

Report Details - EON-366025

ICSR:	2055101
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 10:29:44 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	After FDA issued alert realised our dogs were on limited ingredient, grain free foods. Sweet Potato and Venison and occas. Sweet Potato and Duck. Our Vet drew Taurine levels and B6 s level was B6
	Date Problem Started:	07/30/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	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:	Stored inside and bag clipped shut		
	Product Use Information:	Description:	Fed 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:	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
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	Type Of Species: Dog
	Type Of Breed: Retriever - Golden
	Gender: Female
	Reproductive Status: Neutered
	Weight: 65 Pound
	Age: 8 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
	Other Phone:
	Address: B6
	United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 08/20/2018
	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: 09/13/2018	
Permission to Release Records to FDA: Yes	
Sender Information:	Name:
	Address: B6
	United States
	Contact: Phone:
	Other Phone: B6
	Email:
	Reporter Wants to Remain Anonymous: No
	Permission To Contact: Yes

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

Additional Documents:

Report Details - EON-365643

ICSR:	2054972
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:	2018-09-16 21:39:31 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Heart disease DCM
	Date Problem Started:	01/09/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Eagle Pack Adult dry Holistic Select Canned		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	DNK		
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	10/15/2008		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In plastic in with lid		
	Product Use Information:	Description:	Daily for breakfast and dinner	
		First Exposure Date:	11/01/2008	
		Last Exposure Date:	B6	
		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		
	Type Of Species:	Dog		
	Type Of Breed:	Spaniel - Springer English		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	32 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:	USA
Address:		B6		
		United States		
Date First Seen:	04/02/2018			
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6		
	Address:	B6		
	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-365891		
ICSR:	2055086	
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:	2018-09-18 18:52:19 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: I started feeding my dogs Fresh Pet chicken variety a few months ago. After a couple of months, [B6] developed a cough. It has progressively gotten worse and now his breathing has become irregular. I took him to the doctor and he has an enlarged heart. We are waiting on test results.	
	Date Problem Started: 07/02/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Worse/Declining/Deteriorating	
Product Information:	Product Name: Freshpet Vital Chicken Recipe with Sweet Potatoes and Carrots.	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 4.5 Pound	
	Purchase Date: 08/01/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Sealed in the refrigerator.	
	Product Use Information:	Description: Fed 1 cup, twice a day.
		Time Interval between Product Use and Adverse Event: 2 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: Unknown		
Manufacturer /Distributor Information:		
Purchase Location Information:	Name: Walmart	
	Address: [B6] United States	
Animal Information:	Name: [B6]	
	Type Of Species: Dog	
	Type Of Breed: Spitz - German Pomeranian	

	Gender: Male
	Reproductive Status: Neutered
	Weight: 9 Pound
	Age: 7 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: B6
	Address: B6 United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 09/18/2018
	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:	

Report Details - EON-366513		
ICSR:	2055228	
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:	2018-09-22 17:33:54 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Eating grain free dog food over 6+ years, she has developed CHF. She did not have heart issues prior to this The new studies are indicating CHF with a grain free diet. She is now suffering from CHF and on 4 types of meds to help her but prognosis not good.	
	Date Problem Started: 05/02/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Worse/Declining/Deteriorating	
Product Information:	Product Name: Racheal ray zero grain dog food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 14.0 Pound	
	Purchase Date: 08/15/2018	
	Possess Opened Product: No	
	Storage Conditions: Stored in closet, put in sealed container when opened	
	Product Use Information:	Description: Daily mixed with can food
		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:		
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Terrier - Rat	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 17 Pound	

	Age:	12 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:	
		Email:	B6
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Reported to Other Parties:	None		
Additional Documents:			

Report Details - EON-366547

ICSR:	2055231			
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:	2018-09-23 14:35:32 EDT			
Reporter is the Animal Owner:	Yes			
Reported Problem:	Problem Description:	had B6 taurine level tested and it was low. B6 Golden should be >250.		
	Date Problem Started:	09/04/2018		
	Concurrent Medical Problem:	Yes		
	Pre Existing Conditions:	B6		
	Outcome to Date:	Stable		
Product Information:	Product Name:	Fromm 4 Star Nutritional Beef Frittata Vegetable		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	7270511414		
	Package Type:	BAG		
	Package Size:	4 Pound		
	Purchase Date:	08/31/2017		
	Number Purchased:	1		
	Possess Opened Product:	Yes		
	Storage Conditions:	Stored in closet		
	Product Use Information:	Description:	Food fed according to directions	
		First Exposure Date:	12/08/2017	
		Last Exposure Date:	09/04/2018	
		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:		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 Name:	internet			

	Information:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	81 Pound		
	Age:	5 Years		
	Assessment of Prior Health:	Good		
	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:	09/04/2018			
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:	Screen Shot 2018-09-23 at 2.33.30 PM.png		
	Description:	clinic name		
	Type:	Other		

Report Details - EON-366937		
ICSR:	2055378	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-09-26 16:53:58 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Dog has been diagnosed with a moderated dilated cardiomyopathy. Taurine level at <u>B6</u> Taurine labs completed at UC Davis labs.	
	Date Problem Started: 09/01/2018	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: <u>B6</u>	
	Outcome to Date: Worse/Declining/Deteriorating	
Product Information:	Product Name: Fromm Four Star Nutritionals Pork and Applesauce Formula Grain Free dog food	
	Product Type: Pet Food	
	Lot Number:	
	UPC: 72705 11400	
	Package Type: BAG	
	Package Size: 30 Pound	
	Purchase Date: 08/01/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: Yes	
	Storage Conditions: Product was stored in it's original bag in a metal garbage container.	
	Product Use Information:	Description: Product was fed 2 cups per day to dog.
		First Exposure Date: 08/01/2018
		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: Definitely related		
Other Foods or Products Given to the Animal During This Time Period: Yes		

	Manufacturer /Distributor Information:	
	Purchase Location Information:	Name: Petflow.com Address: United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	77 Pound
	Age:	3.5 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: Referred veterinarian
		Date First Seen: 09/11/2018
		Permission to Release Records to FDA: Yes
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:	Attachment:	B6 Taurine Levels.pdf
	Description:	Taurine blood level from 9/11/18
	Type:	Laboratory Report

Report Details - EON-366972

ICSR: 2055389
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: 2018-09-26 21:35:37 EDT
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Dog is on The Honest Kitchen (Embark) was randomly tested for Taurine deficiency taurine level is **B6**; Recommended level for Golden Retrievers is 250. Echo cardiogram will follow next week.
Date Problem Started: 09/17/2018

Product Information:
Product Name: The Honest Kitchen Embark
Product Type: Pet Food
Lot Number: Lot Number: 1928A7
Expiration Date: 07/11/2019
UPC: not relevant
Package Type: BOX
Package Size: 10 Pound
Purchase Date: 09/18/2018
Number Purchased: 2
Possess Unopened Product: Yes
Possess Opened Product: Yes
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information: Name: **B6**
Address: United States

Animal Information:
Name:
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: Email
Reported to Other Parties: None

Additional Documents:

Report Details - EON-367428

ICSR: 2055600
 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: 2018-10-02 16:32:38 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Noticed **B6** had a small pocket of edema. The next morning it was larger. Took him into the ER on an emergency. Bloodwork showed an elevated white count. He did not have a fever. He was positive for **B6**. He had a lot of ticks in his ears when he was rescued so it could have been there for a long time. He was taken for an abdominal x-ray, then a chest x-ray because the lung field looked abnormal. The chest x-ray showed fluid in his lungs, severe heart enlargement, very little air space left in the lungs. He was started on **B6** **B6** 5mg at morning, 2.5mg at night. He stopped eating and began to have trouble breathing, head tilt, abnormal behavior. He started to improve, then after the next dose he would worsen. He was taken off the **B6**. He was taken for a recheck but the vet couldn't see him. The vet recommended he be left off of it unless he worsened. He worsened and the vet couldn't be reached. **B6** was given a 2.5mg dose. He died shortly thereafter. **B6** is a 5 year old Boston Terrier. After the experience with **B6** was taken to a new vet in August 2018 for his check up. He needed a dental cleaning and chest x-rays were scheduled to happen at the same time. The vet recommended changing the dog food to Hill's. The dental and x-ray were done 10/1/2018. **B6** had right sided heart enlargement and pulmonary hypertension. His bloodwork was done. Nothing was noted with the bloodwork. Blood was sent off for taurine. It was requested to be sent off to UC Davis. Depending on the taurine level, the plan is to see a cardiologist. He's not on any medication right now. He does get very upset when traveling to the vet. He was given **B6** to help with that.

Date Problem Started: 07/29/2018
Concurrent Medical Problem: No
Outcome to Date: Died Other
Date of Death: **B6**

Product Information:
Product Name: Taste of the Wild Sierra Mountain Canine Formula with Roasted Lamb
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Description: Food kept out all the time, 1 bowl for each dog.
First Exposure Date: 05/01/2016
Last Exposure Date: 05/01/2018
Perceived Relatedness to Adverse Event: Probably related
Manufacturer /Distributor Information:
Name: Taste of the Wild - **B6**
Type(s): Distributor
Contact: **Phone:** **B6**
Possess One or More Labels from This Product: Yes
Purchase Location Information:

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Terrier - Boston		
	Gender:	Male		
	Reproductive Status:	Neutered		
	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:	
		Address:	B6	
United States				
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		08/06/2018		
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:	Distributor			
Additional Documents:				

Report Details - EON-367452

ICSR: 2055608
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: 2018-10-02 21:21:53 EDT
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: She hasn't been on NOW Grain Free dog food since she was less than a year old. She collapsed on a walk the first week of January 2018. When rushed to the emergency vet, they showed she had a mass on her spleen and she had cardiomyopathy. Her heart was twice the size it was supposed to be. We were told she would not live another 24 hours.
Date Problem Started: B6
Concurrent Medical Problem: No
Outcome to Date: Died Euthanized
Date of Death: B6

Product Information:
Product Name: NOW Grain Free Adult Large Breed
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Product was stored in an air tight Vittles vault
Product Use Information:
Description: Product was fed twice daily from before age one until death.
Perceived Relatedness to Adverse Event: Possibly related
Manufacturer /Distributor Information:
Purchase Location Information: Name: B6
Address: B6
United States

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Akita
Gender: Female
Reproductive Status: Neutered
Weight: 80 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 Practice Name: B6

Information:	Contact:	Name: Emergency Vet
		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
	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-367607

ICSR:	2055687
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:	2018-10-04 12:36:46 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dog was diagnosed with dilated cardiomyopathy in June 9th of this year, which I found out after he suddenly developed shortness of breath, bilateral lung crackles and was in severe distress. I took him to the nearest ED, an Xray of the chest showed pulmonary edema, dilated heart and my dog was tachypneic, tachycardic and hypoxemic ~83% O2 saturation. They provided immediate attention, received diuretics, and was started on medications for DCM. He was not on any medications prior to this events, and had all his routine vet check ups including labs and vaccines up to date. Since then there have been at least 4-5 episodes of decompensation, it has been so quickly and unexpected given his excellent state of health prior to all these events. The reason why I am submitting this report is because I was looking for information about a heart disease special diet for him, I found a report about the ongoing investigation about possible grain free dog food associated with DCM. My pet has been on grain free diet for a couple of years after he had bad allergies with other dog foods. After switching him to grain free-lamb diet his allergy completely disappear. For the past 4 years I used the California Natural grain-free lamb dry dog food, which went out of the market around April this year. I still had food until June, and then the event happened. After the event I switch to the Wellness Core RawRev grain-free wild game recipe dry dog food. I am concerned if all of this was related to the grain free diet, given the information I found about prior reports similar to my case. I am also concerned because I still have my pet on grain free food and I would like at least to give him the best at this time to see if there is any improvement and to prevent rapid progression of the DCM as much as I can. I would be glad to provide any further information, and I would like to know if there is any website or vet (specialist) I could get in contact with that could provide any advise at this time.
	Date Problem Started:	06/09/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	California Natural, Grain-free Limited Ingredient Diet, Lamb Meal Recipe	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	I dont have it	
	Package Type:	BAG	
	Package Size:	13 Pound	
	Purchase Date:	04/01/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in the bag and another smaller plastic covered container.	
	Product Use Information:	First Exposure Date:	04/01/2018
		Last Exposure Date:	06/01/2018
		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:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	
		Address:	B6
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Terrier - Yorkshire	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	8.5 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
		Other Phone:	B6
		Email:	B6
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	06/09/2018
		Permission to Release Records to FDA:	No
Sender Information:	Name:		
	Address:	B6	

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-368331		
ICSR:	2055996	
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:	2018-10-13 14:40:50 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Dog was diagnosed with congestive heart failure secondary to dilated cardiomyopathy. Taurine level was well below "normal" range. I understand that there are investigations of possible dietary factors. Our dog was on Acana Lamb and Apple food (grain-free). If our case would help further the research, please feel free to contact me or our vet's office [B6] B6 for additional details of the case. Our dog passed away two weeks after diagnosis.	
	Date Problem Started: 11/10/2015	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Other	
	Date of Death: B6	
Product Information:	Product Name: Acana Lamb and Apple, grain-free	
	Product Type: Pet Food	
	Lot Number:	
	Product Use Information: Description: Primary food source for our dog for ~1-2 years	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name:	
	Type Of Species: Dog	
	Type Of Breed: Retriever - Golden	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 80 Pound	
	Age: 6 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
		Type of Veterinarian: Referred veterinarian
Date First Seen: B6		
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:	None		
Additional Documents:			

Report Details - EON-368370

ICSR:	2056002
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:	2018-10-14 19:28:14 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	On Wednesday evening [B6] was breathing heavily with a rapid heartbeat and extended coughing. We scheduled an appointment with our veterinarian Dr. [B6] DVM, of [B6] for Saturday. [B6] did x-rays and an EKG to diagnose any issues. [B6] has fluid on his lungs and an enlarged heart, dilated cardiomyopathy. Based on the prognosis of his condition we elected to go through euthanasia to end his suffering. Care options for the disease are limited on the weekend, and Dr. [B6] believe that it was possible he may not survive the weekend, and even with proper care he may not live more than 6 months.
	Date Problem Started:	[B6]
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Horizon Pulsars with Chicken (also fed the same brand with Turkey, pork, and fish)
	Product Type:	Pet Food
	Lot Number:	
	UPC:	I don't have it
	Package Type:	BAG
	Package Size:	25 Pound
	Purchase Date:	09/22/2018
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
Storage Conditions:	Room temperature in a large rubbermaid container	
Product Use Information:	Description:	Fed twice daily 1 cup each feeding Your date requirements for reporting need looked at - The date we first gave him the product was the day we adopted him (10/03/2013), the last day we purchased it was sometime in September of this year. It will not allow me to give you the correct dates. We started giving him the food 5 years ago, which is definitely not the last time we purchased it.
	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: No

Manufacturer /Distributor Information:

Purchase Location Information:

Name:

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Cattle Dog - Australian (blue heeler, red heeler, Queensland cattledog)

Gender: Male

Reproductive Status: Neutered

Weight: 55 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:

Primary/regular veterinarian

Date First Seen:

B6

Permission to Release Records to FDA:

Yes

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: None

Additional Documents:

Report Details - EON-368485			
ICSR:	2056082		
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:	2018-10-16 09:40:33 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	at 9.5 months the puppy suddenly began swallow, rapid breathing (not panting) and showed less interest in typical puppy play. He was seen by the vet and was diagnosed with an enlarged heart/congestive heart failure and started on medication (diuretic and blood thinner).	
	Date Problem Started:	09/28/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Worse/Declining/Deteriorating	
Product Information:	Product Name:	Performatin Ultra Grain-Free Original Recipe, Puppy	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	13.2 Pound	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	The product was stored in it's bag until opening then stored in a sealed dog food storage bin	
	Product Use Information:	Description:	the puppy was fed this product (per package recommendations based on weight) twice a day from the age of 10 weeks until October 1
		First Exposure Date:	03/31/2018
		Last Exposure Date:	10/01/2018
		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	Name:	PetValu	

