional dilated cardiomyopathy. With diet change and taurine supplementation the dilated cardiomyopathy resolved.

Date Problem Started: 07/28/2016
Date of Recovery: 02/15/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Recovered Completely

Product Information:

Product Name: California Natural Limited Ingredient Diets Lamb Meal and Rice Adult
Product Type: Pet Food
Lot Number:
Package Type: BAG
Purchase Date: 08/01/2016
Possess Unopened Product: Unknown
Possess Opened Product: Unknown
Storage Conditions: Unknown

Product Use Information:

Description: Patient was being fed 1 cup of food daily

Last Exposure Date: 08/09/2016
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: Definitely related
Other Foods or Products Given to the Animal During This Time Period: Unknown

Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:

Name: B6
Type Of Species: Dog
Type Of Breed: Whippet
Gender: Female
Reproductive Status: Neutered

Weight: 9.5 Kilogram

Age: 12 Years

Assessment of Prior Health: Unknown

Number of Animals Reacted: 1

Owner Information:

Owner Information provided: Yes

Contact: Name: [Redacted] Phone: [Redacted] **B6**

Address: [Redacted] **B6**

United States

Healthcare Professional Information:

Practice Name: [Redacted] **B6**

Contact: Name: [Redacted] Phone: [Redacted] Email: [Redacted] **B6**

Address: [Redacted] **B6**

United States

Practice Name: [Redacted] **B6**

Contact: Name: [Redacted] Phone: [Redacted] **B6**

Address: [Redacted] **B6**

United States

Type of Veterinarian: Referred veterinarian

Date First Seen: 07/28/2016

Permission to Release Records to FDA: Yes

Practice Name: [Redacted] **B6**

Contact: Name: [Redacted] Phone: [Redacted] **B6**

Address: [Redacted] **B6**

United States

Type of Veterinarian: Primary/regular veterinarian

Sender Information:

Name: [Redacted]

Address: [Redacted] **B6**

United States

	Contact:	Phone:	B6
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Unknown	

Additional Documents:

Report Details - EON-373373

ICSR: 2059879
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-12-09 21:47:01 EST
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Decreased exercise tolerance. Vet heard murmur . X-ray showed enlarged heart. Pro bnp showed heart issue. Echo showed suspect diet induced dilated cardiomyopathy.
Date Problem Started: 10/01/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Died Other
Date of Death: B6

Product Information:
Product Name: Acana pacifica
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 35 Pound
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: pantry
Product Use Information:
Description: fed to dog twice a day for 2 years
First Exposure Date: 07/01/2015
Perceived Relatedness to Adverse Event: Probably related
Manufacturer /Distributor Information:
Purchase Location Information:
Name:
Address: B6
 United States

Product Name: Go Salmon
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 35 Pound
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: in pantry
Product Use Information:
Description: Feed twice per day for approximately 2 years

First Exposure Date:	10/11/2016
Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	Unknown
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Probably related

Manufacturer /Distributor Information:

Purchase Location Information:	Name:	B6
	Address:	
		United States

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Retriever - Golden
Gender:	Male
Reproductive Status:	Intact
Weight:	70 Pound
Age:	4 Years
Assessment of Prior Health:	Good
Number of Animals Given the Product:	1
Number of Animals Reacted:	1

Owner Information:

Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6 Phone: B6
Type of Veterinarian:		Primary/regular veterinarian
Date First Seen:		09/19/2018
Permission to Release Records to FDA:		Yes
Practice Name:	B6	
	Contact:	Name: B6 Phone: B6 Email: B6
Address:	B6	
	United States	
Type of Veterinarian:	Referred veterinarian	

Date First Seen: 10/01/2018

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: Phone

Reported to Other Parties: Store/Place of Purchase

Additional Documents:

Report Details - EON-373573

ICSR: 2060054
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-12-11 18:14:02 EST
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: My dog has developed DCM after eating grain free/legume-based diet for most of her life. (Orijens brand and then Acana, later in ilfe).
Date Problem Started: 03/07/2018
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Acana Singles Pork and Squash
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Orijen Original Dog Food
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: American Pit Bull Terrier
Gender: Female
Reproductive Status: Neutered
Weight: 20 Kilogram
Age: 9 Years
Assessment of Prior Health: Good
Number of Animals Reacted: 1
Owner Information:
Healthcare Professional Information: Practice Name: B6
 Contact: Name: B6

		Phone:	B6
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	03/27/2018	
	Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

Report Details - EON-373483

ICSR:	2059982
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-12-11 09:32:44 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	She was diagnosed with DCM after having breathing issues. She has been fed Taste of the Wild for her whole life, and is very active. Her Taurine levels are normal (B6), but my vet still said to switch the diet, because of the possibility of nutritional deficiencies. I hope this helps add to the research being done, also, B6 is still alive after being in congestive heart failure. Have a nice day
	Date Problem Started:	11/30/2018
	Date of Recovery:	12/04/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	She has B6 no medications though
	Outcome to Date:	Stable

Product Information:	Product Name:	Taste of the Wild	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	11/01/2018	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Stored in the bag, in the closet.	
	Product Use Information:	Description:	fed 3 handfuls, twice a day, once in the morning and once at night.
		First Exposure Date:	11/06/2018
		Last Exposure Date:	11/20/2018
		Time Interval between Product Use and Adverse Event:	4 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:		Unknown	
Product Use Started Again:		No	
Perceived Relatedness to Adverse Event:		Possibly related	
Other Foods or Products Given to the Animal		No	

During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name:

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: American Pit Bull Terrier

Gender: Female

Reproductive Status: Neutered

Weight: 48 Pound

Age: 4 Years

Assessment of Prior
Health: Good

Number of Animals
Given the Product: 2

Number of Animals
Reacted: 1

Owner Information:

Healthcare Professional
Information:

Practice Name:

B6

Contact:

Name:

B6

Phone:

Address:

B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: 11/30/2018

Permission to
Release Records
to FDA: Yes

Sender Information:

Name:

B6

Address:

United States

Contact:

Phone:

B6

Email:

Permission To Contact
Sender: Yes

Preferred Method Of
Contact: Phone

Reported to Other
Parties: Manufacturer

Additional Documents:

Report Details - EON-373569		
ICSR:	2060048	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2018-12-11 17:14:21 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Because of a lack of the amino acid Taurine in the Taste of the Wild dog food "High Prairie" B6 has developed "Dilated Cardiomyopathy".	
	Date Problem Started: 07/01/2018	
	Date of Recovery: 11/30/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: Taste of the Wild High Prairie	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 30 Pound	
	Purchase Date: 12/01/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Cool spot in closet in it's bag then poured into a plastic covered container	
	Product Use Information:	Description: One cup of dry food twice a day lacked the Taurine
		Last Exposure Date: 12/11/2018
		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:	Name: Chewy	
	Address: United States	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Retriever - Golden	
	Gender: Male	
	Reproductive Status: Neutered	
Weight: 78 Pound		

	Age:	9 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	B6
		Email:	B6
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	08/22/2018	
	Permission to Release Records to FDA:	Yes	
	Sender Information:	Name:	B6
	Address:	B6	
	United States		
	Contact:	Phone:	B6
		Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

Report Details - EON-373371

ICSR:	2059878
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-12-09 21:21:18 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	He had previously been on 4Health Turkey grain free but we switched him to Zignature turkey grain free. He ended up with congestive heart failure before we knew what had happened and we had him put to sleep. He degraded very quickly. He started having a cough. We took him to our vet, who thought it was an upper respiratory infection. This was on [B6] By Sunday evening, [B6] he was struggling to breathe. We took him to emergency and they told us he likely would not survive the night. We had him put to sleep but it was so astonishing to us that we had a necropsy done. The necropsy showed that he had dilated cardiomyopathy and that he had congestion in his lungs and chronic disease in his liver, secondary to the heart failure. He had been on zignature for about a year. He was only 6 years old. I know many of his relatives and some of his ancestors and there was no known heredity tendency to have the dilated cardiomyopathy. The date I show below is an approximate date when we first noticed coughing. I will provide necropsy results if desired.
	Date Problem Started:	[B6]
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Died Euthanized

Product Information:	Product Name:	Zignature Turkey Formula Limited Ingredient Formula	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	27 Pound	
	Purchase Date:	09/10/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In a sealed plastic bin	
	Product Use Information:	Description:	He got 1 cup of this food twice per day
		First Exposure Date:	09/20/2018
Last Exposure Date:		[B6]	
Product Use Stopped After the Onset of the Adverse Event:		No	
Perceived Relatedness to Adverse Event:		Probably related	
Other Foods or Products Given		Yes	

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name: chewy.com

Address: United States

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Mixed (Dog)

Gender: Male

Reproductive Status: Neutered

Weight: 94 Pound

Age: 6 Years

Assessment of Prior
Health: Fair

Number of Animals
Given the Product: 1

Number of Animals
Reacted: 1

Owner Information:

Healthcare Professional
Information:

Practice Name: B6

Contact: Name:

Phone:

B6

Address:

B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: B6

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: Phone

Reported to Other
Parties: None

Additional Documents:

Attachment: B6 necropsy results.pdf (Unable to load attachment)

Description: Necropsy results

Type: Necropsy Report

Report Details - EON-367220

ICSR: 2055503
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Product Problem (an observed or detected product issue or defect that has the potential to cause harm)
Reporting Type: Voluntary
Report Submission Date: 2018-09-29 21:21:00 EDT

Reporter is the Animal Owner: Yes

Reported Problem: Problem Description: **B6** urine level for adult golden retriever
Date Problem Started: 09/13/2018

Product Information: Product Name: Honest Kitchen Embark and Love
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information: Name:
Owner Information:
Healthcare Professional Information:

Sender Information: Name: **B6**
Address: **B6**
United States
Contact: Phone: **B6**
Email: **B6**
Reporter Wants to Remain Anonymous: No
Permission To Contact Sender: Yes
Preferred Method Of Contact: Phone

Additional Documents:

Report Details - EON-367219

ICSR: 2055502
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-09-29 20:02:39 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: I had [B6] taurine level tested by the Amino Acid Laboratory at UC Davis, School of Veterinary Medicine. His taurine level came back as [B6] low/under the normal range. The normal range for Golden Retrievers starts at 250. He had an echocardiogram on Sept 25 at [B6]. His diagnosis was: LV Dysfunction and dilation; suspect taurine-deficiency cardiomyopathy. Trace MR. Mild LA dilation. Hypotension.
Date Problem Started: 09/17/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Natural Balance Limited Ingredient Diet Sweet Potato & Bison Formula
Product Type: Pet Food
Lot Number: Lot Number: N8T0602-18 RLA 22:10
 Expiration Date: 08/19/2019
UPC: 7 23633 42080 8
Package Type: BAG
Package Size: 26 Pound
Purchase Date: 09/05/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: Stored in the original bag in the refrigerator
Product Use Information:
Description: [B6] is fed one cup of food twice a day
First Exposure Date: 09/10/2018
Last Exposure Date: 09/23/2018
Time Interval between Product Use and Adverse Event: 9 Months
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 Name: Natural Balance Pet Foods, Inc.

	/Distributor Information:	Type(s): Distributor		
		Address: San Francisco California 94111 United States		
		Contact: Phone: (800) 829-4493 Web Address: www.naturalbalanceinc.com		
		Possess One or More Labels from This Product: Yes		
	Purchase Location Information:	Name: Chewy.com Address: United States		
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	74 Pound		
	Age:	6 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	B6
Email:			B6	
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		09/11/2018		
Permission to Release Records to FDA:		Yes		
Healthcare Professional Information:		Practice Name:	B6	
	Contact:	Name:	B6	
		Phone:	B6	
		Email:	B6	
	Address:	B6		
		United States		
	Type of Veterinarian:	Referred veterinarian		
	Date First Seen:	09/25/2018		

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:

Description:

Type: Echocardiogram

B6

Cardio Sept 2018.pdf

Cardiologist report from Sept 25, 2018.

Attachment:

Description:

Type: Laboratory Report

B6

Taurine Level Test Sept 2018.pdf

Taurine Level Results for **B6** Level is **B6** which is low and below the normal range of 250 for Golden Retrievers

Report Details - EON-367233

ICSR:	2055505
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-09-30 00:22:58 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	She was previously been fed Pure Balance diet since she was 2 months old, but once she was spayed and we decided to change her diet to Stella & Chewys. About two months later she was looking bloated and she didnt want to play or exercise and her gums were pale. We took her into the vet and she was diagnosed with DCM.
	Date Problem Started:	07/19/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Stella & Chewys Raw Coated Kibble Blend Small Breed		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	3 Pound		
	Purchase Date:	09/21/2018		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	Product was opened and resealed and kept in a cool dry place .		
	Product Use Information:	Description:	Product was fed twice daily in the morning and afternoon.	
		Time Interval between Product Use and Adverse Event:	2 Months	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Unknown	
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Probably related		
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	B6		
	Address:			
		United States		

Animal Information:	Name:	B6
	Type Of Species:	Dog

	Type Of Breed:	Pug
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	17 Pound
	Age:	11 Months
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
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:	None	
Additional Documents:		

Report Details - EON-369260

ICSR: 2056962
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-24 10:55:47 EDT

Reported Problem:

Problem Description: On September 16, 2018 began coughing - was initially treated for Kennel cough due to a one-day boarding, but [B6] was discontinued three days later when he broke with bloody diarrhea. His cough worsened on [B6] and he was diagnosed with possible pneumonia and started on [B6]. After 1.5 days, his appetite declined, he became lethargic, he began losing weight, and his cough showed no improvement. On [B6] he was referred to an ER hospital in congestive heart failure with ascites. He was started on [B6]. He then presented to our ER on [B6] [B6] for continued congestive heart failure and ascites; an abdominocentesis was performed, his [B6] were increased, and he was started on [B6]. A cardiac consultation was performed, and he was diagnosed with dilated cardiomyopathy with concern for Taurine deficiency based on his previous diets; Taurine supplementation was added.

Date Problem Started: 09/16/2018
Date of Recovery: 10/18/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: 4-Health Trout and Lentil
Product Type: Pet Food
Lot Number:
Product Use Information:

Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	Unknown
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Probably related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:
Purchase Location Information:

Product Name: Zignature Kangaroo
Product Type: Pet Food
Lot Number:
Package Type: CAN
Package Size: 13 Ounce
Product Use Information:

First Exposure Date:	03/19/2018
Product Use	Yes

Stopped After the Onset of the Adverse Event:	
Adverse Event Abate After Product Stop:	Unknown
Product Use Started Again:	No
Perceived Relatedness to Adverse Event:	Probably related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: 4-Health Turkey and Potato

Product Type: Pet Food

Lot Number:

Product Use Information:	Product Use Stopped After the Onset of the Adverse Event:	Yes
	Adverse Event Abate After Product Stop:	Unknown
	Product Use Started Again:	No
	Perceived Relatedness to Adverse Event:	Probably related
	Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information: **Name:** B6

Type Of Species: Dog

Type Of Breed: Great Dane

Gender: Male

Reproductive Status: Intact

Weight: 66.8 Kilogram

Age: 2 Years

Assessment of Prior Health: Good

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information: **Owner** Yes

	Information provided:						
	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Email:
Name:	B6						
Phone:							
Email:							
	Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States			
	B6						
United States							
Healthcare Professional Information:	Practice Name:	B6					
	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Email:
Name:	B6						
Phone:							
Email:							
	Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States			
	B6						
United States							
Sender Information:	Name:						
	Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States			
	B6						
	United States						
	Contact:	<table border="1"> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td>B6</td> </tr> </table>	Phone:		Email:	B6	
	Phone:						
Email:	B6						
Permission To Contact Sender:	Yes						
Preferred Method Of Contact:	Email						
Reported to Other Parties:	None						
Additional Documents:	Attachment:	B6 Medical Records.pdf					
	Description:	's SOAPs, communications, labwork, Echo report, and diagnostic ECG					
	Type:	Medical Records					

Report Details - EON-369256

ICSR: 2057002
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-24 14:13:12 EDT

Reported Problem:
Problem Description: B6 is a 4y neutered male Standard Poodle that was presented for an enlarged heart, inappetance, and coughing on 7/20/2018 through our emergency service. He transferred to our Cardiology department to have additional testing performed the next day. Due to uncommon occurrence of DCM in Poodles and the grain free diet we were concerned about nutritional cardiomyopathy. We performed a taurine analysis and an echocardiogram. he was diagnosed with Dilated Cardiomyopathy by Dr. B6 in 7/21/2018. B6 was started on B6 and Taurine B6 was not taurine deficient at a level of B6. A recheck echocardiogram was performed 3 months later (10/23/2018). After this visit the taurine supplement was increased and L-Carnitine was added.
Date Problem Started: 07/20/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Acana Grain Free Pork and Butternut Squash
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Owner kept in a sealed container at all times.

Product Use Information:
Description: Was fed 3-4 cups of food daily
First Exposure Date: 01/01/2014
Last Exposure Date: 07/20/2018
Time Interval between Product Use and Adverse Event: 4 Years
Product Use Stopped After the Onset of the Adverse Event: Yes
Perceived Relatedness to Adverse Event: Definitely related
Other Foods or Products Given to the Animal During This Time Period: Unknown

Manufacturer /Distributor Information:
Purchase Location Information:
 Name: B6
 Address: B6

		B6 United States	
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Poodle - Standard	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	32.4 Kilogram	
	Age:	4 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:		
	Address: B6	United States	
Healthcare Professional Information:	Practice Name:	B6	
	Contact: Name:	B6	
	Phone:		
	Address:	B6	
			United States
	Type of Veterinarian:	Primary/regular veterinarian	
Sender Information:	Name:	B6	
	Address:	B6	
			United States
	Contact: Phone:	B6	
	Email:		
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email		
Reported to Other Parties:	None		
Additional Documents:	Attachment:	B6 RDVM Hx.pdf	
	Description:	History from primary vet	

Type: Medical Records

Attachment:

B6

Care HX.pdf

Description:

History from both visits from

B6

Referral and Emergency

Type:

Medical Records

Report Details - EON-369271

ICSR: 2056512
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-20 13:50:19 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: All five dogs developed dilated cardiomyopathy which resulted in the death of all 5 dogs between [redacted] B6 [redacted] Four died naturally at home and 1 was euthanized. Since they were all littermates, genetics was suspected, but no other dogs in the litter living with other owners developed DCM. At the time of our dogs' diagnosis there was not a correlation yet to the grain free/suspect ingredient foods.
Date Problem Started: 09/02/2014
Concurrent Medical Problem: Yes
Pre Existing Conditions: [redacted] B6 [redacted]
Outcome to Date: Died Naturally
Date of Death: [redacted] B6 [redacted]

Product Information:
Product Name: California Natural Grain Free Limited Ingredient Diet Kangaroo and Red Lentils Recipe and Salmon Meal and Peas Recipe
Product Type: Pet Food
Lot Number:
Possess Unopened Product: Yes
Storage Conditions: Vittle vault storage containers
Product Use Information: **Description:** Regular diet fed 4 times per day
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Mixed Population of Female and Male
Reproductive Status: Neutered
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 5
Number of Animals Reacted: 5
Owner Information:
Healthcare Professional Information:
Practice Name: [redacted] B6 [redacted]
Contact: **Name:** [redacted] B6 [redacted]
Phone: [redacted] B6 [redacted]
Other Phone: [redacted] B6 [redacted]
Practice Name: [redacted] B6 [redacted]
Contact: **Name:** [redacted] B6 [redacted]
Phone: [redacted] B6 [redacted]

		Other Phone:	B6
		Type of Veterinarian:	Primary/regular veterinarian
Sender Information:	Name:	B6	
	Address:		
	United States		
	Contact:	Phone:	B6
		Other Phone:	
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

Report Details - EON-369265

ICSR: 2057000
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-24 13:37:05 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: B6 was tested to have whole blood taurine of B6 and was diagnosed with occult dilated cardiomyopathy by echo.
Date Problem Started: 10/19/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:
Product Name: Fromm Four-Star Nutritionals Game Bird Recipe Dog Food
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 26 Pound
Purchase Date: 09/24/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Food was poured into airtight container to maintain freshness. Original bag was discarded. Same brand and type of food was given for approximately one year. B6 is being transitioned to new food, and will stop eating Fromm within one week. Unfortunately, since I discarded the bag, I do not have a lot number. I contacted both the store I purchased from and Fromm themselves, but they claim to have no way to track lot numbers.

Product Use Information:
Description: B6 was given one cup of food in the morning and evening.
First Exposure Date: 10/19/2018
Last Exposure Date: 10/20/2018
Time Interval between Product Use and Adverse Event: 1 Years
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:	Name: [Redacted] Address: [Redacted] United States
Animal Information:	Name: [Redacted] Type Of Species: Dog Type Of Breed: Retriever - Golden Gender: Female Reproductive Status: Neutered Weight: 28 Kilogram Age: 1 Years Assessment of Prior Health: Excellent Number of Animals Given the Product: 1 Number of Animals Reacted: 1 Owner Information:	Healthcare Professional Information: Practice Name: [Redacted] Contact: Name: [Redacted] Phone: [Redacted] Email: [Redacted] Address: [Redacted] United States Type of Veterinarian: Primary/regular veterinarian Date First Seen: 09/25/2018 Permission to Release Records to FDA: Yes Practice Name: [Redacted] Contact: Name: [Redacted] Phone: [Redacted] Email: [Redacted] Address: [Redacted] United States Type of Veterinarian: Referred veterinarian Date First Seen: 10/19/2018 Permission to Release Records to FDA: Yes
Sender Information:	Name: [Redacted] Address: [Redacted]	B6

		B6 United States				
	Contact:	<table border="1"> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Phone:	B6	Email:	
Phone:	B6					
Email:						
	Permission To Contact Sender:	Yes				
	Preferred Method Of Contact:	Email				
	Reported to Other Parties:	Manufacturer Store/Place of Purchase				
Additional Documents:						
	Attachment:	T_22470.pdf				
	Description:	Taurine test results from University of California Davis				
	Type:	Laboratory Report				
	Attachment:	Discharge instructions.pdf				
	Description:	Discharge instructions given following echo performed by veterinary cardiologist.				
	Type:	Record				

Report Details - EON-369262

ICSR: 2056520
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-21 21:56:44 EDT

Reported Problem:

Problem Description: Congestive heart failure, severe dilated cardiomyopathy, whole blood taurine level deficient; B6 - responding to supplementation.