	Information:	Address:	B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Other Canine/dog		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	35 Pound		
	Age:	10 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	
		Contact: Phone:		
Address:		B6 United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		09/29/2018		
Permission to Release Records to FDA:		Yes		
Sender Information:	Name:	B6		
	Address:	B6 United States		
	Contact: Phone:	B6		
	Contact: 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-368689		
ICSR:	2056321	
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:	2018-10-17 19:48:17 EDT	
Reported Problem:	Problem Description: Low Levels of Taurine	
	Date Problem Started: 09/07/2018	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6	
	Outcome to Date: Stable	
Product Information:	Product Name: Open Farms Whitefish and Lentils	
	Product Type: Pet Food	
	Lot Number:	
	UPC: 628451123095	
	Package Type: BAG	
	Package Size: 24 Pound	
	Purchase Date: 09/15/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: Yes	
	Storage Conditions: Sealed Storage Container	
	Product Use Information:	Description: Feeding 3/4 cups twice daily
		Last Exposure Date: 09/20/2018
		Time Interval between Product Use and Adverse Event: 9 Months
		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:	
	Address: B6 United States	
Animal Information:	Name: B6	

	Type Of Species:	Dog												
	Type Of Breed:	Retriever - Labrador												
	Gender:	Female												
	Reproductive Status:	Neutered												
	Weight:	69 Pound												
	Age:	9 Years												
	Assessment of Prior Health:	Excellent												
	Number of Animals Given the Product:	2												
	Number of Animals Reacted:	2												
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Owner Information provided:	Yes	Contact: Name:	B6	Phone:		Email:		Address:	B6		United States
Owner Information provided:	Yes													
Contact: Name:	B6													
Phone:														
Email:														
Address:	B6													
	United States													
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Practice Name:	B6	Contact: Name:	B6	Phone:		Email:		Address:	B6		United States
Practice Name:	B6													
Contact: Name:	B6													
Phone:														
Email:														
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:	Email												
	Reported to Other Parties:	None												
Additional Documents:														

Report Details - EON-368690

ICSR: 2056322
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: 2018-10-17 20:02:41 EDT

Reported Problem:
Problem Description: Patient has low taurine levels and cardiac ultrasound revealed mildly dilated left ventricle as well as mild mitral regurgitation.
Date Problem Started: 09/28/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:
Product Name: Open Farms Whitefish and Lentils
Product Type: Pet Food
Lot Number:
UPC: 628451123095
Package Type: BAG
Package Size: 24 Pound
Purchase Date: 09/15/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: Sealed Storage Container
Product Use Information:
Description: Fd 3/4 cup twice daily
Last Exposure Date: 09/20/2018
Time Interval between Product Use and Adverse Event: 9 Months
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: Address: B6 United States

Animal Information:

Name:		B6	
Type Of Species:	Dog		
Type Of Breed:	Retriever - Labrador		
Gender:	Female		
Reproductive Status:	Neutered		
Weight:	62.1 Pound		
Age:	5 Years		
Assessment of Prior Health:	Excellent		
Number of Animals Given the Product:	2		
Number of Animals Reacted:	2		
Owner Information:	Owner Information provided:	Yes	
	Contact:	Name:	B6
		Phone:	
		Email:	
	Address:	B6	
		United States	
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	
		Email:	
	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:	Email	
Additional Documents:			

Report Details - EON-369285

ICSR:	2057012		
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 17:07:30 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	I believe feeding our dog a grain free diet contributed to heart disease.	
	Date Problem Started:	10/08/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Worse/Declining/Deteriorating	
Product Information:	Product Name:	http://americannaturalpremium.com/wp-content/uploads/2018/06/bag-duck.png	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	12 Pound	
	Purchase Date:	10/08/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Product Use Information:		
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	Roll over image to zoom in American Natural Premium Grain-Free Duck Meal & Pork Meal Recipe Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	12 Pound	
	Purchase Date:	10/08/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Package emptied into a storage container after purchase	
	Product Use Information:	Description:	Daily feed, dry dog food
		First Exposure Date:	10/08/2018
		Last Exposure Date:	10/24/2018
		Time Interval between Product Use and Adverse Event:	5 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 Information:	Name:	B6
	Address:	
		United States

Animal Information:

Name:	B6	
Type Of Species:	Dog	
Type Of Breed:	Terrier - Boston	
Gender:	Male	
Reproductive Status:	Neutered	
Weight:	23 Pound	
Age:	3.5 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
	Contact: Phone:	B6
	Address:	B6
		United States
	Type of Veterinarian:	Primary/regular veterinarian
	Date First Seen:	10/08/2018
Permission to Release Records to FDA:	Yes	

Sender Information:

Name:	B6
Address:	B6
	United States
Contact: Phone:	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-369421

ICSR:	2058060
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:	2018-10-26 09:34:52 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Began to notice 3 years ago, [B6] energy level was declining--stamina for running and playing decreasing. Then May 2018, he couldn't keep up on daily walks--and didn't want to go on walks. After a weekend of boarding in July 2018, he became lethargic and ultimately went into respiratory distress. Doctor diagnosed congestive heart failure, recommending ultrasound. This showed enlarged heart and mitral valve insufficiency, signs of canine DCM. Heart meds were tried and on 9/30/18, we noticed [B6] heart rate was rapid and heavily pumping. These symptoms couldn't be controlled and he stopped eating, kidney function declined, had difficulty walking and we made decision on [B6] to put him down.
	Date Problem Started:	07/15/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Taste of the Wild Pacific Stream Canine Formula with Smoked Salmon Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	05/19/2014	
	Number Purchased:	1	
	Possess Unopened Product:	Unknown	
	Possess Opened Product:	Yes	
	Storage Conditions:	We emptied the 30lb bag into a storage container with sealed lid.	
	Product Use Information:	Description:	[B6] was fed 1 1/4 cups at breakfast and 1 1/4 cup at dinner
		First Exposure Date:	05/20/2014
		Last Exposure Date:	10/10/2018
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:		Definitely related	
Other Foods or Products Given to the Animal		No	

During This Time Period:	
Manufacturer /Distributor Information:	Name: Diamond Pet Foods, Inc., owned by Schell and Kampeter, Inc., Type(s): Manufacturer Address: Missouri United States Contact: Possess One or More Labels from This Product: Yes
Purchase Location Information:	Name: B6 Address: B6 United States

Animal Information:	Name: B6 Type Of Species: Dog Type Of Breed: Retriever - Labrador Gender: Male Reproductive Status: Neutered Weight: 59 Pound Age: 6.5 Years Assessment of Prior Health: Good Number of Animals Given the Product: 1 Number of Animals Reacted: 1 Owner Information:
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Healthcare Professional Information:	Practice Name: B6 Contact: Name: B6 Phone: Address: B6 United States Type of Veterinarian: Referred veterinarian Date First Seen: 07/29/2018 Permission to Release Records to FDA: Yes Practice Name: B6 Contact: Name: B6 Phone: Address: B6 United States Type of Veterinarian: Primary/regular veterinarian Date First Seen: 07/27/2018 Permission to Release Records to FDA: Yes
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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-370158		
ICSR:	2058370	
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:	2018-11-03 17:44:26 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Taurine levels were low due to grain free dog food.	
	Date Problem Started: 03/01/2016	
	Concurrent Medical Problem: No	
	Outcome to Date: Unknown	
Product Information:	Product Name: Earthborn Holistic Primitive Natural Grain Free	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Possess Unopened Product: No	
	Possess Opened Product: Yes	
	Storage Conditions: In original bag, then within a sealed plastic container.	
	Product Use Information:	Description: Fed twice daily
		Last Exposure Date: 09/17/2018
		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:	
	Type Of Species: Dog	
	Type Of Breed: Retriever - Golden	
	Gender: Female	
	Reproductive Status: Neutered	
	Age: 4 Years	
Number of Animals 1		

	Given the Product:		
	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	
	Date First Seen:	08/17/2018	
	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-370466		
ICSR:	2058527	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-11-07 10:20:01 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Our yellow lab developed Dilated Cardio Myopathy and we have read that there is a link between grain free diet and DCM. She was on a grain free diet due to a very high Pea and Barley allergy	
	Date Problem Started: 04/18/2014	
	Concurrent Medical Problem: No	
	Outcome to Date: Died, Euthanized	
	Date of Death: B6	
Product Information:	Product Name: Nutro Grain Free Food, salmon and rice	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 30 Pound	
	Purchase Date: 06/20/2013	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: stored in garage in an aluminum bucket	
	Product Use Information:	Description: was fed this food 2 times a day, 1 cup morning and 1 cup at night. NOTE- we switched her off of this food because we thought/knew they changed their formula when they changed the bag
		First Exposure Date: 10/31/2013
		Last Exposure Date: 10/31/2013
		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 Name: B6		

	Information:	Address:	B6 United States	
	Product Name:	Pinnacle Trout and Sweet Potato		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	24 Pound		
	Purchase Date:	03/23/2014		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	We stored the food in the garage in an aluminum bucket		
	Product Use Information:	Description:	We fed her 2 times a day, 1 cup in morning and 1 in the evening	
		First Exposure Date:	04/14/2014	
		Last Exposure Date:	B6	
		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		
	Address:	United States		
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Labrador		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	72 Pound		
	Age:	6 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: B6
		Address:	B6 United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	04/18/2014
		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:			

Report Details - EON-370819

ICSR: 2058709
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-11 20:50:35 EST
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: A week and a half ago we noticed **B6** appetite slowly decreasing. 1 week later he started breathing heavy. The next morning his breathing was labored 69 breaths a minute or more. His gums were pale and he was lethargic. I rushed him to the vet. The technologist immediately rushed him in the back to place him on oxygen. We later found out he has a very enlarged heart and is in congestive heart failure. We are currently feeding him Zignature Kangaroo. He has been eating Zignature wet and dry for years. I found your article recently published between canine diets and heart disease. I also saw a veterinarian discussing this issue on the news. They mentioned Kangaroo, grain free foods coming from a small brand dog foods with peas, chickpeas, etc are possibly a link to the pets heart failure. Please look into **B6** case to see if the Zignature food could have possibly been related to his heart disease. We will do whatever we can to save other animals from future suffering of heart disease. My heart has been broken to know my dog will never have the quality life he deserves.

Date Problem Started: 10/31/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: **B6**

Outcome to Date: Stable

Product Information:

Product Name: Zignature Kangaroo Formula

Product Type: Pet Food

Lot Number:

UPC: 8864113132

Package Type: BAG

Package Size: 27 Pound

Purchase Date: 10/24/2018

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: Yes

Storage Conditions: Kept in the bag in Kitchen. When the bag was opened I made a small cut, enough to get the cup in and out. We keep the bag closed with a clip.

Product Use Information:

Description: I feed **B6** 5-7.5 cups of food 2 times a day. Plus estimated once a week we split up duck, kangaroo, salmon, etc wet food from Zignature.

Last Exposure Date: 11/10/2018

Time Interval between Product Use and Adverse Event: 3 Years

Product Use Stopped After the Onset of the Adverse Event: No

Perceived: Probably related

		Relatedness to Adverse Event:		
	Manufacturer /Distributor Information:	Name:	Pets global Inc	
		Type(s):	Manufacturer	
		Address:	28334 Industry drive Valencia California 91355 United States	
		Contact:	Phone: 1888-897-7207 Web Address: Www.zignature.com	
		Possess One or More Labels from This Product:	Yes	
	Purchase Location Information:	Name:	B6	
		Address:	B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Spaniel - Cocker American		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	37 Pound		
	Age:	7 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:		11/07/2018		
Permission to Release Records to FDA:		Yes		
Sender Information:	Name:	B6		
	Address:	B6 United States		
	Contact:	Phone: B6 Email: B6		
	Permission To Contact	Yes		

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

Additional Documents:

Report Details - EON-371427

ICSR: 2059012
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-11-19 12:21:25 EST

Reported Problem:

Problem Description: Presented for evaluation of congestive heart failure. Referring veterinarian saw radiographic changes consistent with CHF, patient was started on [B6] [B6]. He has been eating Zignature kangaroo and lentil for 4 years, and prior to that was on another brand grain free food. Echocardiogram performed on 11/16/2018 consistent with dilated cardiomyopathy and ventricular arrhythmias. Taurine levels pending. An abdominal mass was an incidental finding on physical examination 11/16/2018.

Date Problem Started: 11/07/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: [B6]

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: Zignature Kangaroo Limited Ingredient Formula Dry Dog Food

Product Type: Pet Food

Lot Number:

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Product Use Information:

Description: Fed daily

First Exposure Date: 01/01/2014

Time Interval between Product Use and Adverse Event: 4 Years

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:

Animal Information:

Name: [B6]

Type Of Species: Dog

Type Of Breed: Spaniel - Cocker English

Gender: Male

Reproductive Status: Neutered

Assessment of Prior Health: Good

	Number of Animals Given the Product:	1											
	Number of Animals Reacted:	1											
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Owner Information provided:	Yes	Contact: Name:	B6	Phone:		Address:	B6		United States	
Owner Information provided:	Yes												
Contact: Name:	B6												
Phone:													
Address:	B6												
	United States												
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact: Name:</td> <td rowspan="4">B6</td> </tr> <tr> <td>Phone:</td> </tr> <tr> <td>Other Phone:</td> </tr> <tr> <td>Email:</td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	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												
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-370844

ICSR: 2058724
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Both
Reporting Type: Voluntary
Report Submission Date: 2018-11-12 10:59:45 EST

Reported Problem:
Problem Description: B6 was presented to B6 for further cardiac evaluation after going into heart failure this past September. He is a patient of B6 for ongoing treatment for Addison's disease. He had been eating a grain-free diet since a puppy and was switched to Blue Buffalo chicken and brown rice due to the recent concern over diet related dilated cardiomyopathy. He was started on cardiac medications B6 and is back to his normal self. No coughing with normal breathing, a healthy appetite, and a good energy level. B6 receives Heartgard for seasonal heartworm prevention (discussed the appropriate season for this area is June through November).
Date Problem Started: 09/18/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Grain-free since puppy - unsure of brand
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: Sheepdog - Old English
Gender: Male
Reproductive Status: Neutered
Weight: 32.8 Kilogram
Age: 6 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 Information: Practice Name: B6

Contact: Name:
Phone:
Other Phone:
Email:

B6

Address:

B6

United States

Sender Information:

Name:

Address:

B6

United States

Contact: Phone:

Other Phone:

Email:

B6

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Additional Documents:

Report Details - EON-370845

ICSR:	2058725
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:	2018-11-12 11:12:04 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was diagnosed with dilated cardiomyopathy (DCM). Unfortunately, she was not diagnosed until it was so severe that she could not be treated. Since she was only 6 years old and considered to be a "young pup", heart issues were not suspected. Based on her blood work, she was first treated for liver issues and then upper respiratory infection. It was not until she was not eating, drinking, and could not walk until an ultrasound was done and found she had DCM. We fed B6 Costco Salmon & Sweet Potato food for most of her life. When we heard about the FDA investigation we wanted to report it.
	Date Problem Started:	10/07/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Formula for Dogs		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	35 Pound		
	Purchase Date:	10/01/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in a sealed container for dog food		
	Product Use Information:	Description:	We fed our dog this food for most of her 6 year life.	
		First Exposure Date:	10/05/2018	
		Last Exposure Date:	10/12/2018	
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:		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
Animal Information:	Name: B6 Type Of Species: Dog Type Of Breed: Retriever - Labrador Gender: Female Reproductive Status: Neutered Weight: 85 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: Unknown Unknown Phone: B6 Address: B6 United States Type of Veterinarian: Referred veterinarian Date First Seen: 10/07/2018 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 Date First Seen: 10/08/2018 Permission to Release Records to FDA: Yes Practice Name: B6 Contact: Name: Unknown Unknown Phone: B6 Address: B6