Date Problem Started: 03/12/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: History of B6

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: Stella & Chewy's Carnivore Crunch Beef treats

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Product Use Information:

Description: Many treats given daily

Product Use Stopped After the Onset of the Adverse Event: No

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Earth Animal No Hide Beef Chews

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Product Use Information:

Description: 1 chew every 2 weeks

Product Use Stopped After the Onset of the Adverse Event: No

Perceived Relatedness to Adverse Event: Unrelated

Manufacturer /Distributor Information:

Purchase Location Information:

Product Name: Fruitables Pumpkin Digestive Supplement

Product Type: Pet Food

Lot Number:

Package Type:	CAN
Possess Unopened Product:	Unknown
Possess Opened Product:	Unknown
Product Use Information:	Description: 1/3 can per day
	Product Use Stopped After the Onset of the Adverse Event: No
	Perceived Relatedness to Adverse Event: Unrelated
	Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:	
Purchase Location Information:	
Product Name:	Natural Balance L.I.D. Limited Ingredient Diets® Sweet Potato & Venison Canned Dog Formula
Product Type:	Pet Food
Lot Number:	
Package Type:	CAN
Possess Unopened Product:	Unknown
Possess Opened Product:	Unknown
Product Use Information:	Description: 1/3 can per day
	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:	
Product Name:	Natural Balance L.I.D. Limited Ingredient Diets® Sweet Potato & Venison Dry Dog Formula
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Possess Unopened Product:	Unknown
Possess Opened Product:	Unknown
Product Use	Description: <2 cups fed 2x/day

	Information:	Product Use Stopped After the Onset of the Adverse Event:	No
		Perceived Relatedness to Adverse Event:	Possibly related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Ridgeback - Rhodesian	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	28.9 Kilogram	
	Age:	12 Years	
	Assessment of Prior Health:	Fair	
	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
		Email:	B6
		Address:	B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	10/10/2018
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact: Name:	B6
		Phone:	B6
		Address:	B6

			B6
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	03/12/2018
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact:	Name: B6
			Phone: B6
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
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:	None	
Additional Documents:	Attachment:	B6	2018-10-21_Converted medical history for B6 .pdf
	Description:	Medical history from time of DCM diagnosis, CHF	
	Type:	Medical Records	
	Attachment:	B6	2018-10-21_Taurine UCD.pdf
	Description:	Taurine level (post supplementation) - improvement with supplementation. Prior levels were below reference range.	
	Type:	Laboratory Report	
	Attachment:	B6	Medical history 2018-03-01 to 2018-10-10.pdf
	Description:	More recent medical history from B6	
	Type:	Medical Records	

Report Details - EON-369270

ICSR:	2056518
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-10-21 17:27:56 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	In the past six years, my dog has developed gastrointestinal problems (soft stool and diarrhea) and was diagnosed with Diarrhea and Proteinuria. In the past three years, it was also discovered that he had a slight heart murmur with progression in the past year. He is now diagnosed with Mitral Valve Dysplasia and most recently with Otitis Externa and Congestive Heart Failure. The cardiologist specialist recently discussed with me FDA reports of grain free diets and the link to canine dilated cardiomyopathy (DCM). I have kept a through log of all the dog foods I have given my dog in the past four years, as I tired switching brands thinking it would help with his diarrhea. The two brands that he has been on the longest during the past four years are: Wellness CORE Natural Grain Free Reduced Fat Dry Dog Food and WholeHearted Grain Free All Life Stages Chicken & Pea Recipe Dry Dog Food.
	Date Problem Started:	08/10/2012
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	WholeHearted Grain Free All Life Stages Chicken & Pea Recipe Dry Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Storage Conditions:	Bag stored in the kitchen.		
	Product Use Information:	Description:	Dry dog food given in the morning and evening.	
		Last Exposure Date:	09/01/2018	
		Perceived Relatedness to Adverse Event:	Possibly related	
	Manufacturer /Distributor Information:			
	Purchase Location Information:	Name:	Petco	
	Product Name:	Product Name:	Wellness CORE Natural Grain Free Reduced Fat Dry Dog Food	
		Product Type:	Pet Food	
		Lot Number:		
		Package Type:	BAG	
		Package Size:	25 Pound	
		Storage Conditions:	Product was stored in room temperature in the kitchen, in a sealable bag.	
		Product Use Information:	Description:	Dry dog food given in the morning and evening.
First Exposure Date:			10/01/2009	
Last Exposure Date:			01/01/2018	
Perceived Relatedness to Adverse Event:			Possibly related	
Other Foods or	No			

Products Given to the Animal During This Time Period:

Manufacturer /Distributor Information:

Purchase Location Information: Name: Petco

Animal Information:

Name:

Type Of Species: Dog

Type Of Breed: Terrier (unspecified)

Gender: Male

Reproductive Status: Neutered

Weight: 10.25 Kilogram

Age: 11 Years

Assessment of Prior Health: Excellent

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional Information:

Practice Name:

B6

Contact:

Name:

B6

Phone:

Date First Seen: 10/10/2018

Practice Name:

B6

Contact:

Name:

B6

Phone:

Date First Seen: 10/20/2018

Practice Name:

B6

Contact:

Name:

B6

Phone:

Date First Seen: 09/20/2017

Sender Information:

Name:

Address:

B6

United States

Contact:

Reporter Wants to Remain Anonymous: Yes

Additional Documents:

Report Details - EON-369275

ICSR: 2056830
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-23 10:33:16 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
 Problem Description: Been feeding Wellness Core Rev Grain Free dog food for approximately 1 year. B6 collapsed and died
 Date Problem Started: B6
 Concurrent Medical Problem: No
 Outcome to Date: Died Other
 Date of Death: B6

Product Information:
 Product Name: Wellness Core RawRev Grain Free turkey recipe
 Product Type: Pet Food
 Lot Number:
 Package Type: BAG
 Package Size: 20 Pound
 Purchase Date: 09/25/2018
 Number Purchased: 1
 Possess Unopened Product: No
 Possess Opened Product: No
 Storage Conditions: In sealed dog food bin
 Product Use Information: Description: Fed 2x daily
 Perceived Relatedness to Adverse Event: Probably related
 Manufacturer /Distributor Information:
 Purchase Location Information:

Animal Information:
 Name: B6
 Type Of Species: Dog
 Type Of Breed: Dachshund (unspecified)
 Gender: Female
 Reproductive Status: Neutered
 Weight: 20 Pound
 Age: 3 Years
 Assessment of Prior Health: Excellent
 Number of Animals Given the Product: 3
 Number of Animals Reacted: 1
 Owner Information:
 Healthcare Professional Information:

Sender Information:	Name:	B6		
	Address:			
		United States		
	Contact:	Phone:	B6	
		Email:		
	Reporter Wants to Remain Anonymous:	No		
	Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email			
Reported to Other Parties:	None			

Additional Documents:

Report Details - EON-369279

ICSR:	2056825
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-10-23 10:01:23 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Canine developed heart murmur followed by enlarged heart
	Date Problem Started:	12/14/2013
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Wellness Core Reduced Fat Formula		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	12 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	The food was stored in its original bag after opening. Prior to opening, it was transported in a car or by hand		
	Product Use Information:	Description:	The food was given once a day	
		First Exposure Date:	09/20/2013	
		Last Exposure Date:	10/19/2018	
		Time Interval between Product Use and Adverse Event:	3 Months	
		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:				

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Terrier (unspecified)
	Gender:	Male
	Reproductive Status:	Neutered

	Weight:	27 Pound
	Age:	12 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact:	
	Phone:	B6
	Email:	B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
Preferred Method Of Contact:	Email	
Reported to Other Parties:	None	
Additional Documents:		

Report Details - EON-369250							
ICSR:	2056987						
Type Of Submission:	Initial						
Report Version:	FPSR.FDA.PETF.V.V1						
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)						
Reporting Type:	Voluntary						
Report Submission Date:	2018-10-24 12:06:57 EDT						
Reported Problem:	<p>Problem Description: B6 has been eating Whole Earth Farms Grain Free (mostly Chicken & Turkey) dog food for over a year. The dog was a rescue and is currently heartworm positive. The dog presented to our ER department with ascites. Echocardiogram performed by me (veterinary cardiologist) was performed and dilated cardiomyopathy was diagnosed. Blood was submitted for Taurine levels to UC Davis (plasma B6; whole blood B6). While waiting for samples Taurine (500 mg PO BID) was started. Per the FDA investigation into DCM and grain free diets, this case is submitted.</p> <p>Date Problem Started: 10/08/2018</p> <p>Concurrent Medical Problem: No</p> <p>Outcome to Date: Stable</p>						
Product Information:	<p>Product Name: Whole Earth Farms Grain Free (mostly Chicken & Turkey) dog food</p> <p>Product Type: Pet Food</p> <p>Lot Number:</p> <p>Package Type: BAG</p> <p>Possess Unopened Product: No</p> <p>Possess Opened Product: No</p> <p>Product Use Information:</p> <table border="1"> <tr> <td>Description:</td> <td>Given as regular diet for over a year</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Yes</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Possibly related</td> </tr> </table> <p>Manufacturer /Distributor Information:</p> <p>Purchase Location Information:</p>	Description:	Given as regular diet for over a year	Product Use Stopped After the Onset of the Adverse Event:	Yes	Perceived Relatedness to Adverse Event:	Possibly related
Description:	Given as regular diet for over a year						
Product Use Stopped After the Onset of the Adverse Event:	Yes						
Perceived Relatedness to Adverse Event:	Possibly related						
Animal Information:	<p>Name: B6</p> <p>Type Of Species: Dog</p> <p>Type Of Breed: Retriever - Labrador</p> <p>Gender: Female</p> <p>Reproductive Status: Neutered</p> <p>Weight: 20 Kilogram</p> <p>Age: 3 Years</p> <p>Assessment of Prior Health: Good</p> <p>Number of Animals Given the Product: 1</p> <p>Number of Animals Reacted: 1</p> <p>Owner Information:</p> <table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> </table>	Owner Information provided:	Yes				
Owner Information provided:	Yes						

		Contact: Name: B6
		Phone: B6
	Address: B6	United States
	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: None	
Additional Documents:	Attachment: T_23032.jpg	
	Description: Taurine Levels from UC Davis	
	Type: Laboratory Report	
	Attachment: B6 47275 Cardiology Report.pdf	
	Description: Cardiology Report - Echocardiogram	
	Type: Medical Records	

Report Details - EON-369278

ICSR: 2056824
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-23 09:12:26 EDT

Reported Problem:

Problem Description: The patient started slowing down on walks and had decreased energy for the past 2-3 months. A few weeks ago the patient developed a progressive cough. His appetite became decreased over the past several days. The morning of presentation he was coughing profusely and had a syncopal episode where he collapsed and was stiff for about 20 seconds, then immediately bounced back up. He remains lethargic with a decreased appetite. No overt respiratory signs other than coughing have been noted. He has been on Whole Hearted brand, Salmon, grain free dog food. Also receives pumpkin grain free treats

Date Problem Started: 09/21/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: B6 for some time, but is not currently taking this medication.

Outcome to Date: Worse/Declining/Deteriorating

Product Information:

Product Name: Whole Hearted limited ingredient salmon recipe Simple Grain Free food for dogs

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Product Use Information:

Description: Fed daily to the pet for several years

Last Exposure Date: 10/20/2018

Perceived Relatedness to Adverse Event: Possibly related

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

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Mastiff

Gender: Male

Reproductive Status: Intact

Weight: 120 Pound

Age: 5 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:	
			Phone:	B6
			Email:	
	Address:	B6 United States		
Sender Information:	Name:	B6 United States		
	Address:	B6 United States		
	Contact:	Phone:	B6	
		Email:		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
	Reported to Other Parties:	None		
Additional Documents:	Attachment:	B6	echo report.pdf	
	Description:	Patient report from cardiologist visit		
	Type:	Medical Records		
	Attachment:	B6	OldFood1.jpg	
	Description:	Grain free food label		
	Type:	Product Label		
	Attachment:	B6	echo data (9).pdf	
	Description:	Echocardiographic images and data		
	Type:	Echocardiogram		
	Attachment:	Bw(Chem)CVCA (1).pdf		
	Description:	Chemistry panel prior to starting medications and switching diet.		
	Type:	Laboratory Report		
Attachment:	B6	OldFood2.jpg		
Description:	Grain free food ingredients			
Type:	Product Label			

Report Details - EON-366723

ICSR: 2055310
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-09-25 08:21:47 EDT

Reported Problem:

Problem Description: B6 was presented through the ER service last night for progressive symptoms resulting in tachypnea for the 24 hours prior to admission. Symptoms started about a week ago when he came in panting and gagging after playing with the puppy outside. Over the next few days he intermittently hacked, but seemed to be breathing fine and was otherwise normal. Firday night he was restless like he could not get comfortable which is unusual for him. He was evaluated by the rDVM on Saturday and the owner was told he had a fever (owner thought 102.4) and he was starte on B6 400mg PO SID. His appetite started to decrease and has continued to decline so that now he is hardly eating at all which is unlike him. The owner has noted that his urine is also dark in coloe. He is refusing to go up stairs. He has had ongoing tachypnea since the night before presentation and has had a "wet" sounding cough. His last exam was a couple of years ago, but he has been a healthy dog until now. He is not on heartworm preventive. He has been fed Blue Basics grain free diet his whole life. The owner tried to introduce Wellness diet recently but B6 is not eating much of it.

Date Problem Started: 09/08/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: Blue Basics Grain-free then Wellness
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:

Name: B6
Type Of Species: Dog
Type Of Breed: Great Dane
Gender: Male
Reproductive Status: Neutered
Weight: 69.6 Kilogram
Age: 7 Years
Assessment of Prior Health: Good
Number of Animals Reacted: 1

Owner Information: Yes

Contact: Name: B6
Phone:
Email:
Address: B6

			B6 United States
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	
		Other Phone:	
Email:			
Address:	B6		United States
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Other Phone:	
Email:			
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Additional Documents:			

Report Details - EON-366761

ICSR: 2055326
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Both
Reporting Type: Voluntary
Report Submission Date: 2018-09-25 13:15:49 EDT

Reported Problem: **Problem Description:** See Echocardiogram and Taurine Levels
Date Problem Started: 08/07/2018
Outcome to Date: Better/Improved/Recovering

Product Information: **Product Name:** Zygnature Zssentials Grain Free
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information: **Name:** B6
Type Of Species: Dog
Type Of Breed: Mixed (Dog)
Gender: Male
Reproductive Status: Neutered
Weight: 44.1 Pound
Age: 1 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 Information: **Practice Name:** B6
Contact: **Name:** B6
Phone: B6
Email: B6
Address: B6
United States

Sender Information: **Name:**
Address: B6
United States
Contact: **Phone:** B6

Email: B6

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Reported to Other Parties: None

Additional Documents:

Attachment: LabReport.pdf

Description: Taurine Levels

Type: Other

Attachment: Image_00001.jpg

Description: B6 Echocardiogram Results 1/3

Type: Echocardiogram

Attachment: Image_00002.jpg

Description: B6 Echocardiogram 2/3

Type: Echocardiogram

Attachment: Image_00003.jpg

Description: B6 Echocardiogram 3/3

Type: Echocardiogram

Report Details - EON-369247

ICSR:	2056759
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-10-22 20:38:48 EDT
Initial Report Date:	08/15/2018
Parent ICSR:	2053786
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Diagnosed with mild dilated cardiomyopathy, sinus bradycardia, first degree AV block; found to have taurine deficiency based on analysis of whole blood.
	Date Problem Started:	07/11/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	TruDog FEED ME Crunchy Munchy Beef Bonanza		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Product Use Information:	Description:	Fed in combination with Honest Kitchen vegetarian premix	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Unknown	
		Product Use Started Again:	Unknown	
		Perceived Relatedness to Adverse Event:	Possibly related	
		Other Foods or Products Given to the Animal During This Time Period:	Yes	
		Manufacturer /Distributor Information:		
	Purchase Location Information:			
	Product Name:	Honest Kitchen Dehydrated Grain Free Veggie, Nut & Seed Base Mix (Kindly)		
Product Type:	Pet Food			
Lot Number:				
Package Type:	BOX			
Possess Unopened	No			

Product:													
Possess Opened Product:	No												
Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>Rehydrated and fed as main diet in rotation with other foods; fed in combination with 85% lean ground beef or Trudog raw beef diet</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Yes</td> </tr> <tr> <td>Adverse Event Abate After Product Stop:</td> <td>Unknown</td> </tr> <tr> <td>Product Use Started Again:</td> <td>Unknown</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	Rehydrated and fed as main diet in rotation with other foods; fed in combination with 85% lean ground beef or Trudog raw beef diet	Product Use Stopped After the Onset of the Adverse Event:	Yes	Adverse Event Abate After Product Stop:	Unknown	Product Use Started Again:	Unknown	Perceived Relatedness to Adverse Event:	Probably related	Other Foods or Products Given to the Animal During This Time Period:	Yes
Description:	Rehydrated and fed as main diet in rotation with other foods; fed in combination with 85% lean ground beef or Trudog raw beef diet												
Product Use Stopped After the Onset of the Adverse Event:	Yes												
Adverse Event Abate After Product Stop:	Unknown												
Product Use Started Again:	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:													
Product Name:	Honest Kitchen Grain Free Turkey Recipe (Embark)												
Product Type:	Pet Food												
Lot Number:													
Package Type:	BOX												
Possess Unopened Product:	No												
Possess Opened Product:	No												
Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>Rehydrated and fed as main diet in rotation with other foods</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Yes</td> </tr> <tr> <td>Adverse Event Abate After Product Stop:</td> <td>Unknown</td> </tr> <tr> <td>Product Use Started Again:</td> <td>No</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	Rehydrated and fed as main diet in rotation with other foods	Product Use Stopped After the Onset of the Adverse Event:	Yes	Adverse Event Abate After Product Stop:	Unknown	Product Use Started Again:	No	Perceived Relatedness to Adverse Event:	Probably related	Other Foods or Products Given to the Animal During This Time Period:	Yes
Description:	Rehydrated and fed as main diet in rotation with other foods												
Product Use Stopped After the Onset of the Adverse Event:	Yes												
Adverse Event Abate After Product Stop:	Unknown												
Product Use Started Again:	No												
Perceived Relatedness to Adverse Event:	Probably related												
Other Foods or Products Given to the Animal During This Time Period:	Yes												
Manufacturer /Distributor Information:													
Purchase Location Information:													
Product Name:	Honest Kitchen Grain Free Beef Recipe (Love)												
Product Type:	Pet Food												

	Lot Number:															
	Package Type:	BOX														
	Possess Unopened Product:	No														
	Possess Opened Product:	No														
	Storage Conditions:	Unsure. Owner still has product at home but I do not have any samples of the product.														
	Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>Rehydrated and fed as part of main diet (in rotation with other products)</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Yes</td> </tr> <tr> <td>Adverse Event Abate After Product Stop:</td> <td>Unknown</td> </tr> <tr> <td>Product Use Started Again:</td> <td>No</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	Rehydrated and fed as part of main diet (in rotation with other products)	Product Use Stopped After the Onset of the Adverse Event:	Yes	Adverse Event Abate After Product Stop:	Unknown	Product Use Started Again:	No	Perceived Relatedness to Adverse Event:	Probably related	Other Foods or Products Given to the Animal During This Time Period:	Yes		
Description:	Rehydrated and fed as part of main diet (in rotation with other products)															
Product Use Stopped After the Onset of the Adverse Event:	Yes															
Adverse Event Abate After Product Stop:	Unknown															
Product Use Started Again:	No															
Perceived Relatedness to Adverse Event:	Probably related															
Other Foods or Products Given to the Animal During This Time Period:	Yes															
	Manufacturer /Distributor Information:															
	Purchase Location Information:															
Animal Information:	Name:	B6														
	Type Of Species:	Dog														
	Type Of Breed:	Pointing Dog - Hungarian Short-haired (Vizsla)														
	Gender:	Male														
	Reproductive Status:	Neutered														
	Age:	5 Years														
	Assessment of Prior Health:	Unknown														
	Number of Animals Given the Product:	1														
	Number of Animals Reacted:	1														
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td> <table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table> </td> </tr> </table>	Owner Information provided:	Yes	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Email:		Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States
Owner Information provided:	Yes															
Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Email:										
Name:	B6															
Phone:																
Email:																
Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States													
B6																
United States																
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table> </td> </tr> </table>	Practice Name:	B6	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:							
Practice Name:	B6															
Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:												
Name:	B6															
Phone:																

			Email:	B6
		Address:	B6	
			United States	
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	08/08/2018	
		Permission to Release Records to FDA:	Yes	
		Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
			Email:	
		Address:	B6	
			United States	
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	07/11/2018	
		Permission to Release Records to FDA:	Yes	
		Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
		Address:	B6	
			United States	
		Type of Veterinarian:	Primary/regular veterinarian	
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	UCD Taurine 10-2018.jpg	
	Description:	Recheck taurine level after diet change and taurine supplementation		
	Type:	Laboratory Report		

Report Details - EON-369233

ICSR: 2057007
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-10-24 15:29:57 EDT

Reported Problem:

Problem Description:	Pet has been eating a grain free diet for many years (Instinct Lamb and Pea) over the last year pet has developed a hacking, slowly progressive cough which has not responded to treatment. no murmur heard, mild heart enlargement on radiographs. Went for echocardiogram with cardiologist who identified dilated cardiomyopathy - suspected to be diet related, possibly d/t taurine deficiency. Just started [B6] diet change several weeks ago, taurine levels not available
Date Problem Started:	01/03/2018
Concurrent Medical Problem:	No
Outcome to Date:	Not Applicable

Product Information:

Product Name:	Instinct® Limited Ingredient Diet Grain-Free Recipe with Real Lamb
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Possess Unopened Product:	Unknown
Possess Opened Product:	Unknown
Product Use Information:	Description: fed as on label
Manufacturer /Distributor Information:	
Purchase Location Information:	

Animal Information:

Name:	[B6]										
Type Of Species:	Dog										
Type Of Breed:	Pug										
Gender:	Male										
Reproductive Status:	Neutered										
Weight:	25 Pound										
Age:	11 Years										
Assessment of Prior Health:	Good										
Number of Animals Given the Product:	1										
Number of Animals Reacted:	1										
Owner Information:	<table border="1"><tr><td>Owner Information provided:</td><td>Yes</td></tr><tr><td>Contact:</td><td><table border="1"><tr><td>Name:</td><td>[B6]</td></tr><tr><td>Phone:</td><td>[B6]</td></tr></table></td></tr><tr><td>Address:</td><td>[B6] United States</td></tr></table>	Owner Information provided:	Yes	Contact:	<table border="1"><tr><td>Name:</td><td>[B6]</td></tr><tr><td>Phone:</td><td>[B6]</td></tr></table>	Name:	[B6]	Phone:	[B6]	Address:	[B6] United States
Owner Information provided:	Yes										
Contact:	<table border="1"><tr><td>Name:</td><td>[B6]</td></tr><tr><td>Phone:</td><td>[B6]</td></tr></table>	Name:	[B6]	Phone:	[B6]						
Name:	[B6]										
Phone:	[B6]										
Address:	[B6] United States										

	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6 Phone: B6
Sender Information:	Name:	B6	
	Contact:	Phone:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	

Additional Documents:

Report Details - EON-369243

ICSR: 2056909
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-23 18:46:02 EDT

Reported Problem:

Problem Description:	Echocardiographic evidence of dilated cardiomyopathy. Concurrently being fed grain free diet.
Date Problem Started:	10/23/2018
Concurrent Medical Problem:	Unknown
Outcome to Date:	Stable

Product Information:

Product Name:	Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Possess Unopened Product:	No	
Possess Opened Product:	Yes	
Storage Conditions:	Bag of dog food was emptied into plastic storage container.	
Product Use Information:	First Exposure Date:	10/23/2011
	Last Exposure Date:	10/23/2018
	Product Use Stopped After the Onset of the Adverse Event:	Yes
	Adverse Event Abate After Product Stop:	Not Applicable
	Product Use Started Again:	No
	Perceived Relatedness to Adverse Event:	Possibly related
	Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:	
Purchase Location Information:	Address:	United States

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Boxer (German Boxer)
Gender:	Female
Reproductive Status:	Neutered
Weight:	31 Kilogram
Age:	7 Years

	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6
			Phone:
		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:	
Address:		B6	
		United States	
Date First Seen:	10/23/2018		
Permission to Release Records to FDA:	Yes		
Practice Name:	B6		
	Contact:	Name: B6	
Phone:			
Sender Information:	Name:	B6	
	Address:	B6	
			United States
	Contact:	Phone:	
Email:		B6	
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Additional Documents:	Attachment:	B6.pdf	
	Description:	Clinical summary from CVCA cardiology consultation 10/23/18.	

Report Details - EON-369245

ICSR: 2056940
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-10-24 09:38:52 EDT

Reported Problem:
Problem Description: B6 presented on 9/27/2018 for a swollen abdomen and lethargy. Physical exam revealed a grade 3/6 right sided murmur and a palpable fluid wave in the abdomen. On ultrasound and radiographs there was a large amount of free fluid in the abdomen and the heart was revealed to be greatly enlarged. B6 was diagnosed with right sided heart failure. At this time her owner stated that B6 has been on a grain free diet for the past eight years.
Date Problem Started: 09/27/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Nutro Wholesome Essentials Large Breed Adult
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Taste of the Wild High Prairie Canine Recipe with roasted bison and roasted venison A Grain Free Diet
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:
Product Name: Nutro Natural Choice, Large Breed
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog

	Type Of Breed: Retriever - Labrador
	Gender: Female
	Reproductive Status: Neutered
	Weight: 58 Pound
	Age: 14 Years
	Assessment of Prior Health: Unknown
	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
Sender Information:	Name:
	Address:
	B6
	United States
	Contact:
	Phone:
	Email: B6
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
Additional Documents:	

Report Details - EON-369239

ICSR:	2056936
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-10-24 09:14:45 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My four year old dog was being fed FROMM dog food, as recommended by the local specialty pet food store. After he developed some severe itching, the store recommended we switch to the GO dog food brand since it's a limited diet. Our dog was on this for about 2.5 years. Mid August 2018 he developed a bad cough. We brought him in to see the vet and they found that he had severe DCM in addition to sever mitral valve disease. He had x rays, ECGs, blood tests, and was prescribed 30 pills per day to try and get it under control. The fluid in his lungs was increasing, he stopped eating, his organs began shutting down, and 10 days later we had to put him down because he was drowning on the inside and all his organs were failing. The vet mentioned it was likely the Taurine deficiency due to the dog food he was being fed. This was very upsetting since the local specialty pet food store had told us to feed him this food. Our dog was only four years old and he suffered tremendously at the end of his short life.
	Date Problem Started:	08/13/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Petcurean GO Sensitivity and Shine Limited Ingredient Salmon Recipe		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	07/20/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	The food was kept in the bag as it was resealable.		
	Product Use Information:	Description:	approximately 3 cups per day, as per the directions on the bag	
		Last Exposure Date:	B6	
		Time Interval between Product Use and Adverse Event:	3 Years	
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		No		
Product Use Started Again:		No		
Perceived		Definitely related		

		Relatedness to Adverse Event:
	Manufacturer /Distributor Information:	
	Purchase Location Information:	Name: B6
		Address: B6 Canada
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Poodle - Standard
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	50 Pound
	Age:	4 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	Contact: Name: B6 Phone: B6
		Address: B6 Canada
		Type of Veterinarian: Primary/regular veterinarian
		Date First Seen: B6
		Permission to Release Records to FDA: Yes
Sender Information:	Name:	B6
	Address:	B6 Canada
	Contact:	Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:		

Report Details - EON-369249

ICSR: 2056963
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Both
Reporting Type: Voluntary
Report Submission Date: 2018-10-24 11:06:18 EDT

Reported Problem:
Problem Description: B6 presented to B6 for further evaluation of congestive heart failure and a suspected arrhythmia. B6 has been quieter for the past week and started having a dry cough a few days ago. Last night she seemed dyspneic. The owners have not noted any weakness or collapse. Her appetite has been decreased, but she is normally a finicky eater. She has been on grain-free Taste of the Wild for 7-8 years. She has lost about 5 lbs since August. B6 was seen by B6 had radiographs, an ECG, bloodwork, and a fast scan performed. She was diagnosed with suspected perihilar edema, cardiomegaly, atrial fibrillation, a gallop and heart murmur, as well as yeast on tape prep (skin?). B6 was referred for evaluation by B6 and received no treatment prior to referral to B6 is up to date on vaccines. B6 was hospitalised over night for transfer to B6 and was treated for heart failure.
Date Problem Started: 10/16/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

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

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Mixed (Dog)
Gender: Female
Reproductive Status: Neutered
Weight: 37 Kilogram
Age: 9 Years
Assessment of Prior Health: Good
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: B6
Phone: B6
Email: B6
Address: B6
United States
Healthcare Professional Practice Name: B6

	Information:	B6				
	Contact:	<table border="1"> <tr> <td>Name:</td> <td rowspan="4">B6</td> </tr> <tr> <td>Phone:</td> </tr> <tr> <td>Other Phone:</td> </tr> <tr> <td>Email:</td> </tr> </table>	Name:	B6	Phone:	Other Phone:
Name:	B6					
Phone:						
Other Phone:						
Email:						
	Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States		
	B6					
United States						
Sender Information:	Name:					
	Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States		
	B6					
	United States					
	Contact:	<table border="1"> <tr> <td>Phone:</td> <td rowspan="3">B6</td> </tr> <tr> <td>Other Phone:</td> </tr> <tr> <td>Email:</td> </tr> </table>	Phone:	B6	Other Phone:	Email:
Phone:	B6					
Other Phone:						
Email:						
Permission To Contact Sender:	Yes					
Preferred Method Of Contact:	Email					
Additional Documents:						

Report Details - EON-369235

ICSR:	2057011
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-10-24 16:03:10 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	cough began, vet recommended cardiologist exam. echo showed dilated cardiomyopathy
	Date Problem Started:	10/24/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Currently being treated for [B6] Developed cough.
	Outcome to Date:	Not Applicable

Product Information:	Product Name:	Taste of the Wild, Roasted Lamb-grain free		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	do not have bag		
	Package Type:	BAG		
	Package Size:	50 Pound		
	Purchase Date:	07/01/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	stored in airtight container		
	Product Use Information:	Description:	by mouth - dog food	
		Last Exposure Date:	07/01/2018	
		Time Interval between Product Use and Adverse Event:	8 Years	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
Adverse Event Abate After Product Stop:		No		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Probably related		
Other Foods or Products Given to the Animal During This Time Period:		No		
Manufacturer /Distributor Information:				

	Purchase Location Information:	Name:	B6
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Spaniel - Springer English	
	Reproductive Status:	Neutered	
	Weight:	40 Pound	
	Age:	10 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	B6
	Address:	B6	United States
	Type of Veterinarian:	Primary/regular veterinarian	
Date First Seen:	10/02/2018		
Sender Information:	Name:	B6	
	Address:	B6	United States
	Contact:	Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

Report Details - EON-371718

ICSR: 2059214
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-22 14:09:19 EST

Reported Problem:

Problem Description: Over the past year of being on Acana canine food(all flavors) there was decrease in energy, lack of interest in normal activities, and coughing episodes that would come and go. He has been on grain free food most of his life and had full body radiographs before switching to Acana brand and his heart and lungs were normal. 3 view chest radiographs were performed and seen was an enlarged heart with fluid build up in the lungs. I assisted with the echocardiogram with the cardiologist, that is used in at several different practices all over the [B6] [B6] was diagnosed with moderate dilated cardiomyopathy and mild mitral valve regurgitation. During the echocardiogram I was asked what food [B6] was on. I told him he had been on Acana grain free for about a year. He said he has recently seen multiple cases of taurine deficient DCM in not breed or age exclusive, and almost all the cases were on Acana brand food. Once switch to new food and taurine supplements all showed significant, if not complete, improvement. After a few days of being on Purina Proplan and taurine supplements he was showing great improvement. He has now been on it for 2 weeks and has more energy than he has in a long time and acts more like a puppy. The taurine test that was sent to UC Davis came back as being low and an echocardiogram will be repeated in 3-6 months. We notified the pet store where we were purchasing Acana and they said they knew all about issues that were happening but were still continuing to sell it as "the best". The facebook page "Taurine Deficient Dilated Cardiomyopathy" has a chart of all the cases.

Date Problem Started: 08/01/2017
Date of Recovery: 11/22/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: Acana (all flavors except Chicken or Lamb)
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: In a dog food storage bin in the house

Product Use Information:

Description:	To feed my dog
First Exposure Date:	07/31/2017
Time Interval between Product Use and Adverse Event:	1 Years
Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:	Yes
Product Use Started Again:	No

		Perceived Relatedness to Adverse Event:	Definitely related
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	
		United States	
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd Dog - Australian	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	78 Pound	
	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:	
		Address:	B6
		United States	
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	
		Address:	B6
		United States	
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	10/17/2018
		Permission to Release Records to FDA:	Yes
		Practice Name:	B6
		Contact: Name:	B6
		Phone:	
		Type of Veterinarian:	Primary/regular veterinarian
		Permission to Release Records	Yes

		to FDA:	
		Practice Name:	B6
		Contact:	Name: B6 Phone: B6
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	11/07/2018
		Permission to Release Records to FDA:	Yes

Sender Information:	Name:	B6
	Address:	United States
	Contact:	Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Distributor Manufacturer Store/Place of Purchase

Additional Documents:	Attachment:	IMG_8072.jpg
	Description:	Right lateral chest radiograph
	Type:	Radiographs
	Attachment:	1811090254.pdf
	Description:	Taurine level test
	Type:	Histopathology Report
	Attachment:	IMG_8288.jpg
	Description:	echocardiogram report
	Type:	Echocardiogram

Report Details - EON-371596

ICSR:	2059134			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Both			
Reporting Type:	Voluntary			
Report Submission Date:	2018-11-21 00:18:01 EST			
Reporter is the Animal Owner:	Yes			
Reported Problem:	Problem Description:	transitioned to grain free blue buffalo adult brand food in 2015. transitioned to grain free senior adult blue buffalo brand food in 2018. diagnosed with a heart murmur in 2016 prescribed on meds. conditioned worsened to include increased heart rate in 2018 and prescribed additional meds. now is bloated and has loss of muscle mass.		
	Date Problem Started:	05/30/2016		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Worse/Declining/Deteriorating		
Product Information:	Product Name:	blue buffalo life protection formula senior dog chicken and brown rice with life source bits		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	20200407AH2 B 2058	
		Expiration Date:	04/07/2020	
	UPC:	859610000159		
	Package Type:	BAG		
	Package Size:	15 Pound		
	Purchase Date:	11/16/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	stored in original product bag		
	Product Use Information:	Description:	fed twice daily 1.5 cups each feeding with fresh water	
		Last Exposure Date:	11/20/2018	
Time Interval between Product Use and Adverse Event:		6 Months		
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	Name:	petsmart		

	Information:	Address:	B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Other Canine/dog		
	Gender:	Female		
	Reproductive Status:	Intact		
	Pregnancy Status:	Not Pregnant		
	Lactation Status:	Not lactating		
	Weight:	60 Pound		
	Age:	8 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
		Phone:	B6	
Address:		B6		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		05/30/2015		
Permission to Release Records to FDA:	Yes			
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:	None			
Additional Documents:	Attachment:	Scan.pdf		
	Description:	most recent receipts for medication		
	Type:	Other		

Report Details - EON-371695

ICSR: 2059188
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-11-22 01:07:30 EST
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: One dog has developed Cardiomyopathy and the other one has constant itching problems with hair loss
Date Problem Started: 01/01/2018
Outcome to Date: Unknown

Product Information:
Product Name: Grain Free Food Costco Makersmark
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Retriever - Labrador
Reproductive Status: Neutered
Assessment of Prior Health: Good
Number of Animals Given the Product: 2
Number of Animals Reacted: 2
Owner Information:
Healthcare Professional Information:
Practice Name: B6
Contact: **Name:** B6
Phone: B6
Address: United States
Type of Veterinarian: Primary/regular veterinarian
Permission to Release Records to FDA: Yes

Sender Information:
Name:
Address: B6
United States
Contact: **Phone:** B6
Email: B6
Permission To Contact Sender: Yes

Preferred Method Of Contact:	Phone
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Reported to Other Parties:	Other
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Additional Documents:

Report Details - EON-371614

ICSR: 2059146
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-11-21 09:47:46 EST
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: **B6** has been on a diet of premium grain free dog food her whole life. At 4, she suddenly developed a heart murmur and was diagnosed with DCM. She is now on medication to help her heart as she is in congestive heart failure.
Date Problem Started: 09/08/2018
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Multiple types of grain free food - brands include taste of the wild, Merrick, blue, and others.
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: Pit Bull
Gender: Female
Reproductive Status: Neutered
Weight: 75 Pound
Age: 4 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 4
Number of Animals Reacted: 1
Owner Information:
Healthcare Professional Information: **Practice Name:** **B6**
Contact: **Name:** **B6**
Phone: **B6**

Sender Information:
Name: **B6**
Address: **B6**
Contact: **Phone:** **B6**
Email: **B6**
Reporter Wants to Remain Anonymous: No
Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Additional Documents:

Report Details - EON-371785

ICSR: 2059243
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-23 20:09:05 EST
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: B6 had been eating Rachael Ray dog food for many years, perhaps 5-7 years and developed congestive heart failure due to undetected dilated cardiomyopathy. She was a pit bull Labrador mix and these breeds are not genetically predisposed to this condition. The vet mentioned it could be due to food containing peas or legumes as a main ingredient, which Rachael Ray Nutrish food contains. She passed away after one year of fighting this condition.
Date Problem Started: 09/22/2017
Concurrent Medical Problem: No
Outcome to Date: Died Euthanized
Date of Death: B6

Product Information:
Product Name: Rachael Ray Nutrish real chicken and veggies recipe and Rachael Ray Nutrish real beef, pea and brown rice recipe
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: In bag in cabinet
Product Use Information:
Description: Dry food served in stainless steel metal bowl
Time Interval between Product Use and Adverse Event: 5 Years
Product Use Stopped After the Onset of the Adverse Event: Yes
Perceived Relatedness to Adverse Event: Probably related
Manufacturer /Distributor Information:
Purchase Location Information: Name: Giant eagle

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Pit Bull
Gender: Female
Reproductive Status: Neutered
Weight: 55 Pound
Age: 10 Years
Assessment of Prior Health: Good

	Number of Animals Given the Product:	1												
	Number of Animals Reacted:	1												
	Owner Information:													
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td>Type of Veterinarian:</td> <td>Referred veterinarian</td> </tr> </table>	Practice Name:	B6	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Address:	B6	Type of Veterinarian:	Referred veterinarian
Practice Name:	B6													
Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:										
Name:	B6													
Phone:														
Address:	B6													
Type of Veterinarian:	Referred veterinarian													
Sender Information:	Name:	B6												
	Address:	B6												
		United States												
	Contact:	<table border="1"> <tr> <td>Email:</td> <td>B6</td> </tr> </table>	Email:	B6										
Email:	B6													
	Reporter Wants to Remain Anonymous:	No												
	Permission To Contact Sender:	Yes												
	Preferred Method Of Contact:	Email												
	Reported to Other Parties:	None												
Additional Documents:														

Report Details - EON-371628

ICSR: 2059154
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Both
Reporting Type: Voluntary
Report Submission Date: 2018-11-21 12:06:34 EST
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Died suddenly. Autopsy revealed excellent body condition and death due to DCM. Very few symptoms prior to this other than occasional periods of lethargy.
Date Problem Started: B6
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Died Other
Date of Death: B6

Product Information:
Product Name: Rayne Low Fat Kangaroo Maintenance
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Shepherd Dog - German
Gender: Female
Reproductive Status: Neutered
Weight: 84 Pound
Age: 7 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information:
Healthcare Professional Information: Contact: Name: B6
Phone: B6

Sender Information:
Name: B6
Contact: Email: B6
Reporter Wants to Remain Anonymous: No
Permission To Contact Sender: Yes
Preferred Method Of Contact: Email

Reported to Other Parties: None

Additional Documents:

Report Details - EON-371713

ICSR:	2059213
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-11-22 13:08:15 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	He started coughing and became tired. Not himself. I took him to the vet and he was ex with chf. Put on diaretics and heart meds. Continued to get worse and I had to put him down on B6
	Date Problem Started:	03/21/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Wilderness grain free. Bison and beef. Senior dog food. Dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	20 Pound		
	Purchase Date:	01/26/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Plastic food bin in the bag		
	Product Use Information:	Description:	Feed morning and evening 1 cup	
		First Exposure Date:	01/26/2018	
		Last Exposure Date:	04/04/2018	
		Time Interval between Product Use and Adverse Event:	2 Years	
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		No		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:	No			

	Manufacturer /Distributor Information:	
Animal Information:	Purchase Location Information: Name: Pet smart Address: B6 United States	
Sender Information:	Name: B6 Type Of Species: Dog Type Of Breed: Spaniel - Cocker American Gender: Male Reproductive Status: Intact Weight: 40 Pound Age: 11 Years Assessment of Prior Health: Excellent Number of Animals Given the Product: 1 Number of Animals Reacted: 1 Owner Information: Healthcare Professional Information:	Address: B6 United States Contact: Phone: B6 Email: B6 Reporter Wants to Remain Anonymous: No Permission To Contact Sender: Yes Preferred Method Of Contact: Address Reported to Other Parties: None
Additional Documents:		

Report Details - EON-371567

ICSR: 2059115
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-11-20 17:04:36 EST

Reported Problem:
Problem Description: B6 presented to his primary veterinarian for a dry non-productive cough of 4 days duration. A grade 2/6 heart murmur was auscultated at that time. Thoracic radiographs were performed and cardiomegaly was appreciated. B6 suspected dilated cardiomyopathy (DCM) and she referred B6 here for a cardiology consult. B6 has dilated cardiomyopathy (DCM).
Date Problem Started: 11/09/2017
Date of Recovery: 08/13/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Zignature Kangaroo Formula Limited Ingredient Formula
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Sheepdog - Beauce (Beauceron)
Gender: Male
Reproductive Status: Intact
Age: 9 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: Owner Information provided: No
Healthcare Professional Information:
Practice Name: B6
Contact: Name: B6
Phone: B6
Email: B6
Address: B6

			B6
			United States
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:	None		

Additional Documents:

Report Details - EON-371613

ICSR: 2059144
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-21 09:42:20 EST

Reported Problem:

Problem Description: my dog seemed to be panting more and drinking more water. I asked vet about this during a checkup. I had heard about taurine related DCM and asked if this was symptomatic since I was feeding a grain-free "boutique" food to my dog. Vet recommended blood work and an echo. Cardiac Echo showed mild DCM and cardiac vet recommended Taurine supplements and change food to a grain-free food by an established dog food manufacturer.