			B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	10/16/2018
		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-371481

ICSR:	2059036
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-11-19 18:18:50 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dog was a rescue. He was given up, not a stray & perfect health. Since he is a mixed breed & our knowledge of mixed we were confident we wouldn't have any health issues & didn't for 2 1/2 years. He was always very active & friendly. About 6 months ago he started to act tired alot, hack & cough. Just not himself. About 3 months ago I took him into the vet where they thought it may be bronchitis, but over night he couldn't stop coughing & foaming at the mouth. I rushed him back to the vet where they said he was in heart failure. I remember seeing a news story of the correlation of grain free dog food & DCM in dogs that would never get it. Bottom line I thought I was being a good pet owner by giving him this from the day we adopted him with was exactly 3 years ago. Instead of the spunky active dog he was hes more like an old man & on 2 heart meds for the rest of his life.
	Date Problem Started:	08/15/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	Rachel Ray Grain Free Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	5 Pound		
	Purchase Date:	05/08/2016		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Air tight container		
	Product Use Information:	Description:	In a bowl	
		First Exposure Date:	02/02/2017	
		Last Exposure Date:	07/03/2018	
		Time Interval between Product Use and Adverse Event:	6 Months	
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: B6	
		United States	
Product Name:		Simply Nourish Grain Free Dog Food	
Product Type:		Pet Food	
Lot Number:			
Package Type:		BAG	
Package Size:		5 Pound	
Purchase Date:		11/26/2016	
Possess Unopened Product:		No	
Possess Opened Product:		No	
Storage Conditions:		Air tight container	
Product Use Information:		Description:	In a bowl
		First Exposure Date:	11/27/2016
		Last Exposure Date:	08/09/2018
		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 to the Animal During This Time Period:	No
Manufacturer /Distributor Information:			
Purchase Location Information:		Name:	Petsmart
		Address: B6	
		United States	
Animal Information:	Name:		
	Type Of Species:	Dog	
	Type Of Breed:	Mixed (Dog)	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	14 Pound	
	Age:	6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals	1	

	Reacted:	
	Owner Information:	
	Healthcare Professional Information:	
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact:	Phone: B6
		Ema: 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-371491			
ICSR:	2059042		
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:	2018-11-19 22:43:35 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Our standard poodle became lethargic and stopped eating. We took her to our veterinarian, and with xray showed enlarged heart and water/cancer on the lungs.	
	Date Problem Started:	11/12/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Died Naturally	
	Date of Death:	B6	
Product Information:	Product Name:	Merrick dry dog food: lamb	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	15 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	We have a container that is closed.	
	Product Use Information:	Description:	This was the only food our dog consumed. She was fed approximately 2 cups per day.
		First Exposure Date:	01/01/2017
		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:	No
Manufacturer /Distributor Information:			
Purchase Location Information:	Name:	Through Chewy.com	
	Address:	United States	
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Poodle - Standard	
	Gender:	Female	

	Reproductive Status: Neutered
	Weight: 42 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:	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Other Phone:
	Email: n/a
	Address: B6
	United States
	Type of Veterinarian: Primary/regular veterinarian
Date First Seen: 11/15/2018	
Permission to Release Records to FDA: Yes	
Sender Information:	Name:
	Address: B6
	United States
	Contact: Phone:
	Other 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-371913

ICSR:	2059262
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:	2018-11-26 11:38:50 EST

Reported Problem:	Problem Description:	B6 presents to B6 today for an in-house consult through the Neurology service. He is being evaluated by neurology for seizure episodes which consist of stiffening, drooling and on one occasion incontinence. The episodes last between 21-22 minutes with a post ictal period lasting about 30 minutes and B6 being very disoriented. Thoracic radiographs showed mild generalized cardiomegaly without significant left atrial enlargement and no signs of cardiac decompensation. B6 is fed a grain free diet. HR 55-75bpm. Irregular rhythm consistent with a sinus arrhythmia, but relatively bradycardic. Prominent second heart sound, no murmur. Normal femoral pulses and jugular veins. mm pink, normal refill. inus bradycardia - This is unlikely to cause B6 events, but heart rate responsiveness to B6 prior to anesthetic induction should be determined. Mildly decreased cardiac contractility - B6 heart does not contract as forcefully as expected, though the change is mild. This may be early dilated cardiomyopathy, but he is unlikely to be symptomatic from this mild change. Dilated cardiomyopathy is a disease characterized by weakening of the heart muscle and dilation of the heart chambers. As the disease progresses, it can lead to congestive heart failure (fluid in the lungs causing shortness of breath and cough). Abnormal heart rhythms are common and can result in sudden death. Most commonly this is an inherited disease (this would be very uncommon in a Cavalier), though it can occur secondary to a deficiency in an amino acid called taurine. Recently, a connection between certain diets usually marketed as "grain free" and dilated cardiomyopathy has been established. Since B6 has been fed one of the diets in question, this is a consideration in him.
	Date Problem Started:	11/21/2018
	Concurrent Medical Problem:	Unknown
	Outcome to Date:	Stable

Product Information:	Product Name:	Primal Raw
	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:	Spaniel - King Charles Cavalier
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	8.2 Kilogram
	Age:	1 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:	Name: B6 Phone:
	Address:	B6 United States
	Healthcare Professional Information:	Practice Name: B6
	Contact:	Name: B6 Phone: B6 Other Phone: Email:
	Address:	B6 United States
	Sender Information:	Name: 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-372244			
ICSR:	2059385		
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:	2018-11-28 23:27:36 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	The dog has a heart murmur and a cardiologist has determined that it has been caused/impacted by the grain free dog food diet.	
	Date Problem Started:	04/01/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Unknown	
Product Information:	Product Name:	Taste of the Wild High Prairie Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	We kept the dog food in a sealed plastic container.	
	Product Use Information:	Description:	We fed the product to our two puppies twice a day for meals.
		First Exposure Date:	04/01/2018
		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:		Definitely 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:	Shepherd Dog - Australian	
	Gender:	Male	
	Reproductive Status:	Intact	

	Weight:	27 Pound						
	Age:	10 Months						
	Assessment of Prior Health:	Good						
	Number of Animals Given the Product:	2						
	Number of Animals Reacted:	1						
	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> </table>	Contact:	Name:	B6		Phone:	
Contact:	Name:	B6						
	Phone:							
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-372356		
ICSR:	2059437	
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:	2018-11-29 19:53:03 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: 8 1/2 year old Goldendoodle mix recently diagnosed with Dilated Cardiomyopathy and mitral valve disease. Experiencing symptoms of coughing, bilateral murmur, elevated heartrate, decreased energy, loss of appetite, and change in sleep position.	
	Date Problem Started: 11/09/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Worse/Declining/Deteriorating	
Product Information:	Product Name: Nutrisource	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 30 Pound	
	Product Use Information:	Description: Dog fed various flavors of grain-free kibble (NutriSource) over the last 6+ years.
		First Exposure Date: 01/01/2012
		Last Exposure Date: 11/12/2018
		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: 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: Retriever - Golden	

	Reproductive Status:	Neutered
	Weight:	50 Pound
	Age:	8.5 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: B6
	Address:	B6
	Type of Veterinarian:	Primary/regular veterinarian
	Date First Seen:	11/19/2018
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:		

Report Details - EON-372362

ICSR:	2059441
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-11-29 22:45:25 EST

Reported Problem:	Problem Description:	My dog was on grain free food ever since I adopted him about 3 years ago. He has gone to the be that least twice a year, every year since I have had him. He had been to the vet about 7 months BEFORE the visit where they found out he now has a heart murmur. The vet thinks there is a possibility it could be linked to The grain free food, as its never been there before.
	Date Problem Started:	08/29/2018
	Date of Recovery:	11/29/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Holistic Select Grain free senior dog food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	26 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	The entire bag was emptied into a sealable container.		
	Product Use Information:	Description:	It was fed to my healthy dog twice a day. 3/4 cup of dry kibble in the morning and in the evening.	
		First Exposure Date:	06/01/2015	
		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:		No		
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	B6		
	Address:			

B6

United States

Animal Information:

Name:

Type Of Species: Dog

Type Of Breed: Terrier - Boston

Gender: Male

Reproductive Status: Neutered

Weight: 18 Pound

Age: 8 Years

Assessment of Prior Health: Excellent

Number of Animals Given the Product: 2

Number of Animals Reacted: 1

Owner Information:

Owner Information provided: Yes

Contact:

Name:

Phone:

Email:

B6

Address

B6

United States

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-372494

ICSR:	2059508		
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:	2018-12-01 11:38:32 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	I fed my dogs, both neutered male border collies, Fromm Gold Holistic dog food for a significant amount of time which I think is one that had potatoes, legumes etc as main ingredient. Its hard to tell what the FDA means by main ingredient. From dec 2016 until diagnosis. Bought it from Chewy so I have a record. B6 was later diagnosed with a severe heart condition. I took him to his regular vet and a veterinary cardiologist. I suspect the other dog that ate the food did not get heart disease or hasnt shown symptoms yet because hes quite a bit younger. Dates on this form are approximate but can provide exact details if you need them.	
	Date Problem Started:	12/01/2017	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	He was taking pain medication intermittently due to a past injury	
	Outcome to Date:	Worse/Declining/Deteriorating	
Product Information:	Product Name:	Fromm Gold Holistic Adult Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	33 Pound	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In a plastic bin	
	Product Use Information:	Description:	Dog was fed this as his regular ration for about a year
		First Exposure Date:	12/01/2016
		Last Exposure Date:	12/01/2017
		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:		No	
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: Chewy.com

Animal Information:

Name: **B6**

Type Of Species: Dog

Type Of Breed: Collie - Border

Gender: Male

Reproductive Status: Neutered

Weight: 50 Pound

Age: 10 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: 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-373659

ICSR:	2060110
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-12-12 14:58:25 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 always was an allergic dog. His diet is almost only fish and seaweed proteins. In B6 / we came here from B6 / he ate fish and millet/buckwheat/whole grain noodle and vegetable / beets, carrot, kale etc/ and fruits, and had always dry food Wolfsblut / Cold River/ in his bowl. Since we've come to US, I can't find german food and kashas and good fish in B6 and at December 2017 I choose Acana Single Protein Diet Mackrel or Orijen "Six Fish" diet. He ate only this food and some vegetables orz fruits. In B6 has a surgery - we removed small mass from his leg. He has been more letargic, and his belly was biggest than normal, but doctors think it was allergy reactions. at B6 other doctor diagnosed CHF and sent us to B6 to cardiology department. B6 never had taurine blood test but I've been started taurine and L-carnityne supplementation 5 weeks ago and he feel better and his abnormal heart rate desapidisappeared - our last evaluation in cardiology dept was a very good and give us a little hope for longest life.
	Date Problem Started:	08/15/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Stable

Product Information:	Product Name:	Acana Single Protein Diet - Mackrel Orijen Six Fish		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	13 Pound		
	Purchase Date:	07/31/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	stored in oryiginal package at room temp, near AC		
	Product Use Information:	Description:	dry food available all the time with fresh water / water in separate bowl /	
		First Exposure Date:	08/10/2018	
		Last Exposure Date:	09/10/2018	
Time Interval between Product Use and Adverse Event:		100 Minutes		
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:	amazon
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog - French	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	30 Pound	
	Age:	11 Years	
	Assessment of Prior Health:	Fair	
	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-379742

ICSR: 2062660
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Both
Reporting Type: Voluntary
Report Submission Date: 2019-02-14 10:22:05 EST

Reported Problem:
Problem Description: Acute onset of inappetance and tachycardia felt at home. Dilated cardiomyopathy with multiform ventricular tachycardia. Elevated troponin [B6] (normal <0.2 ng/mL). Idexx 4Dx negative, lept panel negative.
Date Problem Started: 02/05/2019
Concurrent Medical Problem: No
Outcome to Date: Died Euthanized
Date of Death: [B6]

Product Information:
Product Name: Grain-free Rachel Ray Peak dry and canned food
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: 16 Kilogram
Age: 2.5 Years
Assessment of Prior Health: Excellent
Number of Animals Reacted: 1
Owner Information:
Owner Information provided: Yes
Contact: Name: [B6]
Phone: [B6]
Email: [B6]
Address: [B6]
United States
Healthcare Professional Information:
Practice Name: [B6]
Contact: Name: [B6]
Phone: [B6]
Other Phone: [B6]
Email: [B6]

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

Report Details - EON-380197

ICSR:	2062921
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:	2019-02-19 23:19:54 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Reporting per Tufts Cummings School of Veterinary medicine regarding possible Taurine deficiency using boutique grain free diets. I've had dog on Natural Balance Salmon Sweet potato dry kibble for about 7 years. Dog's diet and life in general are very closely monitored due to previous problem described below. We discovered yesterday dog is in severe CHF; was asymptomatic until a few weeks ago. Switched to non chicken based diet after likely poisoning by chicken jerky treats from Target, made in China which occurred about 8 years ago, resulted in B6 near death both times with severe rapid onset dehydration.
	Date Problem Started:	01/14/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	Natural Balance Limited Ingredient Diet Sweet Potato and fish Dry Dog formula		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	12 Pound		
	Purchase Date:	01/02/2019		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	In garage in container with lid		
	Product Use Information:	Description:	Eaten daily, freely fed	
		First Exposure Date:	01/02/2019	
		Last Exposure Date:	02/19/2019	
		Time Interval between Product Use and Adverse Event:	6 Years	
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		Unknown		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Possibly related		
Other Foods or	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: Pekingese

Gender: Female

Reproductive Status: Neutered

Weight: 15 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:

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: Phone

Reported to Other
Parties: None

Additional Documents:

Report Details - EON-381148

ICSR:	2063362
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:	2019-02-28 15:56:19 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was a normal, happy, healthy dog, but then at age 6 1/2, he seemed to tire easily and constantly coughing. Then he had a fainting spell so we took him to emergency vet and they said he was in heart failure and had an enlarged heart. She referred us to a specialist who diagnosed him with DCM and they put him on medication. But a couple of weeks later, he collapsed, howling in pain, so rushed to ER again, and they said he was suffering from massive heart failure, so we had him euthanized. We never knew why a dog so young suffered major heart problems until someone recently showed me the article about the FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease. We fed B6 Blue Buffalo Grain Free from the time he was about two years old until his death at age 6 1/2. Everyone made the whole grain free idea sound like it was really better for dogs, and I never made the connection until reading the FDA article. It's too late for our dog, but I hope his story can help to find out the truth.
	Date Problem Started:	08/25/2016
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Blue Buffalo Life Protection Formula Adult Chicken & Brown Rice Recipe Dry Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Purchase Date:	08/01/2016		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in a plastic pet food container		
	Product Use Information:	Description:	Fed to our rough collie	
		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:		Probably related		
Other Foods or Products Given		Yes		

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: Collie - Rough-haired

Gender: Male

Reproductive Status: Neutered

Weight: 56 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:

Address:

B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: 08/29/2016

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: 08/25/2016

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	DCM.pdf
Description:	Vet records of B6	DCM diagnosis
Type:	Medical Records	
Attachment:	B6	radiograph.pdf
Description:	B6	Radiograph
Type:	Radiographs	