Date Problem Started: 10/29/2018

Concurrent Medical Problem: No

Outcome to Date: Unknown

Product Information:

Product Name: Zignature Trout and Salmon Meal Limited Ingredient Formula Grain-Free Dry Dog Food

Product Type: Pet Food

Lot Number:

UPC: unknown

Package Type: BAG

Package Size: 27 Pound

Purchase Date: 10/10/2018

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: Stored in original bag, tightly rolled up, with no extra air, in cool part of kitchen.

Product Use Information:

Description: 1 cup Food was given 3x a day, dry.

First Exposure Date: 10/11/2018

Last Exposure Date: 11/12/2018

Time Interval between Product Use and Adverse Event: 10 Months

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

Adverse Event Abate After Product Stop: Unknown

Product Use Started Again: No

Perceived Relatedness to Adverse Event: Probably related

Other Foods or Products Given: Yes

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name: Chewy.com and local pet stores

Address: unknown
unknown
B6
unknown
United States

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Other Canine/dog

Gender: Male

Reproductive Status: Neutered

Weight: 53 Pound

Age: 12 Months

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: B6

Contact:

Name: B6

Phone: B6

Address:

B6

United States

Type of
Veterinarian:

Primary/regular veterinarian

Date First Seen: 10/29/2018

Permission to
Release Records
to FDA: Yes

Practice Name: B6

Contact:

Name: B6

Phone: B6

Address:

B6

			B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	11/12/2018
		Permission to Release Records to FDA:	Yes

Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email		
Reported to Other Parties:	None		

Additional Documents:	Attachment:	DCM echo result NOV 2018.pdf
	Description:	test result of ECHO
	Type:	Medical Records

Report Details - EON-359375		
ICSR:	2052141	
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:	2018-07-16 14:38:04 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: B6 has some allergies to certain grains causing him to have yeast infections in the pads of his feet so per our veterinarian's recommendation we switched him to a Grain Free Diet. At only 3 years of age and in previously excellent health he became suddenly ill and diagnosed with Dialated Cardiomyopathy which lead to atrial fibrillation and congestive heart failure. He is doing well considering his prognosis and the fact they gave him only a couple months to live a relatively normal pain free life on medication (which cost approx. \$235/month). After he was diagnosed I did hours of research trying to find out more about the disease and it led me to two facts: 1. DCM is believe to be passed genetically through some breed, Great Danes being one of those breeds and 2. Recently more and more studies have linked grain free diets to Taurine deficiency and the development of DCM. Unfortunately in his case both things were working against him. While there is really no way of knowing if it was something that was passed to him genetically, a result of his diet, or a combination of the two I feel it needed to be reported.	
	Date Problem Started: 05/28/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: 4health Grain Free Large Breed Formula	
	Product Type: Pet Food	
	Lot Number:	
	UPC: 110291599	
	Package Type: BAG	
	Package Size: 30 Pound	
	Purchase Date: 05/21/2018	
	Number Purchased: 2	
	Possess Unopened Product: No	
	Possess Opened Product: Yes	
	Storage Conditions: Prior to opening the product was stored in the original bag in our house. After opening the product was stored in a wooden box/tote in our house.	
	Product Use Information:	Description: Dry Dog Food, he ate approximately 3 1/2 cups morning and night.
		First Exposure Date: 05/21/2018
Last Exposure Date: 05/27/2018		
Time Interval between Product Use and Adverse Event: 3 Years		
Product Use Stopped After the Onset of the Adverse Event: Yes		
Adverse Event Abate After No		

		Product Stop:	
		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Possibly related
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Tractor Supply Company
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Great Dane	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	145 Pound	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:		
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Email:	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

Report Details - EON-359374

ICSR: 2052139
 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: 2018-07-16 14:33:15 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: B6 started having difficulty breathing, and was not interested in her food, which was not like her. When we took her through the vet we learned she dilated cardiomyopathy. She was started on multiple meds, but we were told this disease was fatal. We didn't know how long she would have. She died 4 months after diagnosis.

Date Problem Started: 06/03/2017

Concurrent Medical Problem: Yes

Pre Existing Conditions: B6 had long suffered from allergies, which was why we ended up on this formulation to begin with. She had allergies to almost every other food we had tried. The next step was to be a raw diet.

Outcome to Date: Died Euthanized

Date of Death: B6

Product Information:

Product Name: California Natural Grain Free Kangaroo and Red Lentils Recipe

Product Type: Pet Food

Lot Number:

UPC: Multiple

Package Type: BAG

Package Size: 13 Pound

Purchase Date: 08/31/2017

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: From the store it went in my trunk and then when we got home it would be immediately put in a plastic dog food container to keep it fresh

Product Use Information:

Description: B6 was fed this exact formulation exclusively for at least the last year of her life. She very rarely had any treats due to her extreme allergies. Although this was the last date purchased, we purchased many bags over the course of her (short) life.

Time Interval between Product Use and Adverse Event: 15 Months

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: Animal Information:	<table border="1"> <tr> <td data-bbox="665 351 876 393">Name:</td> <td data-bbox="876 351 1554 393">B6</td> </tr> <tr> <td data-bbox="665 393 876 436">Address:</td> <td data-bbox="876 393 1554 436">United States</td> </tr> <tr> <td data-bbox="665 436 876 468">Type Of Species:</td> <td data-bbox="876 436 1554 468">Dog</td> </tr> <tr> <td data-bbox="665 468 876 500">Type Of Breed:</td> <td data-bbox="876 468 1554 500">Bulldog - French</td> </tr> <tr> <td data-bbox="665 500 876 532">Gender:</td> <td data-bbox="876 500 1554 532">Female</td> </tr> <tr> <td data-bbox="665 532 876 563">Reproductive Status:</td> <td data-bbox="876 532 1554 563">Neutered</td> </tr> <tr> <td data-bbox="665 563 876 595">Weight:</td> <td data-bbox="876 563 1554 595">30 Pound</td> </tr> <tr> <td data-bbox="665 595 876 627">Age:</td> <td data-bbox="876 595 1554 627">3 Years</td> </tr> <tr> <td data-bbox="665 627 876 691">Assessment of Prior Health:</td> <td data-bbox="876 627 1554 691">Fair</td> </tr> <tr> <td data-bbox="665 691 876 755">Number of Animals Given the Product:</td> <td data-bbox="876 691 1554 755">1</td> </tr> <tr> <td data-bbox="665 755 876 819">Number of Animals Reacted:</td> <td data-bbox="876 755 1554 819">1</td> </tr> <tr> <td data-bbox="665 819 876 851">Owner Information:</td> <td data-bbox="876 819 1554 851"></td> </tr> <tr> <td data-bbox="373 851 665 915">Healthcare Professional Information:</td> <td data-bbox="665 851 876 893">Practice Name:</td> <td data-bbox="876 851 1554 893">B6</td> </tr> <tr> <td></td> <td data-bbox="665 893 876 936">Contact: Name:</td> <td data-bbox="876 893 1554 936">B6</td> </tr> <tr> <td></td> <td data-bbox="665 936 876 978">Phone:</td> <td data-bbox="876 936 1554 978">B6</td> </tr> <tr> <td></td> <td data-bbox="665 978 876 1021">Address:</td> <td data-bbox="876 978 1554 1021">B6</td> </tr> <tr> <td></td> <td></td> <td data-bbox="876 1021 1554 1064">United States</td> </tr> <tr> <td></td> <td data-bbox="665 1064 876 1127">Type of Veterinarian:</td> <td data-bbox="876 1064 1554 1127">Primary/regular veterinarian</td> </tr> <tr> <td></td> <td data-bbox="665 1127 876 1170">Date First Seen:</td> <td data-bbox="876 1127 1554 1170">06/03/2017</td> </tr> <tr> <td></td> <td data-bbox="665 1170 876 1234">Permission to Release Records to FDA:</td> <td data-bbox="876 1170 1554 1234">Yes</td> </tr> <tr> <td></td> <td data-bbox="665 1234 876 1276">Practice Name:</td> <td data-bbox="876 1234 1554 1276">B6</td> </tr> <tr> <td></td> <td data-bbox="665 1276 876 1319">Contact: Name:</td> <td data-bbox="876 1276 1554 1319">B6</td> </tr> <tr> <td></td> <td data-bbox="665 1319 876 1361">Phone:</td> <td data-bbox="876 1319 1554 1361">B6</td> </tr> <tr> <td></td> <td data-bbox="665 1361 876 1404">Address:</td> <td data-bbox="876 1361 1554 1404">B6</td> </tr> <tr> <td></td> <td></td> <td data-bbox="876 1404 1554 1447">United States</td> </tr> <tr> <td></td> <td data-bbox="665 1447 876 1510">Type of Veterinarian:</td> <td data-bbox="876 1447 1554 1510">Referred veterinarian</td> </tr> <tr> <td></td> <td data-bbox="665 1510 876 1574">Permission to Release Records to FDA:</td> <td data-bbox="876 1510 1554 1574">Yes</td> </tr> <tr> <td data-bbox="73 1776 373 2002">Sender Information:</td> <td data-bbox="373 1776 665 1819">Name:</td> <td data-bbox="665 1776 1554 1819">B6</td> </tr> <tr> <td></td> <td data-bbox="373 1819 665 1862">Address:</td> <td data-bbox="665 1819 1554 1862">B6</td> </tr> <tr> <td></td> <td></td> <td data-bbox="665 1862 1554 1904">United States</td> </tr> </table>	Name:	B6	Address:	United States	Type Of Species:	Dog	Type Of Breed:	Bulldog - French	Gender:	Female	Reproductive Status:	Neutered	Weight:	30 Pound	Age:	3 Years	Assessment of Prior Health:	Fair	Number of Animals Given the Product:	1	Number of Animals Reacted:	1	Owner Information:		Healthcare Professional Information:	Practice Name:	B6		Contact: Name:	B6		Phone:	B6		Address:	B6			United States		Type of Veterinarian:	Primary/regular veterinarian		Date First Seen:	06/03/2017		Permission to Release Records to FDA:	Yes		Practice Name:	B6		Contact: Name:	B6		Phone:	B6		Address:	B6			United States		Type of Veterinarian:	Referred veterinarian		Permission to Release Records to FDA:	Yes	Sender Information:	Name:	B6		Address:	B6			United States
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		United States																																																																														

	Contact:	Phone:	B6	
		Email:		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Phone		
Reported to Other Parties:	Other			

Additional Documents:	Attachment:	B6 .pdf
	Description:	Report by specialists B6 used (cardiologists) to interpret ECG / X-Rays
	Type:	Medical Records
	Attachment:	B6 175852.pdf
	Description:	Vet report from end of life as her disease was progressing.
	Type:	Medical Records
	Attachment:	B6 July.jpg
	Description:	X ray of chest soon after initial findings - July 2017
	Type:	Radiographs
	Attachment:	B6 .jpg
	Description:	X ray in B6 week of passing
	Type:	Radiographs
	Attachment:	Following Echocardiogram.pdf
	Description:	Doctor's note following Echocardiogram of diagnosis and treatment plan
	Type:	Medical Records

Report Details - EON-359413		
ICSR:	2052179	
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:	2018-07-16 18:47:01 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Diagnosed with right heart failure by x-Ray in the fall 2017 after sudden onset of coughing. Episodic falling/fainting with drastic decrease in energy/life quality.	
	Date Problem Started: 10/24/2017	
	Concurrent Medical Problem: No	
	Outcome to Date: Worse/Declining/Deteriorating	
Product Information:	Product Name: Earth born holistic for small breed	
	Product Type: Pet Food	
	Lot Number:	
	Storage Conditions: Closed container	
	Product Use Information:	
	Description: 1/4 cup 3 times a day for 10 years.	
	Product Use Stopped After the Onset of the Adverse Event: No	
Perceived Relatedness to Adverse Event: Possibly related		
Manufacturer /Distributor Information:		
Purchase Location Information:		
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Schnauzer - Miniature	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 19 Pound	
	Age: 12 Years	
	Assessment of Prior Health: Good	
	Number of Animals Given the Product: 2	
	Number of Animals Reacted: 1	
	Owner Information:	
	Healthcare Professional Information:	
	Sender Information:	Name: B6
Contact: Phone:		
Email: B6		
Reporter Wants to Remain Anonymous: No		
Permission To Contact: Yes		

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

Additional Documents:

Report Details - EON-359365		
ICSR:	2052133	
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:	2018-07-16 13:53:39 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Sudden onset of difficulty breathing with a harsh bark. Gradually lost bark. Lost about 8pounds in weight over 2 month period. Chest x-ray revealed enlarged heart and found fluid on her lungs. EKG showed trigeminy. Subsequent echocardiogram confirmed dilated cardiac myopathy. All blood work within normal range. Did not do taurine level due to cost. Started her on B6 Cartinine.	
	Date Problem Started: 04/01/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: Earthborne Holistic Grainfree Meadow Dry Food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 30 Pound	
	Purchase Date: 06/01/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: Yes	
	Storage Conditions: stored in a dog food storage container	
	Product Use Information:	Description: each dog received 2cups twice a day for many years.
		Last Exposure Date: 07/07/2018
		Time Interval between Product Use and Adverse Event: 3 Years
Product Use Stopped After the Onset of the Adverse Event: Yes		
Adverse Event Abate After Product Stop: Unknown		
Product Use Started Again: No		
Perceived Relatedness to Adverse Event: Definitely related		
Other Foods or Products Given to the Animal During This Time Period: No		
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: Female Reproductive Status: Neutered Weight: 72 Pound Age: 10.5 Years Assessment of Prior Health: Excellent Number of Animals Given the Product: 2 Number of Animals Reacted: 1 Owner Information:	Healthcare Professional Information: Practice Name: B6 Contact: Name: B6 Phone: B6 Address: B6 United States Type of Veterinarian: Primary/regular veterinarian Permission to Release Records to FDA: Yes
Sender Information:	Name: Address: B6 United States Contact: Phone: B6 Email: B6 Permission To Contact Sender: Yes Preferred Method Of Contact: Email Reported to Other Parties: None	
Additional Documents:	Attachment: 603EC830-0EC4-49C4-A095-C3F8BAFCD567.jpeg Description: Completed 1 week after starting B6 Type: Echocardiogram Attachment: D91CB6AA-DF9B-49C4-BF61-AD5DC3EFF10C.jpeg Description: Chest Xray 2. Labored breathing. Prior to treatment.	

	Type: Radiographs
Attachment:	B0B5EE69-5A34-4E1B-8C2A-1087A5007D24.jpeg
Description:	At vet for initial workup. Lost almost 8 pounds.
Type:	Photograph
Attachment:	4D55E466-23D0-4870-8275-3A2061813C71.jpeg
Description:	Chest Xray with labored breathing. Prior to treatment.
Type:	Radiographs

Report Details - EON-359380		
ICSR:	2052146	
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:	2018-07-16 14:52:28 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: My dog [B6] was prescribed a grain free diet due to allergies in 2012. She remained on this diet even after her allergies became scarce due to moving to a different location. In April of 2018, [B6] became lethargic and was taken to the local animal hospital. She was diagnosed with DCM. She passed away in early [B6] due to issues surrounding her diagnosis. I recently read an article on the link between grain free diets and DCM and I believe her diet contributed to her diagnosis and untimely death. [B6] had always been an extremely healthy bulldog, never weighing more than 40 pounds and was extremely active. It was devastating to our family to have her get so sick in such a short period of time and ultimately lose her. We grieve her everyday.	
	Date Problem Started: 04/07/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Euthanized	
	Date of Death: [B6]	
Product Information:	Product Name: Wellness CORE Grain Free Wild Game Duck, Turkey, Boar & Rabbit Natural Dry Dog Food, 26-Pound Bag	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 26 Pound	
	Purchase Date: 09/30/2017	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: opened and poured into large sealed container	
	Product Use Information:	Description: 1 cup given in the am and pm as part of [B6] daily food
		Last Exposure Date: 11/01/2017
		Product Use Stopped After the Onset of the Adverse Event: No
		Perceived Relatedness to Adverse Event: Definitely related
Other Foods or Products Given to the Animal During This Time Period: No		
Manufacturer /Distributor Information:		
Purchase Location Information:		
Product Name: Merrick Grain free real rabbit and chickpeas		

	Product Type:	Pet Food												
	Lot Number:													
	Package Type:	BAG												
	Package Size:	22 Pound												
	Purchase Date:	05/01/2018												
	Number Purchased:	1												
	Possess Unopened Product:	No												
	Possess Opened Product:	Yes												
	Storage Conditions:	in a large sealed food container												
	Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>Given 1 cup in the am and pm daily as main source of food for B6</td> </tr> <tr> <td>Last Exposure Date:</td> <td>B6</td> </tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>6 Months</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>No</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Definitely related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>No</td> </tr> </table>	Description:	Given 1 cup in the am and pm daily as main source of food for B6	Last Exposure Date:	B6	Time Interval between Product Use and Adverse Event:	6 Months	Product Use Stopped After the Onset of the Adverse Event:	No	Perceived Relatedness to Adverse Event:	Definitely related	Other Foods or Products Given to the Animal During This Time Period:	No
Description:	Given 1 cup in the am and pm daily as main source of food for B6													
Last Exposure Date:	B6													
Time Interval between Product Use and Adverse Event:	6 Months													
Product Use Stopped After the Onset of the Adverse Event:	No													
Perceived Relatedness to Adverse Event:	Definitely related													
Other Foods or Products Given to the Animal During This Time Period:	No													
	Manufacturer /Distributor Information:													
	Purchase Location Information:	<table border="1"> <tr> <td>Name:</td> <td>Petco</td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Name:	Petco	Address:	B6		United States						
Name:	Petco													
Address:	B6													
	United States													
Animal Information:	Name:	B6												
	Type Of Species:	Dog												
	Type Of Breed:	Bulldog												
	Gender:	Female												
	Reproductive Status:	Neutered												
	Weight:	36 Pound												
	Age:	7 Years												
	Assessment of Prior Health:	Excellent												
	Number of Animals Given the Product:	1												
	Number of Animals Reacted:	1												
	Owner Information:													
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Type of Veterinarian:</td> <td>Referred veterinarian</td> </tr> </table>	Practice Name:	B6	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Type of Veterinarian:	Referred veterinarian		
Practice Name:	B6													
Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:										
Name:	B6													
Phone:														
Type of Veterinarian:	Referred veterinarian													

		Date First Seen: 04/10/2018
		Permission to Release Records to FDA: Yes
		Practice Name: B6
		Contact: Name: B6 Phone: B6
		Type of Veterinarian: Primary/regular veterinarian
		Permission to Release Records to FDA: Yes
Sender Information:	Name:	B6
	Address:	United States
	Contact: Phone:	B6
	Email:	
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	Other
Additional Documents:		

Report Details - EON-359398

ICSR: 2052158
 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: 2018-07-16 16:18:55 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: finicky with his food starting April 1, threw up, saw vets, rushed to emergency in CHF, diagnosed with DCM -could not stabilize, died. only 3 years old- had hiked 3 days before
Date Problem Started: 04/01/2018
Concurrent Medical Problem: No
Outcome to Date: Died Euthanized
Date of Death: B6

Product Information:
Product Name: Natural Balance Sweet Potato and Bison
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
Last Exposure Date: B6
Time Interval between Product Use and Adverse Event: 3 Years
Product Use Stopped After the Onset of the Adverse Event: Unknown
Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:
Purchase Location Information:
Name: PetCo
Address: B6
 United States

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Doberman Pinscher
Gender: Male
Reproductive Status: Neutered

Weight: 103 Pound

Age: 3 Years

Assessment of Prior Health: Good

Number of Animals Given the Product: 2

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional Information:

Practice Name: B6

Contact: Name: B6

Phone: B6

Email: B6

Address: B6

United States

Type of Veterinarian: Primary/regular veterinarian

Date First Seen: B6

Permission to Release Records to FDA: Yes

Contact: Name: B6

Phone: B6

Email: B6

Address: B6

United States

Type of Veterinarian: Primary/regular veterinarian

Date First Seen: B6

Permission to Release Records to FDA: Yes

Practice Name: B6

Contact: Name: B6

Phone: B6

Address: B6

United States

Type of Veterinarian: Referred veterinarian

Date First Seen: B6

Permission to Release Records to FDA: Yes

Sender Information: Name:

Address:

B6

United States

	Contact:	Phone:	B6
		Email:	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Phone	
Reported to Other Parties:	Unknown		

Additional Documents:

Report Details - EON-359408					
ICSR:	2052177				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Both				
Reporting Type:	Voluntary				
Report Submission Date:	2018-07-16 18:27:29 EDT				
Reporter is the Animal Owner:	Yes				
Reported Problem:	Problem Description: My dog had symptoms related to grain free dog food that has potatoes in it. He had coughing and low energy, we didn't see any coughing beforehand until the day he passed he was coughing more				
	Date Problem Started: 04/29/2018				
	Concurrent Medical Problem: No				
	Outcome to Date: Died Other				
	Date of Death: B6				
Product Information:	Product Name: Nuro sweet potatoes and lamb for large breed				
	Product Type: Pet Food				
	Lot Number:				
	Possess Opened Product: Yes				
	Storage Conditions: In a sealed container				
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>Fed him twice a day with 3 cups each</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> </table>	Description:	Fed him twice a day with 3 cups each	Perceived Relatedness to Adverse Event:	Probably related
	Description:	Fed him twice a day with 3 cups each			
	Perceived Relatedness to Adverse Event:	Probably related			
Manufacturer /Distributor Information:					
Purchase Location Information:					
Animal Information:	Name:				
	Type Of Species: Dog				
	Type Of Breed: Saint Bernard Dog				
	Reproductive Status: Neutered				
	Assessment of Prior Health: Good				
	Number of Animals Reacted: 1				
	Owner Information:				
Healthcare Professional Information:					
Sender Information:	Name: B6				
	Address: <table border="1"> <tr> <td>United States</td> </tr> </table>	United States			
	United States				
	Contact: <table border="1"> <tr> <td>Email: B6</td> </tr> </table>	Email: B6			
	Email: B6				
	Reporter Wants to Remain Anonymous: No				
	Permission To Contact Sender: Yes				
Preferred Method Of Contact: Email					

Additional Documents:

Report Details - EON-359424

ICSR: 2052184
 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: 2018-07-16 21:22:34 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: He was lethargic, wouldnt eat well and had a persistent cough for several years and he died of Dilated Cardiomyopathy DCM.

Date Problem Started: 06/01/2016

Concurrent Medical Problem: No

Outcome to Date: Died Other

Date of Death: B6

Product Information:

Product Name: Nutri source- adult

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: In a plastic bag in a closet

Product Use Information:

Description: Eaten tree times per day

First Exposure Date: 01/30/2015

Last Exposure Date: 05/23/2018

Time Interval between Product Use and Adverse Event: 3 Years

Product Use Stopped After the Onset of the Adverse Event: No

Perceived Relatedness to Adverse Event: Definitely related

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

Manufacturer /Distributor Information:

Purchase Location Information: Name: Petsmart
 Address: B6
 United States

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Great Dane

	Gender: Male
	Reproductive Status: Neutered
	Weight: 130 Pound
	Age: 4 Years
	Assessment of Prior Health: Good
	Number of Animals Reacted: 1
	Owner Information:
	Healthcare Professional Information:
	Contact: Name: B6
	Phone: B6
Sender Information:	Name: B6
	Address: B6
	United States
	Contact: Phone: B6
	Email: B6
	Reporter Wants to Remain Anonymous: No
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
	Reported to Other Parties: None
Additional Documents:	

Report Details - EON-359388

ICSR: 2052151
 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: 2018-07-16 15:08:44 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: We have had [B6] since we rescued him when he was 8 months old. He has never had any health issues and is now 13 years old. Last summer, I noticed [B6] heart was beating "weird" - felt like the rasping sound your lungs get when you have pneumonia. We took him to the vet who sent us immediately to a cardiologist saying we had a "very sick dog". [B6] is now on [B6] twice a day for his heart. He often eats Pedigree Adult Dog Food which has peas as one of the main ingredients.
Date Problem Started: 08/07/2017
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: PEDIGREE® Dry Dog Food Adult Roasted Chicken, Rice & Vegetable Flavor
Product Type: Pet Food
Lot Number:
Package Type: BAG
Storage Conditions: We have an airtight pet food container.
Product Use Information:
Description: [B6] is fed daily.
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:

Animal Information:
Name: [B6]
Type Of Species: Dog
Type Of Breed: Terrier - Jack Russell
Gender: Male
Reproductive Status: Neutered
Weight: 15 Pound
Age: 13 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
Number of Animals Reacted: 1

Owner Information:	Healthcare Professional Information:		Contact:	Name:	B6	
				Phone:		
			Permission to Release Records to FDA:	Yes		
			Contact:	Name:	B6	Not sure of cardiologist name
				Phone:	B6	
			Type of Veterinarian:	Referred veterinarian		
Sender Information:	Name:		B6			
	Address:		B6			
			United States			
	Contact:		Phone:	B6		
			Email:			
	Reporter Wants to Remain Anonymous:		No			
Permission To Contact Sender:		Yes				
Preferred Method Of Contact:		Email				
Reported to Other Parties:		None				
Additional Documents:						

Report Details - EON-359341		
ICSR:	2052114	
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:	2018-07-16 11:32:21 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: I recently lost my 5 year old boxer to heart failure. His heart was so enlarged there was nothing the vet can do to save him. I have been reading to please report to FDA any issues with your animals on grain free food that had heart disease and that is all he ate due to gastric issues. I would like to know if this food had something to do with his death so I can never ever use it again.	
	Date Problem Started: 05/01/2018	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: Gastric issues switched to grain free food per the vet	
	Outcome to Date: Died Euthanized	
	Date of Death: B6	
Product Information:	Product Name: Rachael Ray Grain Free	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 20 Pound	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: In plastic container	
	Product Use Information:	Description: Feed to my dog twice daily 3 cups each feeding
		First Exposure Date: 01/01/2014
		Last Exposure Date: B6
		Other Foods or Products Given to the Animal During This Time Period: No
	Manufacturer /Distributor Information:	
Purchase Location Information:	Name: Acme, Giant eagle	
	Address: B6 United States	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Boxer (German Boxer)	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 126 Pound	
	Age: 5 Years	

	Assessment of Prior Health:	Good																		
	Number of Animals Given the Product:	1																		
	Number of Animals Reacted:	1																		
	Owner Information:																			
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Other Phone:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> <tr> <td>Type of Veterinarian:</td> <td>Primary/regular veterinarian</td> </tr> <tr> <td>Date First Seen:</td> <td>B6</td> </tr> <tr> <td>Permission to Release Records to FDA:</td> <td>Yes</td> </tr> </table>	Practice Name:	B6	Contact: Name:	B6	Phone:	B6	Other Phone:		Address:	B6		United States	Type of Veterinarian:	Primary/regular veterinarian	Date First Seen:	B6	Permission to Release Records to FDA:	Yes
Practice Name:	B6																			
Contact: Name:	B6																			
Phone:	B6																			
Other Phone:																				
Address:	B6																			
	United States																			
Type of Veterinarian:	Primary/regular veterinarian																			
Date First Seen:	B6																			
Permission to Release Records to FDA:	Yes																			
Sender Information:	Name:	B6																		
	Address:	B6																		
		United States																		
	Contact: Phone:	B6																		
	Other Phone:																			
	Email:																			
	Permission To Contact Sender:	Yes																		
	Preferred Method Of Contact:	Email																		
	Reported to Other Parties:	None																		
Additional Documents:																				

Report Details - EON-359368

ICSR: 2052134
 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: 2018-07-16 14:03:37 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: My dog **B6** suddenly became ill and was brought to the animal ER after suffering several collapses. He had suddenly stopped eating or drinking, and was having difficulty breathing. He had been in perfect health and had passed all of his doctor's exams during his checkups. The emergency vet did an xray and advised me that the dog had an enlarged heart and there wasn't much they could do, so we had to put him down. Just a few days I ago, I learned that some ingredients in dog food were causing heart disease in dogs not prone to it. I had been feeding the dog Rachel Ray Nutrish and Nature's Recipe; he really liked the Rachel ray brand and being the spoiled doggie he was, I bought it because I thought I was feeding him something healthy that he enjoyed.

Date Problem Started: **B6**

Concurrent Medical Problem: No

Outcome to Date: Died Euthanized

Date of Death: **B6**

Product Information:

Product Name: Rachel Ray Nutrish

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: stored at room temperature in kitchen

Product Use Information:

Description: twice daily with water, serving size according to instructions

First Exposure Date: 05/01/2017

Last Exposure Date: **B6**

Time Interval between Product Use and Adverse Event: 1 Years

Product Use Stopped After the Onset of the Adverse Event: No

Perceived Relatedness to Adverse Event: Definitely related

Other Foods or Products Given to the Animal During This Time Period: No

Manufacturer /Distributor Information:

Purchase Location Address: United States

	Information:		
Animal Information:	Name:		
	Type Of Species:	Dog	
	Type Of Breed:	Chihuahua	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	4 Pound	
	Age:	10 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name:
Phone:			
Address:		B6	
		United States	
Type of Veterinarian:		Primary/regular veterinarian	
Date First Seen:		B6	
Permission to Release Records to FDA:		Yes	
Sender Information:	Name:		
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	None		
Additional Documents:			

Report Details - EON-359404

ICSR: 2052173
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-07-16 17:58:48 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: My dog was healthy and has been eating WeeBit Solid Gold food with Bison peas and pea protein. She went from a healthy checkup to stage 4 congested heart failure.
Date Problem Started: 10/01/2017
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Solid Gold Wee Bit With Bison
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: sealed container
Product Use Information: **Description:** 1/4 cup 2 times daily
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Chihuahua
Gender: Female
Reproductive Status: Neutered
Weight: 7 Pound
Age: 10 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information:
Healthcare Professional Information: **Practice Name:** B6
Contact: **Name:** B6
Phone: B6
Address: B6
 United States
Type of Primary/regular veterinarian

Veterinarian:	
Date First Seen:	10/01/2017
Permission to Release Records to FDA:	Yes

Sender Information:	Name:	
	Address:	B6 United States
	Contact:	
	Reporter Wants to Remain Anonymous:	Yes
	Reported to Other Parties:	None

Additional Documents:	
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Report Details - EON-359401

ICSR: 2052169
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: 2018-07-16 17:19:31 EDT

Reported Problem:

Problem Description:	Patient experienced an acute onset of left sided congestive heart failure. Patient had been eating Taste of the Wild grain free food, containing approximately 50% lentils, since a puppy. Complete lab work including a CBC, Chem, thyroid and urinalysis were obtained. Patient was negative for heartworm disease. Thoracic rads showed a significantly enlarged cardiac silhouette and perihilar alveolar infiltrate. An echocardiogram was performed and results were interpreted by a boarded cardiologist. M-mode, spectral doppler, B-mode and color Doppler studies were obtained. The patient was diagnosed with trace mitral, aortic, and tricuspid insufficiency, left and right sided
Date Problem Started:	04/12/2018
Concurrent Medical Problem:	No
Outcome to Date:	Better/Improved/Recovering

Product Information:

Product Name:	Taste of the Wild Grain Free Free, both turkey and bison
Product Type:	Pet Food
Lot Number:	
Package Type:	BAG
Product Use Information:	
Manufacturer /Distributor Information:	
Purchase Location Information:	

Animal Information:

Name:									
Type Of Species:	Dog								
Type Of Breed:	Shepherd Dog - German								
Gender:	Male								
Reproductive Status:	Neutered								
Weight:	78 Pound								
Age:	2 Years								
Assessment of Prior Health:	Excellent								
Number of Animals Given the Product:	1								
Number of Animals Reacted:	1								
Owner Information:	<table border="1"><tr><td>Owner Information provided:</td><td>No</td></tr></table>	Owner Information provided:	No						
Owner Information provided:	No								
Healthcare Professional Information:	<table border="1"><tr><td>Practice Name:</td><td>B6</td></tr><tr><td>Contact:</td><td><table border="1"><tr><td>Name:</td><td>B6</td></tr><tr><td>Phon:</td><td></td></tr></table></td></tr></table>	Practice Name:	B6	Contact:	<table border="1"><tr><td>Name:</td><td>B6</td></tr><tr><td>Phon:</td><td></td></tr></table>	Name:	B6	Phon:	
Practice Name:	B6								
Contact:	<table border="1"><tr><td>Name:</td><td>B6</td></tr><tr><td>Phon:</td><td></td></tr></table>	Name:	B6	Phon:					
Name:	B6								
Phon:									

Sender Information:

Name:	B6
Address:	B6

		B6
		United States
	Contact:	Phone:
		Email:
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:	Attachment:	B6 Cardiologist Report.pdf
	Description:	Echo report, Cardiologist Review
	Type:	Medical Records

Report Details - EON-359422	
ICSR:	2052183
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:	2018-07-16 21:10:06 EDT
Reported Problem:	Problem Description: Dog was dx with heart disease.
	Date Problem Started: 01/01/2013
	Concurrent Medical Problem: Yes
	Pre Existing Conditions: B6
	Outcome to Date: Unknown
Product Information:	Product Name: Taste of the Wild
	Product Type: Pet Food
	Lot Number:
	Product Use Information:
	Manufacturer /Distributor Information:
	Purchase Location Information:
Animal Information:	Name:
	Type Of Species: Dog
	Type Of Breed: Beagle
	Gender: Female
	Reproductive Status: Neutered
	Age: 8.5 Years
	Assessment of Prior Health: Unknown
	Number of Animals Given the Product: 2
	Number of Animals Reacted: 2
	Owner Information: Owner Information provided: No
Healthcare Professional Information:	
Sender Information:	Name: B6
	Contact: Email: B6
	Reporter Wants to Remain Anonymous: No
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
Additional Documents:	Attachment: clinicalSummary_AN122856_S10604 B6.pdf
	Description: This dog was also diagnosed with Mitral valve heart disease at the same time in the same household, eating the same grain free food.
	Type: Medical Records

Attachment:	clinicalSummary_AN122856_S10604 B6 pdf
Description:	full hx
Type:	Medical Records

Report Details - EON-359399			
ICSR:	2052159		
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:	2018-07-16 16:26:48 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	I rescued B6 9 years ago. My other dog was on a grain-free diet, so B6 was too. B6 was just diagnosed with Congestive Heart Failure. The veterinarian at B6 suggested I change her food because the grain-free is showing problematic. This happened this month and now I am seeing the newspaper articles. I also use to give both dogs green beans or peas mixed in with their dry food. I look and their dry food's main ingredient is dried peas.	
	Date Problem Started:	06/25/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	V-Dog Kinderkibble	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	06/16/2018	
	Number Purchased:	1	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	Yes	
	Storage Conditions:	I have the bags shipped to my house.	
	Product Use Information:	Description:	Both my dogs have been given this product 2 times a day for years. I did also add canned peas or green beans to the feedings.
		Last Exposure Date:	07/15/2018
		Time Interval between Product Use and Adverse Event:	3 Years
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:	Name:	Online	
	Address:	United States	

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Mixed (Dog)		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	48 Pound		
	Age:	12 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	2		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	B6
Email:			B6	
Address:		B6		
		United States		
Date First Seen:	06/29/2018			
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6		
	Address:	B6		
		United States		
	Contact:	Phone:	B6	
		Email:	B6	
	Reporter Wants to Remain Anonymous:	No		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-359340

ICSR: 2052113
 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: 2018-07-16 11:18:54 EDT

Reported Problem:
Problem Description: B6 was presented on 7/13/18 for evaluation of suspected atrial premature complexes, as documented by the oncology service. Has hx of B6 B6 for which he had a B6 will hack and gag occasionally after eating grass. He has not been as eager to go on evening walks since it's been hotter outside and will take more breaks during walks recently. B6 diet is currently Fromm grain free with red meat. He was previously fed Zignature Kangeroo and Lentil for approximately 2 years from 201 B6 was receiving B6 but was switched to diatomaceous earth at the beginning of the month at the breeders insistence.
Date Problem Started: 05/01/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Fromm grain free with Red Meat
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: Yes
Product Use Information:
Description: 4 and 1/2 cup twice daily from January 2018-Present
Product Use Stopped After the Onset of the Adverse Event: No
Perceived Relatedness to Adverse Event: Possibly related
Manufacturer /Distributor Information:
Purchase Location Information: **Address:** B6 United States

Product Name: Zignature Kangeroo and Lentil
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
Description: 4 and 1/2 cup twice daily from December 2016-January 2018.
Product Use Stopped After the Onset of the Adverse Event: No

		Perceived Relatedness to Adverse Event:	Probably related
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Schnauzer - Giant	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	46.6 Kilogram	
	Age:	9 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6 Phone: B6 Other 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:

Report Details - EON-365912

ICSR: 2055090
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-09-19 07:23:17 EDT

Reported Problem:
Problem Description: Reported as RFR EON-365667. FDA Resubmitting as PER. I am a veterinary cardiologist and diagnosed DCM in a dog named **B6** who is 3 years old, that has been fed a high legume diet for years. Although the diet is not completely grain free it is high in legumes and potatoes. The breed and age of the dog is not typical for genetic DCM and there is concern it is related to the diet. The dog is question has been fed this diet for years and has developed DCM at a young age. We have collected various samples per FDA study VetLIRNCase800. 267 and am ready to submit them
Date Problem Started: 09/17/2018
Outcome to Date: Unknown

Product Information:
Product Name: Merrick Beef with Green Pea and Ancient Grains
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Unknown
Gender: Unknown
Reproductive Status: Unknown
Age: 3 Years
Assessment of Prior Health: Unknown
Number of Animals Reacted: 1
Owner Information: Owner Information provided: No
Healthcare Professional Information:
Practice Name: CVCA
Contact: Name: **B6**
 Phone: **B6**
 Email: **B6**
Address: **B6**
 United States
Type of Veterinarian: Referred veterinarian
Date First Seen: 09/17/2018

Sender Information:
Name: **B6**
Contact: Email: **B6**

Reporter Wants to Remain Anonymous:	No
Permission To Contact Sender:	Yes
Preferred Method Of Contact:	Email

Additional Documents:

[Empty area for additional documents]

Report Details - EON-367073

ICSR: 2055442
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-09-27 17:42:40 EDT

Reported Problem:
Problem Description: 2 day history of acute onset lethargy, anorexia and exhaustion - progressive, today - not eating at all; stopped on walk, layed down and would not get up - had to be carried home Arrhythmia detected on exam - referral to cardiology - diagnosed with DCM - suspected due to grain free diet
Date Problem Started: 09/25/2018
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Instinct (the raw brand) Limited Ingredient Diet - Grain-free recipe with real lamb
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Description: fed twice daily for entire life
Product Use Stopped After the Onset of the Adverse Event: No
Perceived Relatedness to Adverse Event: Probably related
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Retriever - Labrador
Gender: Male
Reproductive Status: Neutered
Weight: 32.1 Kilogram
Age: 3 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 3
Number of Animals Reacted: 1
Owner Information:
Owner Information provided: Yes
Contact:
Name: B6
Phone:
Email:
Address: B6

		B6 United States	
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name: B6	
		Phone: B6	
		Email: B6	
	Address:	B6	
		United States	
	Practice Name:	B6	
	Contact:	Name: B6	
		Phone: B6	
	Address:	B6	
United States			
Type of Veterinarian:	Primary/regular veterinarian		
Date First Seen:	09/27/2018		
Permission to Release Records to FDA:	Yes		
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name: B6	
		Phone: B6	
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	09/27/2018	
	Permission to Release Records to FDA:	Yes	
	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:		None	
Additional Documents:			

Report Details - EON-368293

ICSR: 2055989
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-12 18:27:45 EDT

Reported Problem:

Problem Description: Has had chronic history of skin issues and some GI upset that seems to have been controlled on either California Naturals diet or Zignature Kagaroo and lentil diet, seems to be slowing down and less tolerance to activity, eating the current diet well, checked Taurine level and found to be low, no cough

Date Problem Started: 10/12/2018

Concurrent Medical Problem: Unknown

Outcome to Date: Unknown

Product Information:

Product Name: Zignature Kangaroo Formula

Product Type: Pet Food

Lot Number:

UPC: 888641131327

Package Type: BAG

Package Size: 27 Pound

Possess Unopened Product: Unknown

Possess Opened Product: Yes

Product Use Information:

Description: Fed to dog

Last Exposure Date: 10/12/2018

Product Use Stopped After the Onset of the Adverse Event: No

Perceived Relatedness to Adverse Event: Possibly related

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name:

Type Of Species: Dog

Type Of Breed: Shepherd Dog - German

Gender: Male

Reproductive Status: Neutered

Weight: 35 Kilogram

Age: 6 Years

Assessment of Prior Health: Unknown

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:	CVCA Cardiac Care for Pets
	Contact:	Name: B6 Phone: B6 Email: B6
	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: B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
Additional Documents:	Attachment:	B6 Echocardiogram Report.pdf
	Description:	Echocardiogram Report
	Type:	Medical Records
	Attachment:	B6 BW (chem, cbc) B6.pdf
	Description:	Bloodwork from primary care veterinarian Blood chemistry profile, complete blood count
	Type:	Laboratory Report
	Attachment:	B6 HX B6 (1).pdf
	Description:	Primary care veterinarian history
	Type:	Medical Records
	Attachment:	B6 Echo Data.pdf
	Description:	Echocardiogram Data
	Type:	Echocardiogram

Report Details - EON-370119

ICSR: 2058366
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-02 18:44:44 EDT

Reported Problem:
Problem Description: Has been limping for about 1 year, recent progression and radiographs taken and noted [B6] concern for [B6] has been coughing for months with progressive increase in the cough and decrease in the exercise tolerance, has not been eating well over the past few weeks and changed to a canned diet, currently taking [B6] also taking oral liquid supplements one with [B6] with meds some initial improvement in the clinical signs, chest rads reported to have severe heart enlargement concern for valve disease Diet: 4 health grain free with Aldi and Blue Buffalo Canned Presented to CVCA with advanced dilated cardiomyopathy and bi-ventricular congestive heart failure
Date Problem Started: 10/12/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: 4health - grain free Chicken and vegetables
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** Dry food was fed along with Aldi Grain Free canned and Blue Buffalo Grain Free canned.
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: [B6]
Type Of Species: Dog
Type Of Breed: Sheepdog - Shetland
Gender: Male
Reproductive Status: Neutered
Weight: 17.3 Kilogram
Age: 8 Years
Assessment of Prior Health: Unknown
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:** CVCA Cardiac Care for Pets
Contact: **Name:** [B6]

		Phone: B6
		Email: B6
	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: B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email

Additional Documents:	Attachment:	B6 Echo Data.pdf
	Description:	Echocardiogram Data
	Type:	Echocardiogram
	Attachment:	B6 Chem, CBC.pdf
	Description:	Blood chemistry profile, CBC, T4
	Type:	Laboratory Report
	Attachment:	B6 Echocardiogram Report.pdf
	Description:	CVCA Echocardiogram report and examination
	Type:	Medical Records
	Attachment:	B6 DVM History.pdf
	Description:	Primary care veterinarian history
	Type:	Medical Records
	Attachment:	B6 ECG (CVCA).pdf
	Description:	Electrocardiogram
	Type:	Medical Records

Report Details - EON-359061

ICSR: 2051932
 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: 2018-07-12 20:18:02 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: In June of 2017, I came home and noticed my Pharaoh Hound, [B6] wasn't acting normally. I brought her to our regular vet who found she had a very abnormal heartbeat and we were transferred to Tufts University. She spent a few days there and her heart was on the large side of Normal, but her heart beat was very irregular. She was sent home and eventually recovered, but was given taurine supplements after I read an article on Golden Retrievers and taurine deficiency. She was and is currently being fed 4Health grain free foods. Tufts called me tonight and asked if I could bring her back in for further studies and suggested I report this.
Date Problem Started: 06/10/2017
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: 4health grain free dog food
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: Hound - Pharaoh
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Not Pregnant
Lactation Status: Not lactating
Age: 14 Months
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 10
Number of Animals Reacted: 1
Owner Information:
Healthcare Professional Information:
Practice Name: Tufts University
Contact:
Name: [B6]
Phone: [B6]
Address: [B6]
Type of Veterinarian: Referred veterinarian

Sender Information:
Name: [B6]

	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Phone		
Reported to Other Parties:	Other		

Additional Documents:

Report Details - EON-359076

ICSR: 2051941
 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: 2018-07-13 08:54:05 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: We had 2 dogs we started feeding Natural Balance Venison and Sweet potato dog food approximately 3 years ago. We fed the dogs both the dog food and treats. In May 2018, both dogs were diagnosed with right sided heart enlargement without an obvious cause. A month later, the female dog developed congestive heart failure and died. The female was previously in good health. Our male dog is currently taking **B6** to reduce the coughing symptoms from the enlarged heart and **B6** for skin allergies.