Report Details - EON-382688

ICSR:	2064224
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:	2019-03-18 17:06:09 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 passed out twice back in the spring (May/June 2018) and after taking her to the vet and determining she had an enlarged heart, they referred us to a vet specialist (cardiologist). She had an echocardiogram and ultrasound done and was diagnosed with nutritional DCM. She now takes 9 pills a day B6 to help her heart function and move blood a little better. The Dr said it was very unusual for her breed/size to have this issue, so when I saw the warning on the news, I called them and they said to immediately switch her back to regular food. I did switch her back, but she broke out in hives/rash all over. She was on grain-free food for a reason- she is highly allergic to "normal" dog food. She has been and still does, eat the 4Health brand from Tractor Supply (chicken and vegetable). My B6 at their corporate office and verified with the VP or marketing/merchandising that the formula was changed in order to account for the taurine deficiency, but it still doesn't meet WSAVA guidelines.
	Date Problem Started:	05/25/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	4health Grain Free Whitefish and Potato 4health Grain Free Chicken and Vegetable	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	06/01/2018	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in air tight container	
	Product Use Information:	Description:	B6 ate Blue Buffalo grain free as well as 4health grain free for 6 yrs.
		Last Exposure Date:	09/01/2018
		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:		Not Applicable	
Product Use Started Again:		No	
Perceived Relatedness to		Definitely related	

		Adverse Event:		
		Other Foods or Products Given to the Animal During This Time Period:	No	
	Manufacturer /Distributor Information:	Name:	Tractor Supply	
		Type(s):	Manufacturer	
		Contact:		
		Possess One or More Labels from This Product:	Yes	
	Purchase Location Information:	Name:	Tractor Supply	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	American Pit Bull Terrier		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	45 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
		Address:	B6	
United States				
Type of Veterinarian:		Referred veterinarian		
Date First Seen:		06/14/2018		
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	Distributor			

Parties: Store/Place of Purchase

Additional Documents:

Report Details - EON-382707

ICSR:	2064233
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:	2019-03-18 22:24:32 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was diagnosed with DCM via cardiac ultrasound after a heart murmur was discovered that wasn't present at her previous check up 6 months ago. B6 has been fed Merrick grain free food exclusively for about 3 years. For the last year, she has almost exclusively been on Merrick's grain free chicken and sweet potato. before that, I would rotate between the beef, duck, salmon and chicken with sweet potato. My veterinarian thinks that this case of DCM is associated with her diet because she is not of a breed typically prone to DCM, and she has been fed a grain free diet for most of her life.
	Date Problem Started:	02/28/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Merrick Grain Free Dry Dog Food. Real Chicken and Sweet Potato Recipe		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	01/01/2016		
	Number Purchased:	1		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	Yes		
	Storage Conditions:	The product was stored in an airtight dog food storage container.		
	Product Use Information:	Description:	The product was administered in dog bowls, twice a day. Both dogs were fed 1 and 1/4 cup of food morning and night.	
		First Exposure Date:	03/30/2016	
		Last Exposure Date:	03/02/2019	
		Time Interval between Product Use and Adverse Event:	3 Years	
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		Unknown		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Probably related		
Other Foods or	Yes			

Products Given to the Animal During This Time Period:

Manufacturer /Distributor Information:

Name: Merrick
Type(s): Manufacturer
Address: 101 SE 11th Ave STE 200
Amarillo
Texas
79101
United States
Contact: Phone: 18006647378
Web Address: https://www.merrickpetcare.com
Possess One or More Labels from This Product: Yes

Purchase Location Information:

Name: Amazon
Address: United States

Animal Information:

Name: B6
Type Of Species: Dog
Type Of Breed: Terrier - Airedale
Gender: Female
Reproductive Status: Neutered
Weight: 68.4 Pound
Age: 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
Email: B6
Address: B6
United States
Type of Veterinarian: Primary/regular veterinarian
Date First Seen: 02/27/2019
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:	03/04/2019
		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:	Store/Place of Purchase		
Additional Documents:	Attachment:	Taurine results .pdf	
	Description:	Email from: B6 DVM, with taurine Results for B6	
	Type:	Laboratory Report	
	Attachment:	B6 DCM email.pdf	
Description:	Email from: B6 DVM, detailing B6 Echo results.		
Type:	Echocardiogram		

Report Details - EON-371421

ICSR:	2059005
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-11-19 10:58:08 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	The beginning of April, 2018, B6 became visibly lethargic. On April 6, 2018, I brought him to my primary vet, B6 for a check up. The vet examined him and ran a blood test. He said he was anaplasmosis positive and his platelets were very low. B6 had been treated for anaplasmosis the previous year. The vet was concerned about his platelet level and he suggested I bring him immediately to B6. B6 was examined by 2 additional vets at B6 and they thought the platelet levels were due to the anaplasmosis and put him on a course of B6 and discharged him. Late the night of the 7th he seemed worse and I thought he had blood on his penis. Early on the morning of April 8th, I took him to B6. He was examined and I was asked if anyone had noted a heart issue. I said no and stated 4 other vets had listened to his heart in the previous 2 days. The vet took him for further tests and came back and said she suspected he had DCM. A cardiologist was called in and he diagnosed B6 with DCM, congestive heart failure and atrial fibrillation. He was admitted to the hospital and he was set up with a holter. He was put on many cardiac meds and discharged 2 days later. After 5 days of no appetite even when given anti nausea meds, the B6 was discontinued. A taurine test was requested and came back as B6 plasma. The cardiologist asked which food we had been feeding and I told him Natural Balance Limited Ingredient Grain Free dry food, 3 different flavors... Sweet Potato & Venison, Sweet Potato & Buffalo and Sweet Potato & Fish. I was told to immediately stop the grain free foods and to start supplementing him with 1,000 mg of taurine twice a day. In addition, he takes B6. B6. The cardiologist thought we would have 6 months with B6. The congestive heart failure resolved by the next visit I believe 2 weeks later. In July he had a recheck and the doctor was surprised his heart had decreased in size and his contractility had improved. The cardiologist was sure if this was due to the diet change, taurine supplements or the cardiac meds... or a combo of the 3. Yesterday, November 13th, B6 had another checkup with the cardiologist. He has remained consistent with his July echo. We are continuing with the 20 pill per day regiment and a grain inclusive diet.
	Date Problem Started:	04/06/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Natural Balance L.I.D. Limited Ingredient Diets Sweet Potato & Bison Formula Grain-Free Dry Dog Food
	Product Type:	Pet Food
	Lot Number:	
	UPC:	7 23633 42080 8
	Package Type:	BAG
	Package Size:	26 Pound
	Purchase Date:	03/15/2018
	Number Purchased:	2
	Possess Unopened Product:	Yes
	Possess Opened Product:	No
	Storage Conditions:	Covered galvanized steel bucket
	Product Use Information:	Description: Our dogs eat at will and have multiple bowls of food available throughout the day to graze.

	First Exposure Date:	03/15/2018
	Last Exposure Date:	04/10/2018
	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:	Definitely related
	Other Foods or Products Given to the Animal During This Time Period:	Yes
Manufacturer /Distributor Information:		
Purchase Location Information:	Name:	Chewy's Online
	Address:	United States
Product Name:	Natural Balance L.I.D. Limited Ingredient Diets Sweet Potato & Venison Formula Grain-Free Dry Dog Food	
Product Type:	Pet Food	
Lot Number:		
UPC:	7 23633 42075 4	
Package Type:	BAG	
Package Size:	26 Pound	
Purchase Date:	03/15/2018	
Number Purchased:	2	
Possess Unopened Product:	Yes	
Possess Opened Product:	No	
Storage Conditions:	Covered galvanized steel bucket.	
Product Use Information:	Description:	Our dogs eat at will have have access to multiple bowls of food throughout the day to graze.
	First Exposure Date:	03/15/2018
	Last Exposure Date:	04/10/2018
	Time Interval between Product Use and Adverse Event:	3 Weeks
	Product Use Stopped After the Onset of the Adverse Event:	Yes
	Adverse Event	Unknown

		Abate After Product Stop:	
		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's Online
		Address:	United States
	Product Name:	Natural Balance L.I.D. Limited Ingredient Diets Sweet Potato & Fish Formula Grain-Free Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	7 23633 42037 2	
	Package Type:	BAG	
	Package Size:	26 Pound	
	Purchase Date:	03/15/2018	
	Number Purchased:	2	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	No	
	Storage Conditions:	In a covered galvanized garbage can.	
	Product Use Information:	Description:	Our dogs eat at will. So they have multiple bowls available to graze throughout the day.
		First Exposure Date:	03/15/2018
		Last Exposure Date:	04/10/2018
		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:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer		

	<p>/Distributor Information:</p> <p>Purchase Location Information: Name: Chewy's Online Address: United States</p>
Animal Information:	<p>Name: B6</p> <p>Type Of Species: Dog</p> <p>Type Of Breed: Irish Wolfhound</p> <p>Gender: Male</p> <p>Reproductive Status: Intact</p> <p>Weight: 175 Pound</p> <p>Age: 3 Years</p> <p>Assessment of Prior Health: Excellent</p> <p>Number of Animals Given the Product: 3</p> <p>Number of Animals Reacted: 1</p> <p>Owner Information:</p>
Healthcare Professional Information:	<p>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> <p>Date First Seen: 04/06/2018</p> <p>Permission to Release Records to FDA: Yes</p>
Healthcare Professional Information:	<p>Practice Name: B6</p> <p>Contact: Name: B6 Phone: B6</p> <p>Address: B6 United States</p> <p>Type of Veterinarian: Referred veterinarian</p> <p>Date First Seen: 04/08/2018</p> <p>Permission to Release Records to FDA: Yes</p>
Sender Information:	<p>Name: B6</p> <p>Address: B6 United States</p> <p>Contact: Phone: B6 Email: B6</p> <p>Permission To Contact: Yes</p>

	Sender:	
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Store/Place of Purchase

Additional Documents:

Report Details - EON-378352

ICSR: 2062061
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: 2019-02-01 14:23:34 EST

Reported Problem:
Problem Description: Submitted as RFR EON-378350. 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 4/25/2018. She was being fed a suspect food high in legume ingredients. 2 week history of increased respiratory effort severe generalized cardiomegaly and suspect congestive heart failure moderate to severe global cardiac dilation and severe left ventricular hypokinesis consistent with DCM Diagnosis: Dilated cardiomyopathy leading to ventricular arrhythmia and historical CHF (pleural effusion)
Date Problem Started: 04/25/2018
Outcome to Date: Unknown

Product Information:
Product Name: Earthborn Holistic Grain Free (Unknown Protein/Flavor)
Product Type: Pet Food
Lot Number:
Possess Unopened Product: Unknown
Possess Opened Product: Unknown
Product Use Information:
Manufacturer /Distributor Information:
Name: Midwestern Pet Foods
Type(s): Manufacturer
Address: 617 S D St
Monmouth
Illinois
61462
United States
Contact:
Phone: 800-474-4163x450
Web Address: contact@earthbornholisticpetfood.com
Possess One or More Labels from This Product: Yes
Purchase Location Information:

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Unknown
Reproductive Status: 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:

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-378426

ICSR:	2062081
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:	2019-02-02 11:38:46 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	<p>B6 participated in a 2 mile walk in May 2018 called the B6. It was a 2 mile walk around downtown B6 for owners and their dogs. B6 had walked 2 miles before without any issues. This particular day was cooler and overcast and slightly rainy. During the walk I noticed B6 was panting easily - I attributed that to the excitement of the day. In the days after the walk I noticed he wasn't his usual self - he wouldn't eat, was very listless and had a persistent cough. I thought he may have contracted kennel cough from being around all of the other dogs during the walk, so I made a vet appointment with our normal vet. At this appointment the vet took XRays and performed an ultrasound where it was indicated B6 had an enlarged heart and he had fluid building in his lungs. We were given a low dose of a diuretic for the fluid in his lungs and were told to make an appointment with a specialist sooner rather than later. The next day we went to a canine cardiologist where it was confirmed he had dilated cardiomyopathy. He was put on a host of medications to help his heart and were told he had 6-12 months to live. It was first suspected it was genetic DCM given he was a Boxer Mix. He was eating Zignature grain free Duck formula at the time of is diagnosis due to his food allergies. He was immediately switched to a raw diet with added fish oil and taurine supplements. The improvements were noticeable right away. He has to have checkups every 3-4 months to monitor his condition - at \$500 a visit, it was putting us into debt quickly. My husband lost his job the day of B6 diagnosis and I lost mine a few months later so keeping up with the cost has been difficult. At his most recent visit on January 25th 2018 our cardiologist noticed a significant reduction in the size of his heart and an increase in the output of his heart - all great news. Given his dietary history and diet change she concluded that more than likely it was his previous grain-free diet that was causing the issues. There is no concern of congestive heart failure currently with B6. Note - on the report there is an error. It states that his previous grain-free diet of Fromm probably caused his DCM. He was indeed on Zignature. B6 should have that listed in their records</p>	
	Date Problem Started:	05/11/2018	
	Date of Recovery:	01/25/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	Food allergies to potatoes	
	Outcome to Date:	Better/Improved/Recovering	

Product Information:	Product Name:	Zignature Duck Formula	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	27 Pound	
	Purchase Date:	04/19/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In the original bag sealed with a chip clip	
Product Use Information:	Description:	1 cup administered in the morning & 1 cup administered at night	
	First Exposure	05/01/2018	

Date:	
Last Exposure Date:	05/01/2018
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:	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:

Name:	B6
Address:	
	United States

Animal Information:

Name:	B6	
Type Of Species:	Dog	
Type Of Breed:	Mixed (Dog)	
Gender:	Male	
Reproductive Status:	Neutered	
Weight:	57 Pound	
Age:	8 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:	05/10/2018	

		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: 05/11/2018 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: Email Reported to Other Parties: Distributor	
Additional Documents:	Attachment: DCM 5.11.2018.jpg Description: Summary of first initial visit to B6 Type: Analysis Attachment: DCM 1.25.19.jpg Description: Summary of most recent visit to B6 on 1.25.19 Type: Analysis	

Report Details - EON-378454

ICSR: 2062087
 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: 2019-02-02 19:38:10 EST

Reported Problem:

Problem Description: B6 was put on Royal Canin Multifunction Renal Support Hydrolyzed Protein dry food one year ago and I feel it has been helpful in managing her renal disease and her tendency towards loose stools. Her stools have been perfect and her renal values have been stable. I had some concern regarding her being on a vegetarian, nearly vegan, diet, given recent reports of DCM in dogs on vegetarian and vegan diets, as well as grain free and exotic protein diets. The cardiologist I work with agreed that it was worthwhile to do a baseline echo and the echo showed borderline to decreased heart function. A cardiac pro BNP test was elevated, also supporting myocardial disease. Taurine levels are pending at UC Davis. I have reported this to Royal Canin but am concerned that because B6 has pre-existing medical concerns and was receiving other supplements, treats, and medications, they may not pursue this adequately to ensure the diet does not pose risk to other dogs.

Date Problem Started: 01/25/2019

Concurrent Medical Problem: Yes

Pre Existing Conditions: B6

Outcome to Date: Unknown

Product Information:

Product Name: Royal Canin Multi Function Renal Support and Hydrolyzed Protein

Product Type: Pet Food

Lot Number:

UPC: 18082010RGU04

Package Type: BAG

Package Size: 7.7 Pound

Number Purchased: 1

Possess Unopened Product: Yes

Possess Opened Product: Yes

Storage Conditions: Stored in bag in plastic bin

Product Use Information:

Description: Fed as maintenance diet to B6 for one year and used as main treat for all 3 dogs in home, including B6

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 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: Retriever - Labrador

Gender: Female

Reproductive Status: Neutered

Weight: 50 Pound

Age: 3 Years

Assessment of Prior Health: Fair

Number of Animals Given the Product: 1

Number of Animals Reacted: 1

Owner Information:

Owner Information provided: Yes

Contact:

Name:

Phone:

Email:

B6

Address:

B6

United States

Healthcare Professional Information:

Practice Name:

B6

Contact:

Name:

Phone:

Other Phone:

Email:

B6

Address:

B6

United States

Sender Information:

Name:

Address:

B6

United States

Contact:

Phone:

Other Phone:

B6

Email:

B6

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Reported to Other Parties: Manufacturer

Additional Documents:

Attachment:	B6	labs through Jan '18.docx
Description:	B6	's labwork through January '18, prior to starting diet
Type:	Laboratory Report	
Attachment:	B6	medicalhistory11618.docx
Description:	B6	medical history and diets prior to starting diet (up through January 2018)
Type:	Medical Records	
Attachment:	1901280278.pdf	
Description:	B6	pro BNP results
Type:	Laboratory Report	
Attachment:	001.jpg	
Description:	B6	cardiologist report 1/25/19
Type:	Echocardiogram	
Attachment:	B6	labs Feb-Nov '18.docx
Description:	B6	labwork since on diet
Type:	Laboratory Report	

Report Details - EON-379447

ICSR: 2062532
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 10:21:07 EST

Reported Problem:

Problem Description:	Originally reported as RFR EON-379412. 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 9/4/2018. He was being fed a suspect food high in legume ingredients. acute weakness and abnormal breathing. Atrial fibrillation with average heart rate of 160-180 bpm; QRS complexes appear wide suggestive of LV enlargement. There is moderate to severe generalized cardiomegaly and severe myocardial failure consistent with dilated cardiomegaly. There is mild low velocity mitral regurgitation and mild tricuspid regurgitation with normal velocities. Regurgitation appears secondary to annular dilation. Diagnosis: Dilated cardiomyopathy, atrial fibrillation, Congestive heart failure, Azotemia
Date Problem Started:	09/04/2018
Outcome to Date:	Unknown

Product Information:

Product Name:	Acana (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:	Unknown
Gender:	Male
Reproductive Status:	Unknown
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:	No
Reported to Other:	Unknown

Parties:

Additional Documents:

Report Details - EON-380170											
ICSR:	2062903										
Type Of Submission:	Initial										
Report Version:	FPSR.FDA.PETF.V.V1										
Type Of Report:	Both										
Reporting Type:	Voluntary										
Report Submission Date:	2019-02-19 16:07:14 EST										
Reporter is the Animal Owner:	Yes										
Reported Problem:	Problem Description: My dog starting getting a horrible cough - took her to the vet, they thought maybe kennel cough - gave her antibiotics - condition got worse before a week of antibiotics. Took her back to the vet, they maybe thought she had bronchitis and wanted to sedate her and do x-rays. I got a call a few hours after I dropped B6 off that my dog had turned blue when they went to sedate her, but they found out she had a very enlarged heart and had fluid built up in her lungs. That's when the vet was shocked with her breed and never having seen this, asked history of the dog and then asked what we were feeding. We told the vet Nutrience Sub Zero Grain Free Canadian Pacific Dog Food and that's when she advised us of the FDA Warning regarding the two links.										
	Date Problem Started: 11/02/2018										
	Outcome to Date: Stable										
Product Information:	Product Name: Nutrience Sub Zero Grain Free Canadian Pacific Dog Food										
	Product Type: Pet Food										
	Lot Number:										
	Package Type: BAG										
	Package Size: 22 Pound										
	Possess Unopened Product: No										
	Possess Opened Product: No										
	Storage Conditions: Kept in original bag - bag had a ziplock top										
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>Fed Daily for the last 3 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>Yes</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> </table>	Description:	Fed Daily for the last 3 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
	Description:	Fed Daily for the last 3 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: <table border="1"> <tr> <td>Name:</td> <td>PetSmart Canada</td> </tr> <tr> <td>Address:</td> <td>Canada</td> </tr> </table>	Name:	PetSmart Canada	Address:	Canada							
Name:	PetSmart Canada										
Address:	Canada										
Animal Information:	Name: B6										
	Type Of Species: Dog										
	Type Of Breed: Australian Kelpie										
	Gender: Female										
	Reproductive Status: Neutered										
	Weight: 46 Pound										

	Age:	5 Years
	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
	Type of Veterinarian:	Primary/regular veterinarian
	Date First Seen:	11/02/2018
	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:	Other
Additional Documents:	Attachment:	B6 Radiograph.jpg
	Description:	Radiograph - Shows a very enlarged heart and the fluid in her lungs
	Type:	Radiographs
	Attachment:	B6 Radiopgraph Invoice.jpg
	Description:	Invoice - Day B6 was sedated and turned blue - was able to get one radiograph - was then there all day hooked up to an IV
	Type:	Other

		Email: B6
	Address:	B6 United States
Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6 Phone: Email:
	Address:	B6 United States
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 Parties:	None
Additional Documents:	Attachment:	B6 Medical Records.pdf
	Description:	B6 current medical records (SOAPs, client communication, labwork, and Echo report)
	Type:	Medical Records

Report Details - EON-383815		
ICSR:	2064966	
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:	2019-03-31 13:35:43 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: We rescued our dog 3 years ago and started him on Orijin's Puppy Formula and then after about three months started him on ACANA Heritage Freshwater Fish Food. I've alternated between the Fish and their Lamb and Apple Formula for three years now. Recently in the past three months he's lost 13 lbs, became increasing more fatigued, started coughing, and had little interest in food or any activity. I took him to our vet thinking maybe it could be the change in the season and possibly seasonal allergies. They ran routine blood work and chest x-rays to find that his heart is significantly larger than what it is supposed to be and diagnosed him with dilated cardiomyopathy. Our vet instructed us to take him off of his grain free diet because there has been so many people having the same issues as us.	
	Date Problem Started: 12/01/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Worse/Declining/Deteriorating	
Product Information:	Product Name: ACANA Heritage Freshwater Fish Formula	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 25 Pound	
	Purchase Date: 09/01/2016	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: We store our food in a plastic food bin that has a locked seal and is only opened to scoop out his food in the morning and evening.	
	Product Use Information:	Description: I fed him 1.5 cup of food once in the morning and once in the evening.
		First Exposure Date: 09/03/2016
		Last Exposure Date: 03/28/2019
Time Interval between Product Use and Adverse Event: 1 Minutes		
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:	
		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:	American Pit Bull Terrier	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	72 Pound	
	Age:	3.5 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:	
		Email:	
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	03/29/2019
		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	Yes	

	Sender:	
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	Other

Additional Documents:

Report Details - EON-384061		
ICSR:	2065209	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2019-04-03 11:53:01 EDT	
Reported Problem:	Problem Description: Patient developed DCM and CHF on a grain free diet. Taurine levels were measured and were normal. However, the patient was changed to a non grain free diet and rechecks have shown continued improvement. She is no longer in heart failure 6 months later and her heart is nearly normal	
	Date Problem Started: 09/06/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: Redford Naturals Duck and Sweet Potato	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Product Use Information:	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:		
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Boxer (German Boxer)	
	Gender: Female	
	Reproductive Status: Neutered	
	Age: 4 Years	
	Assessment of Prior Health: Excellent	
	Number of Animals Reacted: 2	
	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	
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-384062											
ICSR:	2065210										
Type Of Submission:	Initial										
Report Version:	FPSR.FDA.PETF.V.V1										
Type Of Report:	Both										
Reporting Type:	Voluntary										
Report Submission Date:	2019-04-03 11:58:27 EDT										
Reported Problem:	Problem Description: B6 was eating a grain free diet when a new heart murmur was detected on a routine exam. Echo showed DCM. He was started on B6 and diet was changed. A housemate was diagnosed with DCM and CHF a few weeks earlier and was eating the same diet. Both dogs have shown significant improvement since changing to a non grain free diet.										
	Date Problem Started: 09/26/2018										
	Concurrent Medical Problem: No										
	Outcome to Date: Better/Improved/Recovering										
Product Information:	Product Name: Redford Naturals Duck and Sweet Potato										
	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>Time Interval between Product Use and Adverse Event:</td> <td>2 Years</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>Yes</td> </tr> <tr> <td>Adverse Event Abate After Product Stop:</td> <td>Yes</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> </table>	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:	Yes	Product Use Started Again:	No	Perceived Relatedness to Adverse Event:	Definitely related
	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:	Yes									
Product Use Started Again:	No										
Perceived Relatedness to Adverse Event:	Definitely related										
Manufacturer /Distributor Information:											
Purchase Location Information:											
Name: B6											
Animal Information:	Type Of Species: Dog										
	Type Of Breed: Boxer (German Boxer)										
	Gender: Male										
	Reproductive Status: Neutered										
	Age: 2 Years										
	Assessment of Prior Health: Excellent										
	Number of Animals Reacted: 2										
	Owner Information: <table border="1"> <tr> <td>Owner</td> <td>Yes</td> </tr> </table>	Owner	Yes								
Owner	Yes										

	Information provided:	
	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:	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-384202					
ICSR:	2065319				
Type Of Submission:	Initial				
Report Version:	FPSR.FDA.PETF.V.V1				
Type Of Report:	Both				
Reporting Type:	Voluntary				
Report Submission Date:	2019-04-04 18:44:45 EDT				
Reporter is the Animal Owner:	Yes				
Reported Problem:	Problem Description: [B6] yellow Labrador retriever, born [B6] passed away [B6] Cancer and heart condition at end. When [B6] was two or three, he was hospitalized with a severe inner ear infection. To keep his ears clean, [B6] [B6] place him on a grain free diet, which he remained on the rest of his life. At age 6, 11/27/16, diagnosed with enlarged heart. Dr. [B6] said it was rare for the breed. Heart medicine rest of life. After his death, I saw the story about FDA linking grain free to enlarged hearts in Labradors. If his medical history can help others, please use.				
	Date Problem Started: 11/27/2016				
	Concurrent Medical Problem: Yes				
	Pre Existing Conditions: Prior to his death, [B6] was taking [B6] a heart medicine, since he was diagnosed with an enlarged heart on 11/27/2016.				
	Outcome to Date: Died Euthanized				
	Date of Death: [B6]				
Product Information:	Product Name: Grain free dog food. Various brand, Merrick, Blue, Nature's Recipe, Natural Balance, other. Purchased mainly at Petco, some at Giant. Mainly bags of dry food, some cans as well				
	Product Type: Pet Food				
	Lot Number:				
	Package Type: BAG				
	Purchase Date: 03/01/2019				
	Possess Unopened Product: No				
	Possess Opened Product: No				
	Storage Conditions: in pantry cabinet				
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>grain free dog food</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> </table>	Description:	grain free dog food	Perceived Relatedness to Adverse Event:	Probably related
	Description:	grain free dog food			
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: Intact				
	Weight: 116 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:	
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:	Other
Additional Documents:		

Report Details - EON-384409		
ICSR:	2065437	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-04-07 13:04:40 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: After approximately 1-2 years on grain-free diet (Fromm's Gold Coast weight management), dog was discovered to have dilated cardiomyopathy. After three months of intensive medication and change of diet, cardiomyopathy has been mostly reversed. Was only discovered because of need for surgery to remove foreign object from intestines. Otherwise, probably would not have been discovered and would likely have been a fatal condition for dog.	
	Date Problem Started: 01/05/2019	
	Date of Recovery: 03/27/2019	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: Fromms Gold Coast Weight Management	
	Product Type: Pet Food	
	Lot Number:	
	Product Use Information: Description: Daily food for dog. Only food dog was receiving.	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name:	
	Type Of Species: Dog	
	Type Of Breed: Hound - Norwegian (Elk Hound)	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 155 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: B6
Sender Information:	Name:	
	Address: B6 United States	
	Contact:	
	Reporter Wants to Yes	

	Remain Anonymous:	
	Reported to Other Parties:	None
Additional Documents:		

Report Details - EON-384612

ICSR:	2065603
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-04-09 18:54:02 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was just diagnosed with Dilated cardiomyopathy (DCM). She has been on a grain free dry pet food for years Acana Lamb & Apple. We have been unaware now of the link between DCM and grain free diets especially with large breed dogs or Golden Retrievers.
	Date Problem Started:	04/03/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Acana Lamb and Apple		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	2 kilogram		
	Purchase Date:	03/03/2016		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	in a plastic container for dog food		
	Product Use Information:	Description:	1-1/4 cups morning and evening	
		First Exposure Date:	07/04/2017	
		Last Exposure Date:	03/27/2019	
		Time Interval between Product Use and Adverse Event:	3 Years	
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		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: Address: <div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 2em; font-weight: bold;">B6</div> Canada
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; display: inline-block; font-weight: bold;">B6</div> Dog Retriever - Golden Female Neutered 80 Pound 8 Years Excellent 1 1 Healthcare Professional Information: Practice Name: Contact: Name: Phone: Address: <div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 2em; font-weight: bold;">B6</div> Canada Type of Veterinarian: Primary/regular veterinarian Date First Seen: 04/03/2019 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:	<div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 3em; font-weight: bold;">B6</div> Canada Phone: Email: <div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 2em; font-weight: bold;">B6</div> No Yes Email Store/Place of Purchase
Additional Documents:	Attachment: Description:	<div style="border: 1px dashed black; padding: 2px; display: inline-block; font-weight: bold;">B6</div> echo-report.pdf Echo taken of <div style="border: 1px dashed black; padding: 2px; display: inline-block; font-weight: bold;">B6</div> heart

Report Details - EON-361685		
ICSR:	2053474	
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 15:53:05 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: My dog developed an enlarged heart.	
	Date Problem Started: 12/30/2017	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6	
	Outcome to Date: Worse/Declining/Deteriorating	
Product Information:	Product Name: Wellness CORE Grain-Free Reduced Fat Turkey & Chicken Recipe Dry Dog Food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 26 Pound	
	Purchase Date: 05/17/2018	
	Possess Unopened Product: No	
	Possess Opened Product: Yes	
	Storage Conditions: in a pet food storage container (kept in bag)	
	Product Use Information:	Description: eaten
		Last Exposure Date: 07/24/2018
		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: Yes
Manufacturer /Distributor Information:		
Purchase Location Information:	Name: Amazon	
	Address: United States	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Mixed (Dog)	
	Gender: Female	

	Reproductive Status: Neutered
	Weight: 45 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:
	Type of Veterinarian: Primary/regular veterinarian
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-364393

ICSR: 2054669
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: 2018-09-06 06:08:59 EDT

Reported Problem:
Problem Description: B6 a 6 year old 100 lb German Shepherd, presented to our clinic on B6 for a routine spay that was to be subsidized by a charitable organization. Due to these circumstances, no preop lab work or imaging was done, but the owner stated that she had been in good health. Preop physical exam by me did not reveal any abnormalities that were concerning for general anesthesia. Shortly after induction and before monitors could be hooked up, B6 became cyanotic and stopped breathing. CPR was administered but she did not respond. Upon questioning, the owner stated that perhaps she had been a little depressed lately, but they attributed this to B6's grief over the recent death of their older dog. Additionally, when asked about her diet, they stated that she had been fed exclusively a grain-free diet for at least the past two years.
Date Problem Started: B6
Concurrent Medical Problem: Unknown
Outcome to Date: Died Other
Date of Death: B6

Product Information:
Product Name: Kirkland Salmon and sweet potato 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: Shepherd Dog - German
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Not Pregnant
Lactation Status: Unknown
Weight: 100 Pound
Age: 6 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
Email: B6
Address:

B6

United States

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-363881		
ICSR:	2054487	
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 14:28:14 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Low taurine levels in whole blood and plasma	
	Date Problem Started: 08/21/2018	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6	
	Outcome to Date: Not Applicable	
Product Information:	Product Name: Taste of the Wold High Prairie	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Storage Conditions: NA	
	Product Use Information:	Description: Fed twice a day
		First Exposure Date: 01/11/2012
		Last Exposure Date: 08/21/2018
		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: 62 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:	
	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-361322

ICSR:	2053224		
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:	2018-08-03 19:43:56 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Took our pet to the vet today because she seems generally more lethargic and experiences difficulties after her daily exercise. Increased panting from which it takes a long time (at least 1/2 hr or more) to recover. An xray revealed an enlarged heart. While researching this I discovered your article linking grainfree dog food with heart disease. Our dog has been eating Kirkland Signature Nature's Domain Organic Chicken & Pea Formula for Dogs (USDA Organic. Grain Free) exclusively since she was eight weeks old.	
	Date Problem Started:	08/03/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Unknown	
Product Information:	Product Name:	Kirkland Signature Nature's Domain Organic Chicken & Pea Formula for Dogs USDA Organic. Grain Free.	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	9661903317	
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	07/31/2018	
	Number Purchased:	1	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	Yes	
	Storage Conditions:	In plastic container	
	Product Use Information:	Description:	1-1/2 -2 cups twice daily
		First Exposure Date:	07/31/2018
		Last Exposure Date:	08/03/2018
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 to the Animal During This Time Period:		No	
Manufacturer			

	/Distributor Information:	<table border="1"> <tr> <td data-bbox="672 116 889 153">Purchase Location Information:</td> <td data-bbox="889 116 1544 153">Name: Costco</td> </tr> <tr> <td data-bbox="672 153 889 319">Address:</td> <td data-bbox="889 153 1544 319"> <div style="border: 1px dashed black; padding: 5px; text-align: center;"> B6 </div> United States </td> </tr> </table>	Purchase Location Information:	Name: Costco	Address:	<div style="border: 1px dashed black; padding: 5px; text-align: center;"> B6 </div> United States
Purchase Location Information:	Name: Costco					
Address:	<div style="border: 1px dashed black; padding: 5px; text-align: center;"> B6 </div> United States					
Animal Information:	Name: B6 Type Of Species: Dog Type Of Breed: Retriever - Golden Gender: Female Reproductive Status: Neutered Weight: 81 Pound Age: 4 Years Assessment of Prior Health: Good Number of Animals Given the Product: 2 Number of Animals Reacted: 1 Owner Information:	<table border="1"> <tr> <td data-bbox="672 325 889 836">Healthcare Professional Information:</td> <td data-bbox="889 325 1544 836"> 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 </td> </tr> </table>	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		
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: Contact: Phone: Permission To Contact Sender: Yes Preferred Method Of Contact: Email Reported to Other Parties: None	<div style="border: 1px dashed black; padding: 5px; text-align: center;"> B6 </div> United States <div style="border: 1px dashed black; padding: 5px; text-align: center;"> B6 </div>				
Additional Documents:						

Report Details - EON-361325		
ICSR:	2053225	
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:	2018-08-03 21:10:49 EDT	
Reported Problem:	Problem Description: Heart enlargement noted on chest x-rays without evidence of heart failure. Echocardiogram on 8/3/18 consistent with a dilated cardiomyopathy phenotype.	
	Date Problem Started: 08/03/2018	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6	
	Outcome to Date: Unknown	
Product Information:	Product Name: Zignature Kangaroo Formula	
	Product Type: Pet Food	
	Lot Number:	
	UPC: unavailable	
	Package Type: BAG	
	Package Size: 1	
	Purchase Date: 07/03/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Unknown	
	Product Use Information:	Description: Fed as main diet for > 1 year due to severe food allergies
		First Exposure Date: 08/03/2018
		Last Exposure Date: 08/03/2018
		Time Interval between Product Use and Adverse Event: 1 Years
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: No		
Manufacturer /Distributor Information:		
Purchase Location Information: Name: Unknown		
Animal Information:	Name: B6	
	Type Of Species: Dog	

	Type Of Breed:	Mixed (Dog)
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	31.2 Kilogram
	Age:	4 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	3
	Number of Animals Reacted:	3
	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:	Email
	Reported to Other Parties:	None
Additional Documents:		

Report Details - EON-361512

ICSR: 2053331
 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 16:23:03 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: She passed out in our kitchen and was taken to the emergency pet hospital **B6** where she was diagnosed with Cardio Myopathy. She was put on a course of meds, but ultimately she did not improve and had to be euthanized. She was fed California Naturals Grain Free Salmon Meal and Peas to help reduce her skin allergies.
Date Problem Started: 07/25/2016
Concurrent Medical Problem: Yes
Pre Existing Conditions: Skin allergies
Outcome to Date: Died Euthanized
Date of Death: **B6**

Product Information:
Product Name: California Naturals Salmon Meal and Peas
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 13 Pound
Purchase Date: 06/15/2016
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: Air tight plastic bin
Product Use Information:
Description: Fed twice a day. Total of 2 cups per day of the dry kibble
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 to the Animal During This Time Period: No
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:	55 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:			
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-359321										
ICSR:	2052106									
Type Of Submission:	Initial									
Report Version:	FPSR.FDA.PETF.V.V1									
Type Of Report:	Both									
Reporting Type:	Voluntary									
Report Submission Date:	2018-07-16 09:42:29 EDT									
Reporter is the Animal Owner:	Yes									
Reported Problem:	Problem Description: B6 was diagnosed with Congestive Heart Failure and Dilated Cardiomyopathy (DCM) and low Taurine. The Cardiologist believes this was caused by his food. He uses Zignature Kangaroo. He is currently stable, but we do not know if he will die from the condition in less than a year or if it will be reversed. We were told that we should know more in September when we go back for a follow up.									
	Date Problem Started: 05/14/2018									
	Date of Recovery: 07/16/2018									
	Concurrent Medical Problem: Yes									
	Pre Existing Conditions: B6									
	Outcome to Date: Stable									
Product Information:	Product Name: Zignature Kangaroo									
	Product Type: Pet Food									
	Lot Number:									
	UPC: Multiple									
	Package Type: BAG									
	Package Size: 27 Pound									
	Possess Unopened Product: No									
	Possess Opened Product: No									
	Storage Conditions: In sealed bag and then in sealed pet food container									
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>Daily feeding</td> </tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>1 Years</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:	Daily feeding	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:
Description:	Daily feeding									
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 Information:	Name: Multiple									
	Address: United States									
Animal Information:	Name: B6									

	Type Of Species: Dog
	Type Of Breed: Bulldog - French
	Gender: Male
	Reproductive Status: Neutered
	Weight: 33 Pound
	Age: 5 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 6
	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: 05/15/2018
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-360773

ICSR:	2052883
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:	2018-07-29 20:08:27 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dog [B6] was 3 years old when we adopted her. Upon adoption, we noticed she had consistently loose stool. With the help of our vet, we determined that grain free food (Blue Wilderness Salmon Grain Free recipe). She was on this food for ~5 years with periods of controlled and mixed stools. In January 2017, when her stool was particularly loose, upon recommendation from our vet we switched to Dr Gary's Grain Free Salmon recipe. In July we were at the vet for lethargy and coughing and by [B6] we were in the emergency room to be linked to a cardiologist to learn that [B6] had DCM. Thankfully, though L-Carnatine and [B6] she is stable. However, upon reading the FDA report where peas, legumes dog food diets were linked to DCM, I wanted to report our case. I am more than willing to provide whatever vet reports, food records, detailed health records to help link grain free diets to DCM. Please do not hesitate to contact me. Note --- we have 2 dogs [B6] is 2 years old and to the best of my knowledge healthy and on the same food). Effectively immediately, I have switched to homemade food.
	Date Problem Started:	08/05/2017
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	My dog [B6] was 3 years old when we adopted her. Upon adoption, we noticed she had consistently loose stool. With the help of our vet, we determined that grain free food (Blue Wilderness Salmon Grain Free recipe). She was on this food for ~5 years with periods of controlled and mixed stools. In January 2017, when her stool was particularly loose, upon recommendation from our vet we switched to Dr Gary's Grain Free Salmon recipe. In July we were at the vet for lethargy and coughing and by [B6] we were in the emergency room to be linked to a cardiologist to learn that [B6] had DCM. Thankfully, though L-Carnatine and [B6] she is stable. However, upon reading the FDA report where peas, legumes dog food diets were linked to DCM, I wanted to report our case. I am more than willing to provide whatever vet reports, food records, detailed health records to help link grain free diets to DCM. Please do not hesitate to contact me. Note --- we have 2 dogs [B6] is 2 years old and to the best of my knowledge healthy and on the same food). Effectively immediately, I have switched to homemade food.
	Outcome to Date:	Stable

Product Information:	Product Name:	Abound Grain free Turkey, pea, berry jerky recipe
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	12 Ounce
	Number Purchased:	6
	Possess Unopened Product:	Yes
	Possess Opened Product:	Yes
	Storage Conditions:	in sealed packaging it was sold in
	Product Use Information:	Description: Daily treat, 2 pieces
	First Exposure Date: 01/01/2017	
	Last Exposure Date: 07/29/2018	

	Time Interval between Product Use and Adverse Event:	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:	Yes
Manufacturer /Distributor Information:		
Purchase Location Information:	Name:	Kroger
	Address:	United States
Product Name:	Dr. Gary's Best Breed Holistic Grain-Free Salmon with Fruits & Vegetables Dry Dog Food	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Package Size:	30 Pound	
Number Purchased:	2	
Possess Unopened Product:	Yes	
Possess Opened Product:	No	
Storage Conditions:	Sealed plastic container	
Product Use Information:	Description:	3 cups daily. We started this food in January, 2017 and gave until I read the FDA article today
	First Exposure Date:	01/01/2017
	Last Exposure Date:	07/29/2018
	Time Interval between Product Use and Adverse Event:	18 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:	Chewy.com
	Address:	United States

Product Name:	Blue Buffalo Wilderness Salmon Recipe Grain-Free Dry Dog Food	
Product Type:	Pet Food	
Lot Number:		
UPC:	several years	
Package Type:	BAG	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Storage Conditions:	Stored in sealed plastic container	
Product Use Information:	Description:	This was the dog food that I fed my dog for ~5 years. 3 cups of food a day.
	First Exposure Date:	01/24/2012
	Last Exposure Date:	01/01/2017
	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:	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:	Name:	Several pet stores
	Address:	United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Labrador
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	62 Pound
	Age:	9 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1
Owner Information:		
Healthcare Professional	Practice Name:	B6

Information:	Contact: Name:	B6
	Phone:	
	Address:	B6
		United States
	Type of Veterinarian:	Referred veterinarian
	Date First Seen:	07/05/2017
	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:	03/20/2017
	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:	07/07/2017	
Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	
	Address:	B6
		United States
	Contact: Phone:	
	Email:	B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	Other Store/Place of Purchase
Additional Documents:		

Attachment:	B6 1.JPG
Description:	Vet diagnosis of DCM
Type:	Medical Records
Attachment:	B6 5.JPG
Description:	Vet Report
Type:	Medical Records
Attachment:	B6 2.JPG
Description:	Vet report
Type:	Medical Records
Attachment:	B6 4.JPG
Description:	Vet Report
Type:	Medical Records
Attachment:	B6 .JPG
Description:	Vet report
Type:	Medical Records

Report Details - EON-366538

ICSR: 2055230
 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: 2018-09-23 09:46:15 EDT

Reported Problem:

Problem Description: Patient presented for increased respiratory rate over the past month. Chest X-rays showed evidence of left and right-sided heart failure. Patient was started on [B6] and condition has remained stable. Owners declined echocardiogram at this time. Patient has been eating a grain-free diet for the last 2 years.

Date Problem Started: 09/08/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: [B6] diagnosed in 2015

Outcome to Date: Stable

Product Information:

Product Name: Canidae Natural Pet Food Company (Owner fed a variety of their grain-free formulas)

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: Unknown

Product Use Information:

Description: Product was fed to both dogs in the household exclusively for the past 2 years.

First Exposure Date: 09/01/2016

Last Exposure Date: 09/08/2018

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: Not Applicable

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:	Address:	B6
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Sheepdog - Shetland	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	60 Pound	
	Age:	8 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	2	
	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:	Manufacturer	
Additional Documents:			

Report Details - EON-365010

ICSR:	2054853
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-09-12 00:56:27 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was recently diagnosed with Dilated Cardiomyopathy. This is not a known problem in this breed and the food he is on is one that has been mentioned frequently in relation to taurine deficiency issues and dogs with DCM.
	Date Problem Started:	08/28/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Zignature Kangaroo		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	Not available		
	Package Type:	BAG		
	Package Size:	26 Pound		
	Purchase Date:	07/01/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	The food was stored in my kitchen in an airtight container		
	Product Use Information:	Description:	This wa	B6 Daily kibble given twice a day
		First Exposure Date:	07/08/2018	
		Last Exposure Date:	08/27/2018	
		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:		Probably related		
Other Foods or Products Given to the Animal During This Time Period:		Yes		
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	Various pet food stores in	B6	
	Address:	Canada		

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Terrier - Black Russian		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	102 Pound		
	Age:	5.5 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:	
			Email:	
		Address:	B6	
			Canada	
		Type of Veterinarian:	Primary/regular veterinarian	
		Date First Seen:	08/18/2018	
		Permission to Release Records to FDA:	Yes	
		Practice Name:	B6	
Contact:		Name:	B6	
		Phone:		
		Email:		
Address:		B6		
		Canada		
Type of Veterinarian:	Referred veterinarian			
Date First Seen:	08/27/2018			
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6		
	Address:	B6		
		Canada		
	Contact:	Phone:	B6	
		Email:		
	Reporter Wants to Remain Anonymous:	No		
Permission To Contact Sender:	Yes			
Preferred Method Of	Email			

	Contact:	
	Reported to Other Parties:	Other
Additional Documents:		

Report Details - EON-364891	
ICSR:	2054815
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:	2018-09-11 09:12:22 EDT
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: My dog has been on a grain free diet for 2-3 years and has previously never had any issues. She was first diagnosed with a heart murmur 2 years ago and now after further looking into it in the past several months we have confirmed it is Dilated Cardiomyopathy. Her breed is not prone to this disease, and otherwise she is in perfect health. I have had numerous treatments and diagnostic tests to treat her DCM.
	Date Problem Started: 05/17/2018
	Date of Recovery: 08/09/2018
	Concurrent Medical Problem: No
	Outcome to Date: Stable
Product Information:	Product Name: Blue Buffalo wilderness - natures evolutionary diet - with chicken and lifsource bits - 100% grain free
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Package Size: 24 Pound
	Number Purchased: 1
	Possess Unopened Product: No
	Possess Opened Product: No
	Storage Conditions: The product was stored in a dog food container after opening. Before it was stored in the original bag in the my kitchen.
	Product Use Information:
First Exposure Date: 04/02/2017	
Last Exposure Date: 05/15/2018	
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: No	
Product Use Started Again: 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:

Name: chewy.com

Address: B6
United States

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Shepherd Dog - Australian

Gender: Female

Reproductive Status: Neutered

Weight: 41 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:

Phone: B6

Email:

Address:

B6

United States

Type of
Veterinarian: Primary/regular veterinarian

Date First Seen: 05/11/2018

Permission to
Release Records
to FDA: Yes

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: None

Additional Documents:

Attachment:	B6 Hx.pdf
Description:	s medical history from the Veterinarian which include - medical charts, medications, echocardiogram reports, and blood and urine work up.
Type:	Medical Records

Report Details - EON-364885

ICSR: 2054811
 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: 2018-09-11 06:22:10 EDT

Reported Problem:
Problem Description: Submitted as RFR EON-364866. FDA resubmitting as PFR. Pit Bull diagnosed with DCM via echocardiogram and has been eating a grain free diet his entire life.
Date Problem Started: 07/10/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Unknown

Product Information:
Product Name: Kirkland signature Natures Domain Saslmon meal and sweet pototoe
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 35 Pound
Possess Unopened Product: Unknown
Possess Opened Product: Unknown
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information: Name: Costco
 Address: **B6**
 United States

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: Pit Bull
Gender: Male
Reproductive Status: Neutered
Weight: 71 Pound
Age: 9 Years
Assessment of Prior Health: Unknown
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	
	Type of Veterinarian:	Referred veterinarian	
Date First Seen:	07/10/2018		
Permission to Release Records to FDA:	Yes		
Sender Information:	Name:	B6	
	Contact:		B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:	Attachment:	RFR EON-364866 - MRx attachments.pdf	
	Description:	Attachments from EON-364866	
	Type:	Medical Records	

Report Details - EON-363608

ICSR:	2054375
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 16:59:25 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 has eaten Acana Singles Duck and Bartlett Pear (with an occasional one-bag change to Acana Singles Lamb & Apple or Acana Singles Pork and Squash or Acana Singles Mackerel & Greens) since he was approximately 2 years old. Shortly after turning 5 years old, I noticed he was lagging behind on walks. x-rays showed a severely enlarged heart (twice normal size) and echo showed DCM. B6 has been taking B6 twice a day since diagnosis on March 21, 2017. I then saw the July 2018 reports of Acana being tied to taurine deficiency. I had B6 tested and his taurine levels are critically low (B6 whole blood test).
	Date Problem Started:	03/01/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Acana Singles Duck & Bartlett Pear	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	08/14/2018	
	Number Purchased:	2	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	The product was stored in the garage for no more than 2 weeks before being opened. Once opened, the product was placed into a plastic bin that sits on top of the dog kennel in an air conditioned room.	
	Product Use Information:	Description:	B6 eats a heaping cup of Acana Singles twice a day
		Last Exposure Date:	08/28/2018
		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:	B6		
		Address:			United States
Animal Information:	Name:	B6			
	Type Of Species:	Dog			
	Type Of Breed:	Retriever - Labrador			
	Gender:	Male			
	Reproductive Status:	Neutered			
	Weight:	74 Pound			
	Age:	6 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:	B6	
		Address:	B6		
			United States		
		Type of Veterinarian:	Primary/regular veterinarian		
		Date First Seen:	03/20/2017		
		Permission to Release Records to FDA:	Yes		
		Practice Name:	B6		
		Contact:	Name:	B6	
			Phone:	B6	
		Address:	B6		
			United States		
		Type of Veterinarian:	Referred veterinarian		
		Date First Seen:	03/21/2017		
		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-362411			
ICSR:	2053786		
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 22:26:04 EDT		
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:	Stable	
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 Product:	No		
Possess Opened Product:	No		
Product Use Information:	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:	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

	Product:															
	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
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Practice Name:	B6															
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Name:	B6															
Phone:																
Email:																
Address:	<table border="1"> <tr> <td>B6</td> </tr> </table>	B6														
B6																

			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:	B6
		Email:	B6
	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:	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:	Other	
Additional Documents:	Attachment:	B6	records.pdf
	Description:	Medical records from	B6
	Type:	Medical Records	

Report Details - EON-383581

ICSR:	2064839
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:	2019-03-28 11:47:06 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	developed cough which quickly became cardiomyopathy
	Date Problem Started:	10/07/2017
	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 Pacific Stream		
	Product Type:	Pet Food		
	Lot Number:			
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in the original bag with a personal use clip to keep the bag closed after opening.		
	Product Use Information:	Description:	Dog free fed daily	
		Time Interval between Product Use and Adverse Event:	11 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:	Tractor Supply		
	Address:	United States		

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Sheepdog - Shetland
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	23 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:	
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:	None	
Additional Documents:		

Report Details - EON-384609

ICSR:	2065601
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-04-09 18:27:47 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	He has been eating grain free diet, diagnosed with CHF DCM last week.	
	Date Problem Started:	03/28/2019	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Unknown	

Product Information:	Product Name:	Natural Balance Limited Ingredient Diet		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	8310804052257	
		Expiration Date:	01/01/2020	
	UPC:	723633420747		
	Package Type:	BAG		
	Package Size:	13 Pound		
	Purchase Date:	03/03/2019		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	I store it in the package it came in.		
	Product Use Information:	Description:	my dog ate it	
		First Exposure Date:	03/03/2019	
		Last Exposure Date:	04/09/2019	
		Time Interval between Product Use and Adverse Event:	7 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:		Probably related		
Other Foods or Products Given to the Animal During This Time Period:		Yes		

Manufacturer /Distributor Information:	Name:	Dick Van Patten's Natural Balance	
	Type(s):	Manufacturer	
	Address:	United States	
	Contact:	Phone: 1-800-829-4493	
	Possess One or More Labels from This Product:	Yes	
Purchase Location Information:	Name:	Petco	
	Address:	B6 United States	
Animal Information:	Name:	B6 black labrador	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Labrador	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	123 Pound	
	Age:	8 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 Other Phone: B6 Email: B6
		Address:	B6 United States
Type of Veterinarian:		Primary/regular veterinarian	
Date First Seen:		04/08/2019	
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	No	

	Remain Anonymous:	
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Manufacturer

Additional Documents:

Report Details - EON-359269

ICSR:	2052029
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 14:11:47 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Sudden onset of DCM (Dilated Cardiomyopathy). B6 was being fed Signature Kangaroo dry kibble for a good part of her life and up to her death. She didn't eat breakfast one day and had been panting on walks, which were shortened due to this panting. The Vet just thought it was the summer humidity, and heat. She had no heart murmur. I took her in to the Vet for observation in the morning, and Vet called late afternoon saying she had an enlarged heart, and recommended we take her to the Emergency Vet Hospital where they had better testing facilities. We did around 4 pm that day, and B6 was gone by the same time next day due to DCM.
	Date Problem Started:	B6
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Zignature Kangaroo Formula Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	Not Available	
	Package Type:	BAG	
	Package Size:	27 Pound	
	Purchase Date:	10/10/2015	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In a Pet Food Storage Container	
	Product Use Information:	Description:	Was used right out of bag as instructed.
		First Exposure Date:	10/17/2015
		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 Relatedness to		Probably related	

		Adverse Event:	
		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 - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	73 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:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	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	Yes

to FDA:

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:

Attachment: Her Last Medical.pdf

Description: Her Vet Clinic Medical Test on day she passed.

Type: Record

Attachment: **B6** Video Tribute.docx

Description: This is **B6** in a Video Tribute I did after she passed. **B6**

B6

Type: Photograph

Report Details - EON-378037		
ICSR:	2061913	
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 08:14:54 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Dog went into congestive heart failure on 09/05/2018. X-rays and PROBNP inconclusive. Ultrasound showed DCM. Dog is now being treated. Dog was fed Zignature Kangaroo exclusively for at least a year. Was fed Acana Duck and Pear prior to that. Cardiologist confirmed DCM.	
	Date Problem Started: 09/05/2018	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: Dog had been coughing - we had put him on an antibiotic and cough medicine to help him. Had an x-ray 2 weeks prior to the dog going into CHF. X-ray was inconclusive although showed an enlarged heart. PROBNP came back good.	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: Zignature Kangaroo Formula Limited Ingredient Formula	
	Product Type: Pet Food	
	Lot Number: Lot Number: 8C27P 1905 3	
	Expiration Date: 09/25/2019	
	UPC: 88641 13132	
	Package Type: BAG	
	Package Size: 27 Pound	
	Purchase Date: 08/01/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: Yes	
	Storage Conditions: Before it was opened, it was stored in the bag on a shelf in the basement. After opened it was stored in a Vittle Vault.	
	Product Use Information:	Description: I fed it to the dog 2x a day. Approximately 2 cups each time.
		First Exposure Date: 08/03/2018
		Last Exposure Date: 09/05/2018
Time Interval between Product Use and Adverse Event: 1 Months		
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: Yes		

	Manufacturer /Distributor Information:	Name:	Pets Global, Inc	
		Type(s):	Manufacturer	
		Address:	28334 Industry Drive Valencia California 91355 United States	
		Contact:	Phone: 1-888-897-7207 Web Address: www.zignature.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:	Akita		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	86 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	
Other Phone:				
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:	09/05/2018			
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:			
	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:

Report Details - EON-378020			
ICSR:	2061897		
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 19:56:25 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	During a routine physical exam, it was discovered that my pet has moderate reduced heart function. We conducted a brief echo at the veterinarian and were referred to a veterinary cardiologist who confirmed the diagnosis and recommended we change her food.	
	Date Problem Started:	01/05/2019	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Unknown	
Product Information:	Product Name:	Kirkland Nature's Domain Salmon and Sweet Potato	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	35 Pound	
	Purchase Date:	01/02/2019	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	The product was placed into a clean, empty, airtight plastic tub designed specifically for storing dog food and sold at pet stores.	
	Product Use Information:	Description:	This dog food had been fed to two of my pets continually for the last 18-24 months. I had also just begun to switch my third dog (17 months old) from Kirkland brand puppy food to this food as well. Then one of my dogs was diagnosed with DCM likely related to the food we had been feeding her. I switched all dogs over to a different brand of food.
		Last Exposure Date:	01/16/2019
		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:		Definitely related	
Other Foods or Products Given to the Animal		Yes	

		During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Costco
		Address:	B6
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog - American	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	65 Pound	
	Age:	6 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:	
		Email:	
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	01/05/2019
		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:	01/09/2019
		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	69.pdf
	Description:	Discharge information from specialist noting likely nutrition cause DCM and recommendation to switch foods.	
	Type:	Echocardiogram	

Report Details - EON-383217

ICSR:	2064472
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:	2019-03-24 21:36:22 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	We've been feeding [B6] Six-fish Orijen (purchased at our local vet clinic, [B6] vet services) since puppy-hood. Recently our vet detected heart noise which led to a cardiac ultrasound and a diagnoses of DCM (in a breed that is not genetically disposed to DCM). Difficult to pick a "Date problem started", this has clearly been a developing issue over months so I picked a date somewhat at random. We are in the process of further bloodwork and testing, change of diet (to Royal Canin cardiac diet) and meds and supplementation as recommended by the vet cardiologist. March 24 update: [B6] blood taurine levels are normal.
	Date Problem Started:	02/02/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	Six Fish Orijen	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In a sealed bag at room temperature.	
	Product Use Information:	Description:	This was our dog's diet, 1 cup two times a day, for years - since puppyhood.
		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:	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]	
		Canada	

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Brittany
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	39 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
		Canada
	Contact:	B6
	Phone:	
	Email:	
	Permission To Contact Sender:	Yes
Preferred Method Of Contact:	Email	
Reported to Other Parties:	None	
Additional Documents:		

Report Details - EON-383287	
ICSR:	2064520
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:	2019-03-25 14:11:11 EDT
Reported Problem:	Problem Description: Patient presented to another animal hospital ~2 weeks ago with acute onset of coughing. Pet was treated for "kennel cough", cough resolved, then reoccurred. She presented to our hospital for assessment on 3/21/19.
	Date Problem Started: 03/21/2019
	Concurrent Medical Problem: Yes
	Pre Existing Conditions: B6
	Outcome to Date: Better/Improved/Recovering
Product Information:	Product Name: Four Health
	Product Type: Pet Food
	Lot Number:
	Product Use Information: Description: Patient was switched to Four Health brand (unknown type) two months prior to being seen for symptoms of DCM.
	Manufacturer /Distributor Information:
	Purchase Location Information:
	Product Name: Holistic Select Adult Health Lamb Meal Recipe
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Product Use Information: Description: Patient was fed this food several years before switching to Four Health pet food two months before symptoms began
	Manufacturer /Distributor Information:
	Purchase Location Information:
	Animal Information:
Type Of Species: Dog	
Type Of Breed: Mixed (Dog)	
Gender: Female	
Reproductive Status: Neutered	
Weight: 47.4 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:	

		Address: B6 United States
Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6 Phone: Email:
	Address:	B6 United States
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 ultrasound report.jpg
	Description:	Telemedicine report from B6 Imaging Services for B6 echocardiogram on 3/22/2019
	Type:	Laboratory Report
	Attachment:	1.2.840.114387.3035446363.33448.16721.36371.141015575653105.jpg
	Description:	V/D Thoracic Radiograph taken 3/22/2019
	Type:	Radiographs
	Attachment:	1.2.840.114387.1741247097.32798.16918.37672.148704924972713.jpg
	Description:	Lateral Right Thoracic Radiograph taken 3/22/2019
	Type:	Radiographs

Report Details - EON-362992

ICSR:	2054045			
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:	2018-08-21 19:47:37 EDT			
Reporter is the Animal Owner:	Yes			
Reported Problem:	Problem Description:	Blood plasma test result was B6 from blood draw on 8/13/18. B6 has been eating Fromm's Lamb & Lentil for approximately 14 months. Scheduled to have echocardiogram on 8/28/18 to verify heart condition.		
	Date Problem Started:	08/13/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Unknown		
Product Information:	Product Name:	Fromm 4-Star Lamb & Lentil Recipe Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	26 Pound		
	Product Use Information:	First Exposure Date:	06/16/2017	
		Last Exposure Date:	08/21/2018	
		Time Interval between Product Use and Adverse Event:	14 Months	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Unknown	
		Product Use Started Again:	No	
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:		No		
Manufacturer /Distributor Information:				
Purchase Location Information:				
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Other Canine/dog		
	Gender:	Male		
	Reproductive Status:	Neutered		

	Weight:	70 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:
	Address:	B6
		United States
	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
	Reported to Other Parties:	Other
Additional Documents:		

Report Details - EON-364639

ICSR:	2054765
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:	2018-09-08 15:52:11 EDT

Reported Problem:	Problem Description:	Patient has developed severe dilated cardiomyopathy with evidence of both left and right sided congestive heart failure.
	Date Problem Started:	08/06/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Pure Balance Wild and Free Superfood Blend Trout and Lentil Recipe		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	DL81101 18.22	
		Expiration Date:	06/22/2019	
	UPC:	8113112387		
	Package Type:	BAG		
	Package Size:	24 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	Uncertain		
	Product Use Information:	Description:	Fed daily a minimum of 6 months	
		First Exposure Date:	01/01/2018	
		Last Exposure Date:	08/12/2018	
		Time Interval between Product Use and Adverse Event:	8 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:		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:	Catahoula Leopard Dog	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	27.4 Kilogram	
	Age:	2 Years	
	Assessment of Prior Health:	Fair	
	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	
		Email: B6	
Address:	B6		
	United States		
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact:	Phone: B6	
		Email: B6	
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email		
Reported to Other Parties:	Other		
Additional Documents:	Attachment:	IMG_5297.JPG	
	Description:	food bag	
	Type:	Photograph	

Attachment:	IMG_5295.JPG
Description:	food bag
Type:	Product Label
Attachment:	IMG_5293.JPG
Description:	food bag
Type:	Product Label
Attachment:	IMG_5298.JPG
Description:	food bag
Type:	Product Label
Attachment:	IMG_5296.JPG
Description:	food bag
Type:	Product Label

Report Details - EON-359970

ICSR:	2052529		
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:	2018-07-21 15:27:09 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	February 6th, 2018 - Dr. B6 discovered a heart murmur (not heard prior) during routine visit. Referred to Cardiologist. February 12, 2018 - Dr. B6 performed an echocardiogram and Taurine blood test. B6 was diagnosed with Dilated Cardiomyopathy. Taurine level: B6	
	Date Problem Started:	02/06/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Stable	
Product Information:	Product Name:	ZIGNATURE LAMB FORMULA	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	8 88641 13105 1	
	Package Type:	BAG	
	Package Size:	27 Pound	
	Purchase Date:	01/25/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	STORED IN AN AIRTIGHT PLASTIC TUPPERWARE TYPE OF CONTAINER	
	Product Use Information:	Description:	DATE PRODUCT (ZIGNATURE LAMB) WAS FIRST GIVEN: JUNE 2015 LAST DATE FED THIS PRODUCT FEBRUARY 12, 2018 (THE DAY DIAGNOSED WITH DCM) ONE AND A HALF CUPS TWICE A DAY -
		Time Interval between Product Use and Adverse Event:	5 Weeks
		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:		Unrelated	
Other Foods or Products Given		Yes	

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: Retriever - Golden

Gender: Male

Reproductive Status: Intact

Weight: 80 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:

Practice Name:

B6

Contact:

Name:

Phone:

Other Phone:

Email:

B6

Address:

B6

United States

Type of
Veterinarian: Primary/regular veterinarian

Date First Seen: 02/06/2018

Permission to
Release Records
to FDA: Yes

Practice Name:

B6

Contact:

Name:

Phone:

Other Phone:

Email:

B6

Address:

B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: 02/12/2018

Permission to
Release Records
to FDA: Yes

Release Records to FDA:	
Practice Name:	B6
Contact:	Name: B6
	Phone: B6
	Other Phone: B6
	Email: B6
Address:	B6
	United States
Type of Veterinarian:	Referred veterinarian
Date First Seen:	03/05/2018
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:	Phone
Reported to Other Parties:	Manufacturer Store/Place of Purchase

Additional Documents:

Attachment:	B6	2nd Echocardiogram.pdf
Description:	May 14,2018 Evaluation and follow up Echocardiogram	
Type:	Echocardiogram	
Attachment:	B6	Cardiologist SummaryEcho.pdf
Description:	Evaluation and Echocardiogram - Dr. B6	February 12, 2018
Type:	Echocardiogram	
Attachment:	B6	Summary.pdf
Description:	Evaluation and second opinion completed by Dr. B6	B6
Type:	Analysis	

Report Details - EON-371510

ICSR: 2059066
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 10:17:26 EST

Reported Problem: **Problem Description:** **B6** had been fed a grain free diet for 3.5 years (Zignature lamb and rice low ingredient grain free diet). Diagnosed with dilated cardiomyopathy in Feb 2018. Taurine levels measured **B6** nmols/ml at that time. He was switched to Hill's ideal balance and started on **B6**. His condition, as determined by repeat echocardiography did not improve nor progress over the subsequent 3 months. No change in therapy was recommended, and taurine was rechecked in May 18 (**B6** nmols/ml) and July **B6** nmols/ml). After 6 months **B6** a very slight improvement was detected by echo. The dog never showed signs of congestive heart failure nor any arrhythmias during these evaluations. But on **B6** **B6** he died suddenly (fell over out of the blue, witnessed by the owners)-presumably due to a fatal ventricular arrhythmia, (ventricular fibrillation). Full post mortem pasted below: Patient name: **B6** Pet ID/Chart: **B6** CANINE 18-0284 Order requested by: **B6**
B6
Report Date: 10/24/2018 DOB: **B6** Surgical Pathology Clinical Pathology
B6
B6 Species: Breed: GOLDEN RETRIEVER Sex: Pathology Laboratory M Final Autopsy Report Internal Case history 3 year old M intact Golden retriever diagnosed with dilated cardiomyopathy on 2/12/18. Initial taurine levels were low normal at **B6** mmol/mL (200-350 is normal). At that time he had been eating a grainfree diet for 3 years. He was started on **B6** **B6** taurine supplementation, and carnitine supplementation. Diet was changed. Taurine level was rechecked on 5/7/18 and measured **B6** mmol/mL. Taurine level was checked again on 7/23/18 and measured **B6** mmol/mL. Recheck echocardiogram yesterday showed unchanged left ventricular and left atrial enlargement but improved systolic function. Historically asymptomatic. This AM, fell over and died suddenly. Gross Description This is a 36 kg 4-year-old intact male golden retriever dog in good postmortem and nutritional condition.
B6
This report continues... (Final) 1: **B6** Sample ID: 18-0284 - Patient: **B6** HEART: mild eccentric left and right ventricular eccentric hypertrophy with left atrial and biventricular chamber dilation SPLEEN: focal siderofibrotic plaque Histopathology HEART (LEFT VENTRICULAR FREE WALL (1, 2); INTERVENTRICULAR SEPTUM (3); RIGHT VENTRICULAR FREE

WALL (4): cardiomyopathy characterized by moderate multifocal to regionally extensive (right atrium) variation in cardiac myofiber size with undulating profiles (consistent with attenuated wavy fibers); mild (diffuse) to severe (left atrium) subendocardial fibrosis with regional mineralization (left atrial jet lesion); rare multifocal lymphohistiocytic myocardial infiltrates ATRIOVENTRICULAR VALVES (1, 4): mild (tricuspid) to severe (mitral) myxomatous valvular degeneration (endocardiosis) ASCENDING AORTA (3): mild focal subintimal fibrosis; mild focal medial arteriopathy with chondroid metaplasia PULMONARY VASCULATURE (5): prominent subpleural arteries; diffuse congestion with minimal multifocal acute alveolar hemorrhage and rare erythrophagocytosis; mild multifocal tunica medial hypertrophy LUNGS (5): moderate diffuse pulmonary edema with alveolar histiocytosis; mild subpleural fibrosis with multifocal chronic lymphohistiocytic pleuritis and mesothelial hypertrophy

B6

B6

B6

Final Diagnosis

CARDIOMYOPATHY CHARACTERIZED BY BIVENTRICULAR ECCENTRIC HYPERTROPHY WITH CHAMBER DILATION AND MODERATE REGIONALLY EXTENSIVE (RIGHT ATRIUM) ATTENUATED WAVY CARDIAC MYOFIBERS (FEATURES CONSISTENT WITH DILATED CARDIOMYOPATHY) MILD TO SEVERE VALVULAR ENDOCARDIOSIS WITH LEFT ATRIAL DILATION AND FOCAL JET LESION WITH MINERALIZATION

Comments Multiple sections from the heart are histologically examined. Myocardial changes are most profound within the right atrium, which demonstrates separation and occasional isolation of individual myofibers by clear space. There is a generalized tinctorial change and size variation of individual myofibers; myofibers are often thinned and elongate (<6-12 um diameter) with an undulating variably amphophilic profile. The clear space associated with attenuated fibers in the right heart may represent edema. Within the right ventricle, there are few foci of adipocyte deposition, however these areas lack associated myofiber degeneration. The left and right ventricular myocardium is rarely infiltrated by low numbers of lymphocytes and histiocytes. The endocardium is diffusely expanded by some degree of fibrosis; the left atrium most severely affected with spicules of mineral enmeshed in bundles of fibrous collagen. Given the clinical findings and histologic features, the cardiac changes are most compatible with attenuated wavy fiber type dilated cardiomyopathy (DCM). The cause of sudden death in this patient may be attributed to a fatal arrhythmia. Taurine deficiency has linked to DCM in golden retrievers. While the exact etiology is unclear, one study postulated that both genetics and nutrition are contributing factors. [Belanger MC, et al. "Taurine deficient dilated cardiomyopathy in a family of golden retrievers." J Am Anim Hosp Assoc (2005); 41:284-291.] The significance of the prominent arterial profiles within the visceral pleural/subpleural space is unknown. Photomicrographs have been submitted for consultation with a specialist in veterinary pulmonary pathology at: B6 These lesions are unrelated to the DCM and there is some histologic overlap with the condition of intrapulmonary sequestra described in people. Further consultation is pending and if further information becomes available an addendum will follow. Sections from multiple tissues are collected as directed for enrolled research study purposes. Additional formalin-fixed tissue samples and histologic sections are submitted to the FDA- EON 359970 c/o Drs. 18-0284 report status: This report continues... (Final) 2 B6 Diagnostic Lab - Sample ID: 18-0284 - Patient: B6 Jennifer Jones, Renate Reimschuessel and Rotstein. Signed by: B6 10/24/2018 @ 10:23 AM Signed by: B6 B6 10/24/2018 @ 10:40 AM 18

Date Problem Started: 02/07/2018

Concurrent Medical Problem: No

Outcome to Date: Died Naturally

Date of Death: B6

Product Information:

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

Product Type: Pet Food

Lot Number:

Package Type: BOX

Storage Conditions: n/a

Product Use Description: Fed as daily diet for 3 years

Information:	First Exposure Date:	01/01/2015		
	Last Exposure Date:	02/15/2018		
	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:	No		
Manufacturer /Distributor Information:				
Purchase Location Information:				
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	33.7 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:	B6
			Email:	B6
	Address:	B6		
United States				
Healthcare Professional Information:	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

Additional Documents:

Report Details - EON-384610

ICSR: 2065602
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-04-09 18:43:24 EDT

Reported Problem:

Problem Description: March 19th presented for gradual onset of lethargy/panting/decreased exercise tolerance. Exam: weak pulses, tachycardia. Labwork, thorax rads, ecg consistent with dilated cardiomyopathy. Submitted taurine levels to: B6 normal levels. Discontinued Taste of Wild diet and started oral taurine pending results /cardiologist consult. Scheduled exam with B6 cardiologist/echocardiogram, no rx started since not in CHF. Presented to an emergency center B6 dx with DCM via echo/cardiologist review and CHF. Started on oral B6 B6 clinically no improvement. B6 and concurred with dx, DCM/CHF, concerning for related to diet (Taste of the Wild High Praire (Bison /Venison) for number of years but past 9-12months has only been on the Taste of the Wild PREY Trout formula). Owner elected euthanasia and consented to necropsy/tissue sampling to aid in diagnosis.

Date Problem Started: 03/19/2019

Concurrent Medical Problem: No

Outcome to Date: Died Euthanized

Date of Death: B6

Product Information:

Product Name: Taste of the Wild PREY Trout formula

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Storage Conditions: in bag or sealed plastic container

Product Use Information:

Description: daily feeding (previous to 9-12 months ago was on Taste of the Wild High Praire (Bison/Venison) since owner acquired puppy)

First Exposure Date: 06/01/2018

Last Exposure Date: 03/19/2019

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: No

Product Use Started Again: 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**

Type Of Species: Dog

Type Of Breed: Retriever - Golden

Gender: Female

Reproductive Status: Neutered

Weight: 61 Pound

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**
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:

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

03/23/2019

		Date First Seen:	
		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:	None		
Additional Documents:	Attachment:	03.24.19	B6 Report - DCM B6 pdf
	Description:	B6	
	Type:	Medical Records	
	Attachment:	B6	EMR.pdf
	Description:	B6 cardiologist report	
	Type:	Medical Records	
	Attachment:	B6	EMR.pdf
	Description:	B6 medical records	
	Type:	Medical Records	

Report Details - EON-386113

ICSR: 2066298
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Adverse Event (a symptom, reaction or disease associated with the product)
 Reporting Type: Voluntary
 Report Submission Date: 2019-04-26 16:19:24 EDT

Reported Problem:

Problem Description: Presented to the **B6** for evaluation of tachypnea and lethargy on **B6** at 6:23 pm. On 4/8/2019, the owners heard him gagging, then progressed to panting and breathing heavily over the next **B6** hrs. On **B6** **B6** would not eat and ambulate, and was then brought to **B6** was in cardiogenic shock and needed rapid stabilization with mechanical ventilation. Owners elected humane euthanasia. Myocardial tissue samples were collected and frozen at -80, as well as placed in formalin for your analysis.

Date Problem Started: 04/08/2019

Concurrent Medical Problem: No

Outcome to Date: Died Euthanized

Date of Death: **B6**

Product Information:

Product Name: ACANA Meadowland Formula Grain Free Dry Dog Food

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 50 Pound

Purchase Date: 04/01/2019

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: No

Storage Conditions: Unknown

Product Use Information:

Description: Administered orally

Last Exposure Date: 04/09/2019

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 to the Animal During This Time Period: Unknown

Manufacturer /Distributor Information:

Purchase Location Information: Name: Unknown

Animal Information: Name: **B6**

	Type Of Species:	Dog																								
	Type Of Breed:	Great Dane																								
	Gender:	Male																								
	Reproductive Status:	Neutered																								
	Weight:	81 Kilogram																								
	Age:	3 Years																								
	Assessment of Prior Health:	Good																								
	Number of Animals Given the Product:	1																								
	Number of Animals Reacted:	1																								
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Owner Information provided:	Yes	Contact: Name:	B6	Phone:		Email:		Address:	B6		United States												
Owner Information provided:	Yes																									
Contact: Name:	B6																									
Phone:																										
Email:																										
Address:	B6																									
	United States																									
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Practice Name:	B6	Contact: Name:	B6	Phone:		Email:		Address:	B6		United States	Practice Name:	B6	Contact: Name:	B6	Phone:		Email:		Address:	B6		United States
Practice Name:	B6																									
Contact: Name:	B6																									
Phone:																										
Email:																										
Address:	B6																									
	United States																									
Practice Name:	B6																									
Contact: Name:	B6																									
Phone:																										
Email:																										
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:	Email																								
	Reported to Other Parties:	Unknown																								

Additional Documents:

Attachment:	B6 .pdf
Description:	Medical Records
Type:	Medical Records
Attachment:	B6 2.pdf
Description:	Treatment
Type:	Medical Records

Report Details - EON-381035

ICSR:	2063283
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-27 13:12:39 EST
Initial Report Date:	09/10/2018
Parent ICSR:	2054793
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Presented for exercise intolerance and was diagnosed with moderate pulmonic stenosis, a possible PDA, and possible tricuspid valve dysplasia; she was started on B6 and referred to B6 for a balloon valvulplasty. However, prior to the procedure a repeat echocardiogram showed idiopathic dilated cardiomyopathy, and she was started on Taurine supplementation; she did not improve and required being started on B6
	Date Problem Started:	03/01/2016
	Date of Recovery:	02/12/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Earthborn Holistic Meadow Feast		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	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:	Retriever - Labrador
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	37 Kilogram
	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:	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:	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 02072019 SOAP.pdf
	Description:	B6 most recent cardiac recheck
	Type:	Medical Records

Report Details - EON-381031

ICSR:	2063280
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-27 13:07:15 EST
Initial Report Date:	11/06/2018
Parent ICSR:	2058477
Follow-up Report to FDA Request:	Yes

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 and started on 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 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: **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: **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	02192019 SOAP.pdf
Description:	B6	most recent cardiac recheck
Type:	Medical Records	

Report Details - EON-370539		
ICSR:	2058584	
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:	2018-11-08 10:29:48 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description:	<p>This submission is in furtherance of your nutritionally-mediated DCM investigation. My young, energetic and very healthy Golden Retriever male had his second echocardiogram on Thursday, October 25, 2018. His first was approximately one year ago in September 2017. The 2017 echo was normal. The one from last week was not. It showed a subjective increase in sphericity of his heart, as well as mild systolic dysfunction compared with last year. ACK!!! His whole blood taurine level at U.C. Davis was B6 in September 2018. I had scheduled echocardiograms for B6 and my other two Golden Retrievers out of an abundance of caution after two B6 (and his littermate brother) tested below 250 nmol/ml for taurine in whole blood. I'm glad I did. My veterinary cardiologist is B6. At last week's echocardiogram, he drew blood for CBC, chemistry, a repeat of the taurine test with paired samples, a full tick-borne disease panel, and thyroid tests. All test results are in except for the repeat taurine test from U.C. Davis. All B6 results were unremarkable or normal, except for a slightly low globulin level. That test will be repeated this week. I never purposely fed a "grain-free" food or an "exotic protein" food. I'm a physicist and I believe in science and common sense. HOWEVER, after FDA's investigation was announced, I noted that some of the commercial food I was feeding B6 which I thought was perfectly conventional) met the FDA's description of "suspect diets". In addition, I had been giving my three Golden Retrievers a probiotic from Purina -- their Fortiflora product -- as a routine part of feeding after a period in which all three dogs had loose stool and diarrhea. I added the Fortiflora to their food for a period of over a year. I think the current thinking on this issue is that it's multifactorial, I wanted to mention first that I had added the Fortiflora and that while I didn't purposely choose a grain-free food (high in legumes), I've also found that the food itself has added "probiotics". I was surprised to see that. Now, I wonder if my accidental food choice for him, plus my "probiotic" supplement, changed something in how his body processed the taurine precursors and dietary taurine. In addition, he's definitely an "easy-keeper", eating nowhere near the amount of food advised on the bag. After his "equivocal" taurine level in mid-September 2018, I stopped feeding Fortiflora to all three Golden Retrievers. Their stool is perfectly fine, perhaps even better. I changed B6 diet from Fromm to Purina ProPlan Sport 30/20 at the same time. Please do