Date Problem Started: 05/25/2018

Concurrent Medical Problem: No

Outcome to Date: Died Euthanized

Date of Death: **B6**

Product Information:

Product Name: Natural Balance Venison and Sweet potato dog food

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: Kitchen counter in original packaging

Product Use Information:

Description: Fed 1 cup dry twice daily

First Exposure Date: 11/13/2015

Last Exposure Date: 06/20/2018

Time Interval between Product Use and Adverse Event: 2 Years

Product Use Stopped After the Onset of the Adverse Event: No

Perceived Relatedness to Adverse Event: Possibly related

Other Foods or Products Given to the Animal During This Time Period: No

Manufacturer /Distributor Information:

Purchase Location Information: Name: Chewy.com

Animal Information: Name:

	Type Of Species:	Dog															
	Type Of Breed:	Mixed (Dog)															
	Gender:	Mixed Population of Female and Male															
	Reproductive Status:	Neutered															
	Assessment of Prior Health:	Good															
	Number of Animals Given the Product:	2															
	Number of Animals Reacted:	2															
	Owner Information:																
	Healthcare Professional Information:	<table border="1"> <tr> <td>Contact:</td> <td>Name:</td> <td>B6</td> </tr> <tr> <td></td> <td>Phone:</td> <td></td> </tr> <tr> <td>Type of Veterinarian:</td> <td colspan="2">Primary/regular veterinarian</td> </tr> <tr> <td>Date First Seen:</td> <td colspan="2">05/18/2018</td> </tr> <tr> <td>Permission to Release Records to FDA:</td> <td colspan="2">Yes</td> </tr> </table>	Contact:	Name:	B6		Phone:		Type of Veterinarian:	Primary/regular veterinarian		Date First Seen:	05/18/2018		Permission to Release Records to FDA:	Yes	
Contact:	Name:	B6															
	Phone:																
Type of Veterinarian:	Primary/regular veterinarian																
Date First Seen:	05/18/2018																
Permission to Release Records to FDA:	Yes																
Sender Information:	Name:	B6															
	Address:	B6 United States															
	Contact:	<table border="1"> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Phone:	B6	Email:												
Phone:	B6																
Email:																	
	Reporter Wants to Remain Anonymous:	No															
	Permission To Contact Sender:	Yes															
	Preferred Method Of Contact:	Email															
	Reported to Other Parties:	Other															
Additional Documents:																	

Report Details - EON-359125

ICSR:	2051971
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-07-13 14:12:37 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	A few years ago I started feeding my dog Blue Buffalo Healthy Weight Chicken & Brown Rice Recipe dry dog food. Earlier this year she was diagnosed with an enlarged heart and is now on twice/day heart medication. She is now on a special prescription diet called Early Cardiac. Prior to starting the Blue Buffalo she had a perfectly good heart, and has always been monitored for health (every year) but a veterinarian. It seems to me after eating the Blue Buffalo for a few years she has now developed heart disease.
	Date Problem Started:	03/01/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Blue Buffalo Life Protection Healthy Weight Chicken & Brown Rice Recipe		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	01/01/2012		
	Number Purchased:	25		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Product was stored in an air-tight container in my pantry.		
	Product Use Information:	Description:	Food was given to her daily as needed. She ate this food for roughly 6-7 years.	
		First Exposure Date:	01/02/2012	
		Last Exposure Date:	03/15/2018	
		Time Interval between Product Use and Adverse Event:	7 Years	
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		Unknown		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Probably related		
Other Foods or Products Given	No			

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name:

Petsmart

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Retriever - Labrador

Gender: Female

Reproductive Status: Neutered

Weight: 32 Pound

Age: 9 Years

Assessment of Prior
Health: Excellent

Number of Animals
Given the Product: 1

Number of Animals
Reacted: 1

Owner Information:

Healthcare Professional
Information:

Sender Information:

Name:

B6

Address:

United States

Contact:

Phone:

B6

Email:

Permission To Contact
Sender: Yes

Preferred Method Of
Contact: Phone

Reported to Other
Parties: None

Additional Documents:

Report Details - EON-359161

ICSR: 2051995
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-07-13 18:19:35 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: My dog began breathing abnormally and was taken to the vet. The vet reported my dogs heart rate was severely high and his lungs filled up with fluid due to heart failure. Several test were ran and we had to take my dog to a specialist vet at another location where my dog was hospitalized for a day and then the vet stated his condition was not getting better and we had to put my dog down.

Date Problem Started: B6

Concurrent Medical Problem: Yes

Pre Existing Conditions: B6
 prior to hospitalization.

Outcome to Date: Died Euthanized

Date of Death: B6

Product Information:

Product Name: BLUE WildernessChicken For Senior Dogs

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 24 Pound

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: Yes

Storage Conditions: stored in sealed plastic container

Product Use Information:

Description: dry dog food eaten regularly by dog orally

Last Exposure Date: B6

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

Adverse Event Abate After Product Stop: No

Product Use Started Again: No

Perceived Relatedness to Adverse Event: Possibly related

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

Manufacturer /Distributor Information:

Purchase Location Information: Name: petco

		Address:	B6
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd Dog - German	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	107 Pound	
	Age:	11 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	B6
		Other Phone:	
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	B6
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6	
			United States
	Contact:	Phone:	B6
		Other Phone:	
		Email:	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

Report Details - EON-359221

ICSR:	2052012
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:	2018-07-14 15:07:28 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	For a dog his age, he has been in excellent health. (vet is even amazed) I switched his kibble when my Chihuahua started gaining weight as she aged as he seemed to like it,(she has reacted as well) a few months ago. I went ahead and also switched to a different kibble for my larger dog, a mixed breed, from the same company. The small ones get FROMM Grain-Free Weight Mgt and the bigger dog gets FROMM Adult Grain-Free. NONE of these dogs ever had health issues. The Miniature Pinscher, [B6] & the Chihuahua [B6] were both diagnosed with CVM recently after being on this food for 5-6 months. My mixed breed 55# (now only 48#) dog [B6] is lethargic, weak, has collapsed a few times and is also now coughing but haven't got him in to see the Vet yet as this just started the previous week. This is WAY too coincidental. After reading the article from the FDA stating CVM probs with grain free dog food containing legumes (lentils, peas, etc) and potatoes as their main ingredients, as my new food indeed has, I am immediately discontinuing use. The Min Pin is just finishing up a medication regimine which has not made one difference and he is not improving at all. The Chihuahua has been on meds since May 1, 2018, "stable" and the Mixed Breed is also deteriorating. Vet thinks just "old age" but they have never been unhealthy dogs. He even stated my 15 year old Min Pin, half blind, arthritic, etc., really IS quite healthy. Until now. Same symptoms as the Chi. I have mentioned this to my friend who owns the Pet Store where I bought this product from. I am switching food immediately to see if they improve.
	Date Problem Started:	05/01/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	FROMM Adult Grain Free Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	not available	
	Package Type:	BAG	
	Package Size:	20 Pound	
	Purchase Date:	07/07/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	air tight plastic food container/bin	
	Product Use Information:	Description:	Fed twice daily
		Last Exposure Date:	07/13/2018
Time Interval between Product Use and Adverse Event:		3 Months	
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
	Product Name:	FROMM Weight Management Grain Free Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	not available	
	Package Type:	BAG	
	Package Size:	4 Pound	
	Purchase Date:	07/07/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	air tight plastic food storage bin	
	Product Use Information:	Description:	fed twice daily as main food
		Last Exposure Date:	07/13/2018
		Time Interval between Product Use and Adverse Event:	3 Months
		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:	Pinscher - Miniature	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	9.5 Pound	

	Age:	15 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	3
	Number of Animals Reacted:	3
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact:	
	Phone:	B6
	Email:	B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
Preferred Method Of Contact:	Email	
Reported to Other Parties:	Store/Place of Purchase	
Additional Documents:		

Report Details - EON-359263

ICSR:	2052025			
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:	2018-07-15 13:03:10 EDT			
Reporter is the Animal Owner:	Yes			
Reported Problem:	Problem Description:	Dog developed sudden cardiac disease following being fed high protein grain free diet - Zignature grain free zessential formula. With sudden acute heart contition and significant elevation of probnp.		
	Date Problem Started:	05/19/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Zignature Zessential		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	20 Pound		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	Yes		
	Storage Conditions:	In cool dry storage location.		
	Product Use Information:	Description:	Fed per directions by amount per weight.	
		First Exposure Date:	05/01/2018	
		Last Exposure Date:	07/14/2018	
		Time Interval between Product Use and Adverse Event:	3 Weeks	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Unknown	
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Possibly related		
Other Foods or Products Given to the Animal During This Time Period:		No		
Manufacturer /Distributor Information:				
Purchase Location Information:				

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Boxer (German Boxer)		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	40 Pound		
	Age:	6 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	2		
	Number of Animals Reacted:	2		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	B6
			Other Phone:	
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		05/21/2018		
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6		
	Address:	B6		
		United States		
	Contact:	Phone:	B6	
		Other Phone:	B6	
Email:		B6		
Reporter Wants to Remain Anonymous:	No			
Permission To Contact Sender:	Yes			
Preferred Method Of Contact:	Email			
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-359282

ICSR:	2052075
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:	2018-07-15 19:21:39 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 had always been fed a primarily homecooked diet - beef, chicken, salmon - usually mixed with rice and vegetables. When we adopted a puppy in 2014 B6 (an English Pointer) I fed the puppy with the kibble sent home with him from the rescue organization and continued to feed him the same brand of kibble through 2015. To keep things simple, I started feeding B6 the kibble as well beginning in 2014. Both dogs would eat kibble with fresh food added (meat, fruit and vegetables). In January of 2015, B6 was diagnosed with dilated cardiomyopathy and was in congestive heart failure (fairly rapid onset). He immediately started on B6 . In June of 2015, B6 was also diagnosed with DCM, at only 1.5 years of age. We did extensive testing at the time to try to determine what could have caused our second and very young dog to be diagnosed with the same heart condition. He is now also on B6 .
	Date Problem Started:	01/01/2015
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Natural Balance L.I.D. Limited Ingredient Diets Sweet Potato & Venison Formula Grain-Free Dry Dog Food, 26-lb bag
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	26 Pound
	Purchase Date:	12/26/2015
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	I had the product autoshipped from an online retailer. So it never really sat unopened in our home. Once it was opened it was poured into a container with a lid.
Product Use Information:	Description:	B6 was fed this kibble twice a day usually mixed with a serving of homecooked chicken or beef and some fruits /vegetables. He hadn't had kibble before other than as a very young puppy. He had it in 2014 through 2015.
	Time Interval between Product Use and Adverse Event:	1 Years
	Product Use Stopped After the Onset of the Adverse Event:	No
	Perceived Relatedness to Adverse Event:	Probably related
	Other Foods or Products Given	Yes

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name: Chewy.com

Address: United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Pointing Dog - Hungarian Short-haired (Vizsla)

Gender: Male

Reproductive Status: Neutered

Weight: 57 Pound

Age: 13 Years

Assessment of Prior
Health: Excellent

Number of Animals
Given the Product: 2

Number of Animals
Reacted: 2

Owner Information:

Healthcare Professional
Information:

Practice Name:

B6

Contact:

Name:

B6

Phone:

Address:

B6

United States

Type of
Veterinarian: Primary/regular veterinarian

Date First Seen: 01/15/2018

Sender Information:

Name:

Address:

B6

United States

Contact:

Phone:

B6

Email:

Permission To Contact
Sender: Yes

Preferred Method Of
Contact: Phone

Reported to Other
Parties: None

Additional Documents:

Report Details - EON-359284

ICSR: 2052078
 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: 2018-07-15 19:36:55 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: We brought **B6** home at 12 weeks of age in January of 2014 He was part of a litter that had been rescued - the rescue organization sent us home with a dry kibble that they had been feeding him. I continued to buy the same product throughout 2014 and in 2015 began having it delivered from an online retailer. **B6** was fed this kibble twice a day and to the kibble I would add chicken, beef or salmon as well as fruits and/or vegetables. Our other dog at the time was not quite 9 years old and in excellent health. He had never really had kibble other than as a very young puppy, instead he had always had homecooked food - meats /rice/veg/fruit etc. But I began feeding him the kibble as well to keep things simple. In January of 2015 our older dog was diagnosed with DCM and then 6 months later **B6** was as well. He was only 1.5 years old.

Date Problem Started: 06/01/2015

Concurrent Medical Problem: No

Outcome to Date: Stable

Product Information:

Product Name: Natural Balance L.I.D. Limited Ingredient Diets Sweet Potato & Venison Formula Grain-Free Dry Dog Food, 26-lb bag

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 26 Pound

Purchase Date: 12/26/2015

Possess Unopened Product: No

Storage Conditions: Please see Individual Case Safety Report Number (ICSR) of 2052075

Product Use Information:

Description: Please see Individual Case Safety Report Number (ICSR) of 2052075

Time Interval between Product Use and Adverse Event: 1 Years

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: chewy.com

Animal Information:

Name: **B6**

Type Of Species: Dog

Type Of Breed: Pointer - English Pointer

Gender: Male

	Reproductive Status: Neutered
	Weight: 50 Pound
	Age: 4.5 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 2
	Number of Animals Reacted: 2
	Owner Information:
Healthcare Professional Information:	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Address: B6
	United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 06/01/2015
Sender Information:	Name:
	Address: B6
	United States
	Contact: Phone: B6
	Email:
	Permission To Contact Sender: Yes
Preferred Method Of Contact: Phone	
Reported to Other Parties: None	
Additional Documents:	

Report Details - EON-359492

ICSR: 2052234
 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: 2018-07-17 10:57:56 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Rapid on-set of veterinarian diagnosed canine dilated cardiomyopathy. Collapsed in morning and taken to veterinarian for diagnosis.
Date Problem Started: 05/19/2018
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Kirkland Signature Nature's Domain Organic Chicken & Pea Dog Food 30 lb.
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 30 Pound
Purchase Date: 06/20/2018
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: Stored in pantry closet in a special dog food bin.
Product Use Information:
Description: Fed to dog per label suggestions.
Last Exposure Date: 07/17/2018
Time Interval between Product Use and Adverse Event: 2 Years
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: No
Manufacturer /Distributor Information:
Purchase Location Information: Name: Costco
 Address: **B6**
 United States

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

	Type Of Breed: Retriever - Labrador
	Gender: Male
	Reproductive Status: Neutered
	Weight: 82 Pound
	Age: 8 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
	Healthcare Professional Information:

Sender Information:	Name:	
	Address:	B6
		United States
	Contact:	
	Phone:	
	Email:	B6
	Reporter Wants to Remain Anonymous:	No
Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email	
Reported to Other Parties:	Other	

Additional Documents:

Report Details - EON-359583

ICSR: 2052273
 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: 2018-07-17 19:01:42 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
 Problem Description: **B6** developed Congestive Heart Failure and Dilated Cardiomyopathy after eating Earthborn Holistic Great Plains Feast.
 Date Problem Started: 01/20/2018
 Concurrent Medical Problem: Yes
 Pre Existing Conditions: **B6**
 Outcome to Date: Stable

Product Information:
 Product Name: Earthborn Holistic Great Plains Feast kibble
 Product Type: Pet Food
 Lot Number:
 Package Type: BAG
 Package Size: 28 Pound
 Purchase Date: 12/20/2017
 Number Purchased: 1
 Possess Opened Product: No
 Storage Conditions: before and after stored in a dry area at room temperature.
Product Use Information:
 Description: Regular food for years
 First Exposure Date: 12/21/2017
 Last Exposure Date: 04/25/2018
 Time Interval between Product Use and Adverse Event: 5 Weeks
 Product Use Stopped After the Onset of the Adverse Event: No
 Perceived Relatedness to Adverse Event: Definitely related
 Other Foods or Products Given to the Animal During This Time Period: Yes
 Manufacturer /Distributor Information:
 Purchase Location Information:

Animal Information:
 Name: **B6**
 Type Of Species: Dog
 Type Of Breed: Retriever - Golden

	Gender: Female
	Reproductive Status: Neutered
	Weight: 70 Pound
	Age: 7 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
	Healthcare Professional Information:

Sender Information:	Name:	B6	
	Address:		
		United States	
	Contact:	Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	

Additional Documents:

Report Details - EON-359809

ICSR: 2052430
 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: 2018-07-19 16:35:58 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Diagnosed with endocardiosis, enlarged heart, heart failure
Date Problem Started: 05/01/2018
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Blue Buffalo Life Protection Formula Healthy Weight Adult Chicken & Brown Rice Recipe Dry Dog Food
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 30 Pound
Purchase Date: 06/25/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: sealed container
Product Use Information:
Description: 1 cup twice a day
Last Exposure Date: 07/17/2018
Time Interval between Product Use and Adverse Event: 1 Years
Perceived Relatedness to Adverse Event: Probably related
Other Foods or Products Given to the Animal During This Time Period: No
Manufacturer /Distributor Information:
Purchase Location Information:
Name: Petsmart
Address: B6
 United States

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Mixed (Dog)
Gender: Female
Reproductive Status: Neutered

	Weight: 53 Pound
	Age: 11 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
Healthcare Professional Information:	Contact: Name: B6
	Phone: B6
	Type of Veterinarian: Primary/regular veterinarian
Sender Information:	Name: B6
	Address: B6
	United States
	Contact: Phone: B6
	Email: B6
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
Additional Documents:	

Report Details - EON-360521

ICSR: 2052783
 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: 2018-07-26 15:41:51 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: B6 had sudden heart failure (3rd degree blockage) and got a pacemaker put in. I had been feeding her a grain-free dog food (Blue Buffalo, various flavors)
Date Problem Started: 01/01/2018
Date of Recovery: 02/01/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Blue Buffalo Freedom
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 50 Pound
Storage Conditions: In an air tight container
Product Use Information:
Description: Dry dog food, fed 2 meals per day
First Exposure Date: 01/01/2013
Last Exposure Date: 01/15/2018
Time Interval between Product Use and Adverse Event: 5 Years
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: Possibly related
Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:
Purchase Location Information: Name: various

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Weimaraner

	Gender: Female
	Reproductive Status: Neutered
	Weight: 60 Pound
	Age: 10 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 2
	Number of Animals Reacted: 1
	Owner Information:
Healthcare Professional Information:	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Other Phone: B6
	Address: B6
	United States
	Type of Veterinarian: Referred veterinarian
	Date First Seen: 01/01/2018
Permission to Release Records to FDA: Yes	
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:	

Report Details - EON-361132

ICSR:	2053113
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-08-02 07:31:39 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	He was on a grain free dog food diet because I thought that was the healthiest way to go after doing research. He was diagnosed with advanced DCM a couple of months ago and is not doing very well. He's on 2 different types of heart medication that is very expensive. But the worst part of all of this is that I feel I did this to him and it's killing me.
	Date Problem Started:	06/30/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Grain free dry dog food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	8 Pound		
	Purchase Date:	05/01/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In a closed container		
	Product Use Information:	Description:	Fed to him twice daily	
		Last Exposure Date:	06/30/2018	
		Time Interval between Product Use and Adverse Event:	6 Years	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	No	
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:		No		
Manufacturer /Distributor Information:				

	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Sheepdog - Shetland	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	40 Pound	
	Age:	11 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact:	Name: B6 Phone:
		Address:	B6 United States
Type of Veterinarian:		Primary/regular veterinarian	
Date First Seen:		06/30/2018	
Permission to Release Records to FDA:		Yes	
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone: B6 Email:	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	None	
Additional Documents:			

Report Details - EON-361623

ICSR:	2053410
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-08-07 20:18:55 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My boxer has IBD (Irritable Bowel Disease), she's been diagnosed with it several years ago and has been on a variety of foods and due to her IBD I've had to try different kinds of protein (beef, fish, etc..). Beginning of last year 2017 I came across pet food with limited ingredients, the protein being Bison meat. At that time I wasn't really paying attention to any other ingredients (weather it's grain free or not). The bison seemed to sit well with her IBD. However, a few months late, early summer of 2017 she developed exercise intolerance and difficulty breathing. At first I attributed it to her getting older and the hot weather. However, in September 2017 I took her to see a vet and she was diagnosed with DCM and was in heart failure and had to be hospitalized. She was started on B6 B6 taurine supplement. She started looking better. On her first recheck a couple months ago, her heart disease was pretty much gone. On her next recheck it was even better. The vet attributed it to the likely Taurine deficiency, since that is the only instance when DCM reverses itself. She asked me if my pet was on grain free food. At that time I didn't really understand how that was related, neither was she, but she advised me that there have been more and more instances across the country. Sure enough, I got home and checked the bag and it is indeed a grain free diet that I've been feeding my dog since the beginning of last year (the one with bison meat). The vet, and myself, now after reading all the research, are pretty certain her heart disease was caused by taurine deficiency which was brought on by feeding grain free diet.
	Date Problem Started:	07/01/2017
	Date of Recovery:	07/18/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Canidae (Pet Food made by Pet People), Grain Free PURE Land Limited Ingredient Diet made with Fresh Bison, Adult	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	640461015801	
	Package Type:	BAG	
	Package Size:	24 Pound	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Some of it was stored in a tupperware type bin for pet food in a cabinet, and the remainder in the original package/bag also in the cabinet	
Product Use Information:	Description:	The pet was fed one cup of this food in the morning and one cup in the evening	
	First Exposure Date:	01/01/2017	
	Time Interval between Product Use and Adverse	5 Months	

		Event:	
		Product Use Stopped After the Onset of the Adverse Event:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Amazon.com
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Boxer (German Boxer)	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	58 Pound	
	Age:	9 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	3	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	B6
		Email:	B6
		Address:	B6
			United States
		Type of Veterinarian:	Referred veterinarian
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Email	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	

Additional Documents:

Attachment:	B6 .pdf
Description:	Recheck summary by Cardiologist
Type:	Record
Attachment:	B6 .pdf
Description:	Recheck by Cardio2
Type:	Record

Report Details - EON-361414

ICSR:	2053249
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-08-05 20:44:20 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	After being told by friends and reading on the internet that grain free/Gluten free food was good for dogs, I switched over. After about 6 months, my dog developed a "Hack" (cough) that refused to get better. He also began to gain weight and ballooned up to 75 lbs from about 55 lbs in that same period. By the time I got him to the vet, he could barely walk and had become very bloated. The vet checked him and his heart was extremely enlarged and they pulled 7 liters of fluid out of his abdomen. They did blood tests and they came back that he had very low taurine levels. They said he developed DCM which led to congestive heart failure.
	Date Problem Started:	04/09/2018
	Date of Recovery:	08/05/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Pure Balance Wild & Free Grain Free Formula	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	24 Pound	
	Purchase Date:	11/01/2017	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In a sealed container	
	Product Use Information:	Description:	2 cups/day
		First Exposure Date:	11/01/2017
		Last Exposure Date:	07/23/2018
		Time Interval between Product Use and Adverse Event:	6 Months
		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	No		

Products Given
to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name:

Walmart

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Shepherd Dog - Australian

Gender: Male

Reproductive Status: Neutered

Weight: 59 Pound

Age: 7 Years

Assessment of Prior
Health: Excellent

Number of Animals
Reacted: 1

Owner Information:
Healthcare Professional
Information:

Sender Information:

Name:

B6

Address:

United States

Contact:

Email:

B6

Reporter Wants to
Remain Anonymous: No

Permission To Contact
Sender: Yes

Preferred Method Of
Contact: Email

Reported to Other
Parties: Unknown
Other
Manufacturer

Additional Documents:

Report Details - EON-361453

ICSR:	2053279
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-08-06 10:38:25 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Has been coughing for last couple weeks. He is seemingly breathing hard without any activity to induce it. He is lethargic, but that is part of his normal nature as an older Labrador. Heard report on TV (NBC) 8/5/2018 indicating there is a concern with grain free dog food and heart disease. Symptoms described included lethargy, difficulty breathing, and coughing. We have been using grain free food for about 5 yrs. Started due to the diabetes. Have used only two brands for the duration, latest is from Members Mark (Sams club brand) Salmon and Pea has been for the last three years or so. Previous brand was Exceed (Walmart Store brand), also Salmon and Pea, nearly identical ingredients to the Members Mark product.
	Date Problem Started:	07/21/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Unknown

Product Information:	Product Name:	Members Mark - Wild Caught Salmon & Pea Recipe Grain Free, No Wheat, No Soy, No Corn		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	078742248158		
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	06/23/2018		
	Number Purchased:	2		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	Before opening, in garage After opening, in the house.		
	Product Use Information:	Description:	2 cups 2x/day (every 12hrs due to the	B6
		First Exposure Date:	06/25/2018	
		Last Exposure Date:	08/06/2018	
		Time Interval between Product Use and Adverse Event:	4 Years	
Product Use Stopped After the Onset of the Adverse Event:		No		
Perceived Relatedness to Adverse Event:		Possibly related		
Other Foods or Products Given		No		

		to the Animal During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Sams Club
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Labrador	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	105 Pound	
	Age:	12 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Reacted:	1	
	Owner Information:		
	Healthcare Professional Information:		
Sender Information:	Name:	B6	
	Address:	B6 United States	
	Contact:	Phone:	B6
		Other Phone:	
		Email:	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
	Reported to Other Parties:	Other	
Additional Documents:	Attachment:	20180805_172302.jpg	
	Description:	Members Mark Grain Free dog food ingredients	
	Type:	Other	

Report Details - EON-361556

ICSR: 2053381
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-07 12:02:49 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: My dog was dx with congestive heart failure. She is now on medications and dependent on the medication to live. She has been fed Grain Free dog food for the last 3 months
Date Problem Started: 07/05/2018
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Rachel Ray Grain Free
Product Type: Pet Food
Lot Number:
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: In bag it came in
Product Use Information:
Description: Dog bowel was filled up in the morning and pet ate on as desired
Perceived Relatedness to Adverse Event: Definitely related
Other Foods or Products Given to the Animal During This Time Period: No
Manufacturer /Distributor Information:
Purchase Location Information: Name: Krogers
 Address: B6
 United States

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Dachshund - Miniature
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Not Pregnant
Lactation Status: Not lactating
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information:

Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	B6
	Address:	B6	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	07/05/2018	
Permission to Release Records to FDA:	Yes		
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone:	B6
		Email:	B6
	Reporter Wants to Remain Anonymous:	No	
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Reported to Other Parties:	None		
Additional Documents:			

Report Details - EON-361576

ICSR: 2053385
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-07 13:28:37 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Critical taurine deficiency plasma level [B6] new onset murmur and decreased systolic function on echo
Date Problem Started: 04/27/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Zignature lamb Zignature Zessential Earthborm Meadowfeast
Product Type: Pet Food
Lot Number:
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Airtight container
Product Use Information:
Description: Fed daily for last 5 years
First Exposure Date: 09/12/2013
Product Use Stopped After the Onset of the Adverse Event: Yes
Adverse Event Abate After Product Stop: No
Product Use Started Again: No
Perceived Relatedness to Adverse Event: Probably related
Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:
Purchase Location Information: Name: [B6]

Animal Information:
Name: [B6]
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Female
Reproductive Status: Neutered
Assessment of Prior Health: Good
Number of Animals: 1

	Given the Product:	
	Number of Animals Reacted:	1
	Owner Information:	
	Healthcare Professional Information:	Practice Name: B6
		Contact: Name: B6
		Phone: B6
		Address: B6
		Permission to Release Records to FDA: Yes
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact: Phone:	B6
		Email
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
Preferred Method Of Contact:	Email	
Reported to Other Parties:	None	
Additional Documents:		

Report Details - EON-361586

ICSR: 2053389
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-07 14:34:01 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: When buying dog food I was talked into a "healthier" grain-free brand **B6** gained weight during the year she was eating grain-free, developed a persistent cough, wheezing and excessive panting worsened over time. She was diagnosed with an enlarged heart with fluid in her lungs and will see a cardiologist soon.
Date Problem Started: 07/25/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: **B6**
Outcome to Date: Stable

Product Information:
Product Name: Performatrim Ultra Senior
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Bag was on shelf in the pet store when i bought it and in an airtight pet food container at home
Product Use Information:
Description: Fed to dog twice a day
First Exposure Date: 08/02/2017
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: No
Manufacturer /Distributor Information:
Purchase Location Information:
Name:
Address: **B6**
 United States

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: Terrier - Rat

	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	16 Pound
	Age:	14 Years
	Assessment of Prior Health:	Good
	Number of Animals Reacted:	1
	Owner Information:	
Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6
		Phone: B6
	Address:	B6
		United States
	Type of Veterinarian:	Primary/regular veterinarian
	Date First Seen:	07/06/2018
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact:	Phone: B6
		Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
Preferred Method Of Contact:	Email	
Reported to Other Parties:	Other	

Additional Documents:

Report Details - EON-361680

ICSR: 2053465
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-08 15:00:25 EDT

Reported Problem:
Problem Description: CVM resubmitting PFR reported as RFR EON-361676. No dates or animal signalment provided. Was on grain free diet, Acana grain free, for over a year prior to cardiac evaluation showing dilated cardiomyopathy. Whole blood level for taurine was below critical level. Developed dilated cardiomyopathy while on the diet, and died within 4 weeks of developing congestive heart failure despite medications and taurine.
Date Problem Started: B6
Outcome to Date: Died Other
Date of Death: B6

Product Information:
Product Name: Acana Lamb and Apple
Product Type: Pet Food
Lot Number:
Possess Unopened Product: Unknown
Possess Opened Product: Unknown
Product Use Information: **Product Use Stopped After the Onset of the Adverse Event:** Unknown
Manufacturer /Distributor Information: **Name:** Acana grain free CHAMPION PETFOODS USA
Type(s): Unknown
Address: B6
 United States
Contact: **Phone:** B6
Possess One or More Labels from This Product: Yes
Purchase Location Information:

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Unknown
Gender: Unknown
Reproductive Status: Unknown
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** Yes
Contact: **Name:** B6
Phone:
Email:
Address: Unknown

		Unknown B6 Unknown United States
Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6
		Phone: B6
		Email: B6
	Address:	B6 United States
	Type of Veterinarian:	Referred veterinarian
Sender Information:	Name:	B6
	Contact:	Email: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Unknown
Additional Documents:		

Report Details - EON-361683

ICSR: 2053472
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-08 15:52:15 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: I am reporting this after reading an article about grain free dog food and dilated cardiomyopathy in otherwise healthy dogs. Our dog [B6] was almost 9 years old and in perfect health. We had to put her down on [B6] due to congestive heart failure from what the doggie ICU and our vet told us was dilated cardiomyopathy on xray. She began eating grain free dog food from Petco (Whole Earth Farms) about 18 months before she died. The store had recommended we switch to a grain free food as we had little white moths flying around in the house and they explained that they could be from the grain in her dog food. She had no health problems before she started with a cough and ended up in ICU for days but after spending many \$\$\$ on her care over the course of a couple weeks her lungs continued to fill up and we had to put her down or watch her continue to struggle to breath. It was heart breaking and I just wanted to report her food after I read 2 articles on grain free dog food and dogs dying just incase it can be of any help.

Date Problem Started: 02/08/2018

Concurrent Medical Problem: No

Outcome to Date: Died Euthanized

Date of Death: [B6]

Product Information:

Product Name: Whole Earth Farms grain free dog food

Product Type: Pet Food

Lot Number:

Package Type: BAG

Purchase Date: 03/01/2018

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: Stored in our laundry room in a sealed bin

Product Use Information:

Description: [B6] was fed this dog food twice a day, one cup, for about 18 months.

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: No

Manufacturer /Distributor Information:

Purchase Location Information:

Name: Petco

Address: [B6]

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Spaniel - French

Gender: Female

Reproductive Status: Neutered

Weight: 45 Pound

Age: 8 Years

Assessment of Prior Health: Excellent

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional Information:

Practice Name: B6

Contact:

Name: B6

Phone: B6

Other Phone: B6

Address: B6

United States

Type of Veterinarian: Primary/regular veterinarian

Permission to Release Records to FDA: Yes

Sender Information:

Name: B6

Address: B6

United States

Contact:

Phone: B6

Other Phone: B6

Email: B6

Reporter Wants to Remain Anonymous: No

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Reported to Other Parties: None

Additional Documents:

Report Details - EON-361690

ICSR: 2053477
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-08 16:48:06 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: B6 began coughing frequently and his respiratory rate went higher. Had given him prophylactic B6 for years to prevent what seemed an innocent murmur from becoming more. Xrays at B6 B6
 Changed diet to Acana grain free diet and he began coughing which worsened until he could not sleep. Veterinary at B6 B6 said heart was widely dilated, huge on xray now. B6 now on twice B6 and expensive med for heart failure. Took him to cardiologist at B6 B6 prescribed B6 Dr. B6 who

Date Problem Started: 04/27/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:

Product Name: ACANA Heritage Grain Free Foods <https://acana.com/usa/our-foods/>
Product Type: Pet Food
Lot Number:
UPC: 64992 50125
Package Type: BAG
Package Size: 25 Pound
Purchase Date: 01/30/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: Stored in its bag until opened and then put in pet food container with air tight lid.

Product Use Information:

Description: Two cups for B6 who is 19.3 Kg and one cup for B6 who is approx 11.4 Kg, served in AM then remainder in bowls put in plastic bag and finished that evening on my return from work.
First Exposure Date: 01/30/2018
Last Exposure Date: 08/08/2018
Time Interval between Product Use and Adverse Event: 3 Months
Product Use Stopped After the Onset of the Adverse Event: No
Perceived Relatedness to Adverse Event: Probably related

Manufacturer:

/Distributor Information:

Purchase Location Information:

Name:

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Whippet

Gender: Male

Reproductive Status: Neutered

Weight: 19.3 Kilogram

Age: 13 Years

Assessment of Prior Health: Good

Number of Animals Given the Product: 2

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional Information:

Practice Name:

B6

Contact:

Name:

Phone:

B6

Address:

B6

United States

Type of Veterinarian: Primary/regular veterinarian

Permission to Release Records to FDA: Yes

Practice Name:

B6

Contact:

Name:

Not Sure

Phone:

B6

Address:

B6

United States

Type of Veterinarian: Primary/regular veterinarian

Date First Seen: 05/06/2018

Permission to Release Records to FDA: Yes

Practice Name:

B6

Contact:

Name:

Phone:

B6

Address:

B6

United States

Type of Veterinarian:	Referred veterinarian
Date First Seen:	07/11/2018
Permission to Release Records to FDA:	Yes

Sender Information:

Name:	B6	
Address:		
	United States	
Contact:	Phone:	B6
	Email:	
Reporter Wants to Remain Anonymous:	No	
Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email	
Reported to Other Parties:	Other	

Additional Documents:

Report Details - EON-361708

ICSR: 2053490
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-08 22:08:36 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: I fed my dog **B6** the foods ACANA and ORIJEN. I did extensive research on these products and they were supposed to be the best. Now **B6** is 2 years old and has an enlarged heart by 75%. She can develop congestive heart failure within the year if these symptoms don't reverse. This grain free food is poisoning our dogs. I'm very upset & very scared to lose her. She's apart of my family. I want this stuff taken off the market immediately. I've spent \$1,845 to date in treating her enlarged heart. She is from a blue blood line, top of the line Labrador retriever. She's the healthiest dog you could imagine, until now. PLEASE help others to remove this from their diets before it's too late.

Date Problem Started: 06/20/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:

Product Name: ACANA grain free dog food
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 18 Pound
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Sealed container

Product Use Information:

Description: Fed 2 times per day for 1 year
Product Use Stopped After the Onset of the Adverse Event: Yes
Perceived Relatedness to Adverse Event: Definitely related
Other Foods or Products Given to the Animal During This Time Period: No

Manufacturer /Distributor Information:

Purchase Location Information: Name: **B6**

Animal Information:

Name: **B6**
Type Of Species: Dog
Type Of Breed: Retriever - Labrador
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Not Pregnant

	Lactation Status:	Not lactating										
	Weight:	90 Pound										
	Age:	2 Months										
	Assessment of Prior Health:	Excellent										
	Number of Animals Given the Product:	1										
	Number of Animals Reacted:	1										
	Owner Information:											
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> </table>	Practice Name:	B6	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Address:	B6
Practice Name:	B6											
Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:								
Name:	B6											
Phone:												
Address:	B6											
Sender Information:	Name:	B6										
	Address:	United States										
	Contact:	<table border="1"> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Phone:	B6	Email:							
Phone:	B6											
Email:												
	Reporter Wants to Remain Anonymous:	No										
	Permission To Contact Sender:	Yes										
	Preferred Method Of Contact:	Phone										
Additional Documents:												

Report Details - EON-361816

ICSR: 2053548
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-08-10 11:10:10 EDT
Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description:	Victor Hero Grain Free Dog Food: Sudden onset congestive heart failure. passed away within weeks after starting care with a cardiologist	B6
Date Problem Started:	02/27/2018	
Concurrent Medical Problem:	No	
Outcome to Date:	Died Other	
Date of Death:	B6	

Product Information:

Product Name:	Victor Hero Grain Free	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Storage Conditions:	Stored in an air tight pet food storage container	
Product Use Information:	Description:	Fed twice a day. 3 cups in the morning & 3 cups in the evening.
	Product Use Stopped After the Onset of the Adverse Event:	Yes
	Adverse Event Abate After Product Stop:	No
	Product Use Started Again:	No
	Perceived Relatedness to Adverse Event:	Definitely related
	Other Foods or Products Given to the Animal During This Time Period:	No
	Manufacturer /Distributor Information:	
Purchase Location Information:	Name:	B6
	Address:	United States

Animal Information:

Name:	B6
Type Of Species:	Dog
Type Of Breed:	Pointing Dog - German Short-haired

	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 57 Pound	
	Age: 3 Years	
	Assessment of Prior Health: Excellent	
	Number of Animals Given the Product: 3	
	Number of Animals Reacted: 1	
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact:	
	Phone:	B6
	Email:	
	Reporter Wants to Remain Anonymous:	No
Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email	
Reported to Other Parties:	Store/Place of Purchase	
Additional Documents:		

Report Details - EON-361903

ICSR:	2053581
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-08-11 15:01:25 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 started panting very heavily. He also acted like he was trying to tell me something. I took him to Vet and a chest exray showed his enlarged heart. We go for a follow up to see how the medication is helping on Monday August 13 2018. The med had slowed his panting but he has developed a cough in the mornings.
	Date Problem Started:	04/01/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	Members Mark Wild Caught Salmon & Pea Recipe Grain Free Food For Dogs		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	7874224815		
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	12/01/2016		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	Either in the bag with ziplock closed or in a plastic dog food container I would dump it into.		
	Product Use Information:	Description:	Been feeding about 1 1/2 years 2 cups morning and 2 cups evening.	
		First Exposure Date:	12/02/2016	
		Last Exposure Date:	07/31/2018	
Time Interval between Product Use and Adverse Event:		1 Years		
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		No		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Probably related		
Other Foods or Products Given to the Animal	No			

During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Name:

Sams Club

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Retriever - Chesapeake Bay

Gender: Male

Reproductive Status: Neutered

Weight: 98 Pound

Age: 8 Years

Assessment of Prior
Health: Excellent

Number of Animals
Given the Product: 2

Number of Animals
Reacted: 1

Owner Information:

Healthcare Professional
Information:

Practice Name:

B6

Contact:

Name:

B6

Phone:

Address:

B6

United States

Type of
Veterinarian:

Primary/regular veterinarian

Date First Seen: 04/01/2018

Permission to
Release Records
to FDA: Yes

Sender Information:

Name:

B6

Address:

United States

Contact:

Phone:

Email:

B6

Permission To Contact
Sender: Yes

Preferred Method Of
Contact: Email

Reported to Other
Parties: None

Additional Documents:

Report Details - EON-362358

ICSR: 2053769
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Product Problem (an observed or detected product issue or defect that has the potential to cause harm)
Reporting Type: Voluntary
Report Submission Date: 2018-08-15 14:44:18 EDT
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: My 25 mo- 2 yr old German Shepherd Dropped dead 4 wks ago. We had an Autopsy his left ventricle 3 times size of rt. also some liver enlargement . Cardiomyophthy ! Choose not to have labs drawn because of added cost. Cannot tell you how devastating this is My heart is broken. The breeder has offered to replace with new puppy. So I was doing some research on puppy food a Vet had told me that Lg Breed food best. So was looking @ purchase of food When I told sales person I wanted Lg Breed Grain free puppy. She told me about Dogs dieing from heart issues that had been on Grain free food. My first knowledge of this My GS was on Grain Free most of his life. So I thought I should report this to you . And also ask what has been proven? My Labradoodle is on Grain free . Both have been on Merrick Grain free Beef and Duck and Buffalo ? Did I kill my beautiful boy thinking I was giving him the best food out there?Please advise me if I am reporting to wrong place or where else I should send this info?
Date Problem Started: 07/18/2018

Product Information:
Product Name: Merrick Grain Free Real Texas Beed Sweet potatoRecipe Adult
Product Type: Pet Food
Lot Number:
UPC: 22808 38344
Package Type: BAG
Package Size: 25 Pound
Purchase Date: 05/15/2018
Number Purchased: 1
Possess Unopened Product: Yes
Possess Opened Product: Yes
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information: **Name:** Chew.Com
Address: United States

Animal Information:
Name:
Owner Information:
Healthcare Professional Information:

Sender Information:
Name:
Address: B6
United States
Contact: **Phone:** B6
Email: B6
Reporter Wants to No

	Remain Anonymous:	
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	None

Additional Documents:

Report Details - EON-362368

ICSR: 2053777
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-15 16:08:43 EDT

Reported Problem:
Problem Description: diagnosed with congestive heart failure in april of 2016. Had been on a grain free diet since 2012 because of allergies. he is currently on a grain free food, takes **B6** and fish oil capsules. Now with this recent article released he has been started on CardioStrength capsules.
Date Problem Started: 04/28/2016
Concurrent Medical Problem: Yes
Pre Existing Conditions: **B6** no medications given though.
Outcome to Date: Stable

Product Information:
Product Name: california natural, venison now wellness simple, turkey
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 25 Pound
Possess Unopened Product: Yes
Possess Opened Product: Yes
Storage Conditions: before- in bag on a shelf after opening- in a sealed food container
Product Use Information:
Description: one cup twice daily for years
First Exposure Date: 11/11/2012
Last Exposure Date: 08/15/2018
Time Interval between Product Use and Adverse Event: 4 Years
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: No
Manufacturer /Distributor Information:
Purchase Location Information:
Name: chewy.com
Address: United States

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: American Pit Bull Terrier

	Gender: Male
	Reproductive Status: Neutered
	Weight: 60 Pound
	Age: 10 Years
	Assessment of Prior Health: Good
	Number of Animals Reacted: 1
	Owner Information:
	Owner Information provided: Yes
	Contact: Name: [Redacted] B6
	Phone: [Redacted]
	Address: [Redacted] B6
	United States
	Healthcare Professional Information:
Sender Information:	Name: [Redacted] B6
	Address: [Redacted] B6
	United States
	Contact: Phone: [Redacted] B6
	Email: [Redacted]
	Reporter Wants to Remain Anonymous: No
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
	Reported to Other Parties: None
Additional Documents:	Attachment: [Redacted] B6.jpg
	Description: I don't have an attachment. So here is a picture of [Redacted] B6
	Type: Other

Report Details - EON-362795

ICSR: 2053917
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-19 18:43:44 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: B6 (Labradoodle) died on B6 of congestive heart failure & DCM but I feel I need to report her passing as a possible health failure due to her diet of Taste of the Wild dog food. B6 began having episodes of heavy panting, restlessness and unable to sleep at night, fluttering heart beats with no specific rhythm and periods of passing out. She was on a regiment of 3 heart meds B6 and Taurine for 6 months before she died. Up until 6 months before her death she seemed to be a very healthy dog. I will also notify our vet as to my thoughts and get his opinion on if it could have been the cause of her death.

Date Problem Started: B6

Concurrent Medical Problem: No

Outcome to Date: Died Euthanized

Date of Death: B6

Product Information:

Product Name: Taste of the Wild dog food

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: In an airtight tote.

Product Use Information:

Description: Approximately 2 cups per day

Time Interval between Product Use and Adverse Event: 8 Years

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:

Name: B6

Address: B6

United States

Animal Information:	Name:	B6 Labradoodle		
	Type Of Species:	Dog		
	Type Of Breed:	Mixed (Dog)		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	100 Pound		
	Age:	10 Years		
	Assessment of Prior Health:	Excellent		
	Number of Animals Given the Product:	1		
	Number of Animals Reacted:	1		
	Owner Information:			
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	B6
Other Phone:				
Address:		B6		
		United States		
Type of Veterinarian:	Primary/regular veterinarian			
Date First Seen:	B6			
Sender Information:	Name:	B6		
	Address:	B6		
		United States		
	Contact:	Phone:	B6	
		Other Phone:		
		Email:		
Permission To Contact Sender:	Yes			
Preferred Method Of Contact:	Phone			
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-362796

ICSR:	2053918
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-08-19 19:04:35 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My sweet dog B6 passed away last month from CHF. She had been diagnosed with a heart murmur several years ago and monitored. She had an episode where she fainted in March 2018. At that time I was told she had an enlarged heart and was in CHF. She was treated with a prescription diet and medications for her final months of life. She passed away B6 . She was healthy the majority of her life up to the last year when she slipped a disc, had a couple UTIs, then developed CHF. She had eaten Fromms grain free food most of her life. After hearing the potential link between grain free foods and CHF, I looked at her label and peas and potatoes were indeed listed as main ingredients. I am already so grief stricken over her death and now I am tormented by the fact that I may have been feeding her heart disease. I am angry that I cannot trust people who should be more knowledgeable than myself in these areas. Fromm is not a cheap food and I felt I was feeding a quality food to my sweet pup. My other shih tzu is now 8 and a slight heart murmur was recently detected. Please keep us informed of the outcomes of these findings. I would also like someone to be accountable for this. I do a lot of research on my own but I cannot be an expert in every area and rely on people who claim to be for my health and the health of my pets.
	Date Problem Started:	03/15/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Naturally
	Date of Death:	B6

Product Information:	Product Name:	Fromm Grain Free Beef Fritata		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	12 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in kitchen cupboard where other food items are stored		
	Product Use Information:	Description:	Half cup in the morning, half cup in the evening with canned food	
		First Exposure Date:	06/01/2004	
Last Exposure Date:		03/15/2018		
Time Interval between Product Use and Adverse Event:		10 Years		
Other Foods or Products Given to the Animal During This Time Period:		Yes		
Manufacturer:				

	/Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shih Tzu	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	14 Pound	
	Age:	14 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Reacted:	2	
	Owner Information:		
Healthcare Professional Information:	Practice Name:	B6	
	Contact: Name:	B6	
	Phone:	B6	
	Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact: Phone:	B6	
	Email:	B6	
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email		
Reported to Other Parties:	None		
Additional Documents:			

Report Details - EON-363453

ICSR:	2054237
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-08-26 22:56:29 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was an 8 year old chihuahua in excellent health. He had been on a diet of Kibbles and Bits Bistro mix for about a year. Suddenly about 2 weeks before his death he had been acting lethargic and not himself. He developed a cough as well. We immediately got him to the veterinarian for diagnosis and treatment. The vet thought he may have Valley fever and did a tiger test and started him on meds right away. Several days later the tiger came back negative for valley fever
	Date Problem Started:	06/07/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Other
	Date of Death:	B6

Product Information:	Product Name:	Kibbles and Bits Chefs Choice Bistro AND Homestyle		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	50 Pound		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In bag inside air tight container.		
	Product Use Information:	Description:	Dog was fed small bowl twice daily.	
		First Exposure Date:	05/03/2017	
		Time Interval between Product Use and Adverse Event:	1 Years	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Not Applicable	
		Product Use Started Again:	No	
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:		No		
Manufacturer				

	/Distributor Information:	<table border="1"> <tr> <td data-bbox="667 72 889 236">Purchase Location Information:</td> <td data-bbox="889 72 1554 236"> <table border="1"> <tr> <td data-bbox="889 72 992 236">Name:</td> <td data-bbox="992 72 1554 236">Walmart</td> </tr> <tr> <td data-bbox="889 114 992 236">Address:</td> <td data-bbox="992 114 1554 236"> <table border="1"> <tr> <td data-bbox="992 114 1045 236">B6</td> <td data-bbox="1045 114 1554 236">United States</td> </tr> </table> </td> </tr> </table> </td> </tr> </table>	Purchase Location Information:	<table border="1"> <tr> <td data-bbox="889 72 992 236">Name:</td> <td data-bbox="992 72 1554 236">Walmart</td> </tr> <tr> <td data-bbox="889 114 992 236">Address:</td> <td data-bbox="992 114 1554 236"> <table border="1"> <tr> <td data-bbox="992 114 1045 236">B6</td> <td data-bbox="1045 114 1554 236">United States</td> </tr> </table> </td> </tr> </table>	Name:	Walmart	Address:	<table border="1"> <tr> <td data-bbox="992 114 1045 236">B6</td> <td data-bbox="1045 114 1554 236">United States</td> </tr> </table>	B6	United States																																																			
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</tr> <tr> <td data-bbox="370 619 667 661">Owner Information:</td> <td data-bbox="667 619 1554 661"></td> </tr> <tr> <td data-bbox="370 661 667 1093">Healthcare Professional Information:</td> <td data-bbox="667 661 1554 1093"> <table border="1"> <tr> <td data-bbox="667 661 889 704">Practice Name:</td> <td data-bbox="889 661 1554 704">B6</td> </tr> <tr> <td data-bbox="667 704 889 746">Contact:</td> <td data-bbox="889 704 1554 746"> <table border="1"> <tr> <td data-bbox="889 704 1045 746">Name:</td> <td data-bbox="1045 704 1554 746">B6</td> </tr> <tr> <td data-bbox="889 746 1045 789">Phone:</td> <td data-bbox="1045 746 1554 789">B6</td> </tr> </table> </td> </tr> <tr> <td data-bbox="667 746 889 959">Address:</td> <td data-bbox="889 746 1554 959"> <table border="1"> <tr> <td data-bbox="889 746 1045 959">B6</td> <td data-bbox="1045 746 1554 959">United States</td> </tr> </table> </td> </tr> <tr> <td data-bbox="667 959 889 1002">Date First Seen:</td> <td data-bbox="889 959 1554 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Preferred Method Of Contact:	Address																																																												
Reported to Other Parties:	None																																																												
Additional Documents:																																																													

Report Details - EON-363580

ICSR: 2054348
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-08-28 13:47:37 EDT

Reported Problem:

Problem Description: Diagnosed with congestive heart failure secondary to dilated cardiomyopathy and has been fed California Natural kangaroo and lentil diet. Normal taurine levels in whole blood and plasma

Date Problem Started: 08/07/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: [B6] and this was the reason that his owner, a veterinarian, was feeding the kangaroo and lentil diet. He had been a previously vigorous healthy dog, but was diagnosed with [B6] about 6 months ago and has had progressive stridor over that time. He was diagnosed with biventricular congestive heart failure one week prior to presentation to my clinic and had been treated with [B6] prior to my evaluation.

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: California Natural Limited Ingredient Diet Kangaroo and red lentil

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: Yes

Possess Opened Product: Yes

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: 35.4 Kilogram

Age: 11 Years

Assessment of Prior Health: Good

Number of Animals Reacted: 1

Owner Information: Owner Information provided: Yes

Contact: Name: [B6]
Phone: [B6]
Email: [B6]

Address: [B6]

		B6
		United States
Healthcare Professional Information:	Practice Name:	B6
	Contact: Name:	B6
	Phone:	
	Other Phone:	
	Email:	
	Address:	B6
		United States
	Practice Name:	B6
	Contact: Name:	B6
	Phone:	
Other Phone:		
Email:		
Address:	B6	
	United States	
Type of Veterinarian:	Primary/regular veterinarian	
Date First Seen:	08/07/2018	
Permission to Release Records to FDA:	Yes	
Practice Name:	B6	
Contact: Name:	B6	
Phone:		
Other Phone:		
Address:	B6	
	United States	
Type of Veterinarian:	Referred veterinarian	
Date First Seen:	08/07/2018	
Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	
	Address:	B6
		United States
	Contact: Phone:	B6
	Other Phone:	
	Email:	
	Permission To Contact	Yes

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

Additional Documents:	Attachment:	cardio0034.pdf
	Description:	Initial echocardiogram report from 8/16/18
	Type:	Echocardiogram

Report Details - EON-363900

ICSR:	2054498
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-08-30 17:00:55 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Redbone started coughing and would not sleep. Started throwing up. Took her to vet and they noticed she had an enlarged heart. They put her on a number of medications. Two weeks later she was coughing so bad over night we took her to the emergency vet. That next day we had to put her down. Boston terrier was originally on non-grain free diet for 10 years. We switched her to grain free the last two years. She did not have any issues prior to feeding her grain free food. She began losing weight and her heart was enlarged as well. She began throwing up and coughing. Her and the redbone both had DCM and passed away from that. I have asked my vet if the grain free food could have led to this as there was no history in either of the dogs bloodlines that had history of DCM. The vet said no. This is very scary as consumers are still feeding their animals grain free food and it is not being researched.
	Date Problem Started:	07/09/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Earthborne coastal catch grain free dry dog food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	28 Pound		
	Purchase Date:	08/01/2016		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Kept in original bag inside home. Tempature of 76 degrees		
	Product Use Information:	Description:	Dry food kept in original bag and given with measuring cup	
		First Exposure Date:	08/04/2016	
		Last Exposure Date:	B6	
Time Interval between Product Use and Adverse Event:		1 Years		
Product Use Stopped After the Onset of the Adverse Event:		No		
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given		No		

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:
Purchase Location
Information:

Animal Information:

Name:	B6	(Boston terrier 12yo)
Type Of Species:	Dog	
Type Of Breed:	Coonhound - Redbone	
Gender:	Female	
Reproductive Status:	Neutered	
Weight:	50 Pound	
Age:	2 Years	
Assessment of Prior Health:	Excellent	
Number of Animals Given the Product:	2	
Number of Animals Reacted:	2	
Owner Information:		
Healthcare Professional Information:	Contact: Name:	B6
	Phone:	
Permission to Release Records to FDA:	Yes	

Sender Information:

Name:	B6	
Address:	United States	
Contact:	Phone:	B6
	Email:	
Reporter Wants to Remain Anonymous:	No	
Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email	
Reported to Other Parties:	Other	

Additional Documents:

Report Details - EON-363924

ICSR: 2054503
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-30 21:34:04 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: Fed him California Naturals Kangaroo and Red Lentils which has since been recalled and stopped being made. We have read that you are collecting data on dogs dying from cardiomyopathy that were on a grain free diet. [B6] died of cardiomyopathy at age 8. When he reached a point that he couldn't breathe any more we euthanized him to relieve his suffering.

Date Problem Started: 08/01/2014

Concurrent Medical Problem: Yes

Pre Existing Conditions: Allergy medications and anti anxiety medications

Outcome to Date: Died Euthanized

Date of Death: [B6]

Product Information:

Product Name: California Naturals Grain Free Red Lentils and Kangaroo

Product Type: Pet Food

Lot Number:

Purchase Date: 06/01/2014

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: Stored in airtight container

Product Use Information:

Description: Dry dog food as directed twice a day

Product Use Stopped After the Onset of the Adverse Event: No

Perceived Relatedness to Adverse Event: Probably related

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name: [B6]

Type Of Species: Dog

Type Of Breed: Shih Tzu

Gender: Male

Reproductive Status: Neutered

Weight: 15 Pound

Age: 8 Years

Assessment of Prior Health: Fair

Number of Animals Reacted: 1

Owner Information:

Healthcare Professional:

	Information:	Practice Name:	B6
		Contact:	Name: B6 Phone: B6
		Type of Veterinarian:	Primary/regular veterinarian
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Contact:	Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			

Report Details - EON-364300	
ICSR:	2054624
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-09-05 09:13:24 EDT
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: Over the last 9 years, our dog's health and energy level declined. She began to pant often, even when not exercising, she has lost significant weight (20 percent of body weight) over the last 3 years. She is lethargic, lost appetite. Her vet has suggested that she has heart disease but we have not done the testing.
	Date Problem Started: 01/01/2015
	Concurrent Medical Problem: No
	Outcome to Date: Worse/Declining/Deteriorating
Product Information:	Product Name: Kirkland Natures Domaine Salmon and Sweet Potato dog food
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Possess Unopened Product: Yes
	Possess Opened Product: Yes
	Product Use Information:
	Description: Dog has been fed this food since age 2
	Time Interval between Product Use and Adverse Event: 10 Years
	Perceived Relatedness to Adverse Event: Possibly related
Other Foods or Products Given to the Animal During This Time Period: No	
Manufacturer /Distributor Information:	
Purchase Location Information:	
Animal Information:	Name: B6
	Type Of Species: Dog
	Type Of Breed: Coonhound - Redbone
	Gender: Female
	Reproductive Status: Neutered
	Weight: 33 Pound
	Age: 15 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 1
Number of Animals Reacted: 1	

	Owner Information:	
	Healthcare Professional Information:	Contact: Name: B6
		Phone: B6
	Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6
	Contact:	Phone:
		Email:
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:		

Report Details - EON-364337

ICSR:	2054649			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)			
Reporting Type:	Voluntary			
Report Submission Date:	2018-09-05 14:28:42 EDT			
Reporter is the Animal Owner:	Yes			
Reported Problem:	Problem Description:	Dog was eating a grain free diet. The dog rushed to the emergency room after 2 vomiting episodes and lethargy. Dog was in ventricular tachycardia and had to be kept 2 nights and cardiologist performed Echo plus treated for pleural effusion.		
	Date Problem Started:	09/02/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Authority Grain Free		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	TL1	
		Expiration Date:	02/02/2019	
	UPC:	73725753557		
	Package Type:	BAG		
	Package Size:	15 Pound		
	Purchase Date:	08/16/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Storage Conditions:	pouch has ziplock top , food was sealed each time to ensure freshness		
	Product Use Information:	Description:	Dog food poured from bag to dog bowl	
		First Exposure Date:	08/20/2018	
		Last Exposure Date:	09/02/2018	
Time Interval between Product Use and Adverse Event:		13 Days		
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		No		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:		Yes		
Manufacturer Name:	Authority Pet Food Company			

	/Distributor Information:	Type(s): Distributor Address: 19601 N. 27th Ave Phoenix Arizona 85027 United States Contact: Phone: 18005855249 Web Address: www.petsmart.com/authority Possess One or More Labels from This Product: Yes
	Purchase Location Information:	Name: PetSmart Address: B6 United States
Animal Information:		Name: B6 Type Of Species: Dog Type Of Breed: Hound (unspecified) Gender: Male Reproductive Status: Neutered Weight: 27.6 Kilogram Age: 6 Years Assessment of Prior Health: Excellent Number of Animals Given the Product: 1 Number of Animals Reacted: 1 Owner Information: Healthcare Professional Information: Practice Name: B6 Contact: Name: B6 Phone: B6 Email: Address: B6 United States Type of Veterinarian: Referred veterinarian Date First Seen: 09/04/2018 Permission to Release Records to FDA: Yes
Sender Information:		Name: Address: B6 United States Contact: Phone: B6 Email:

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

Additional Documents:

Attachment:	B6 195401-1 (1).pdf
Description:	Medical record of adverse event for B6 the dog
Type:	Multiple Document Types

Report Details - EON-365105

ICSR: 2054889
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Product Problem (an observed or detected product issue or defect that has the potential to cause harm)
Reporting Type: Voluntary
Report Submission Date: 2018-09-12 19:22:46 EDT
Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: I switched from feeding Eukanuba large breed puppy food to Taste of the Wild Pacific Stream (TOTWPS) exclusively for past several years to all of my 10 Labradors. Two of my labs **B6** both 1 year of age have only been fed TOTWPS. Last month **B6** died suddenly. She got up with the rest of the pack at 3:30 in the morning to poop, trotted back to bed. By 7Am she was dead. She had been completely normal prior to this. Necropsy report showed cupping of mitral and tricuspid valve but no cardiac myopathy. Cause of death was suspected cardiac arrhythmia. Subsequently, I had cardiac echo's done on **B6** mom **B6** which was normal, and **B6** which showed mild DCM. I have a pending taurine level on **B6** drawn last week. Currently **B6** is symptom free. I am concerned that possibly what I feed my dogs is unsafe.

Date Problem Started: 08/17/2018

Product Information:

Product Name: Taste of the Wild Pacific Stream
Product Type: Pet Food
Lot Number:
Package Type: PACKAGE
Package Size: 30 Pound
Purchase Date: 08/03/2018
Number Purchased: 12
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:

Name:
Owner Information:
Healthcare Professional Information:

Sender Information:

Name: **B6**
Address: **B6**
Contact: **Phone:** **B6**
Email: **B6**
Reporter Wants to Remain Anonymous: No
Permission To Contact Sender: Yes
Preferred Method Of Contact: Email

Reported to Other Parties: Other

Additional Documents:

Attachment:	B6 Echo.jpg
Description:	Echo
Type:	Echocardiogram

Report Details - EON-365518

ICSR: 2054927
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type: Voluntary
Report Submission Date: 2018-09-14 11:28:58 EDT

Reported Problem:
Problem Description: Receiving grain free diet (Natural Balance primarily with Wellness treats, Mother Hubbard treats, 1/2 rice cake with peanut butter, turkey slice). Had low taurine levels (whole blood: **B6** critical <150), now being supplemented. Echocardiogram on 9/13/18: within normal limits (performed 2 weeks after starting taurine supplementation).
Date Problem Started: 08/22/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Natural Balance
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Female
Reproductive Status: Neutered
Weight: 32 Kilogram
Age: 7 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** No
Healthcare Professional Information:
Practice Name: **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:

Other Phone:

Email:

B6

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Reported to Other Parties: None

Additional Documents:

Report Details - EON-366031

ICSR: 2055104
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2018-09-19 10:46:42 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: After FDA Alert realised their dog food was grain free and limited ingredients. Had Taurine level drawn and his level was **B6** immediately after blood draw changed their food.
Date Problem Started: 07/30/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Natural Balance Sweet Potato and Venison
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 30 Pound
Purchase Date: 06/04/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Inside and clipped shut
Product Use Information:
Description: 3/4 cup AM and PM
Last Exposure Date: 08/20/2018
Product Use Stopped After the Onset of the Adverse Event: Yes
Adverse Event Abate After Product Stop: Unknown
Product Use Started Again: No
Perceived Relatedness to Adverse Event: Probably related
Other Foods or Products Given to the Animal During This Time Period: Yes
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: Retriever - Golden

	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	72 Pound
	Age:	11 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
	Owner Information:	
Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6
		Phone: B6
		Other Phone:
	Address:	B6
		United States
	Type of Veterinarian:	Primary/regular veterinarian
	Permission to Release Records to FDA:	Yes
	Practice Name:	B6
	Contact:	Name: B6
	Phone: B6	
	Other Phone:	
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
		Other Phone:
		Email:
	Reporter Wants to Remain Anonymous:	No
Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email	
Reported to Other	Other	

Parties:

Additional Documents: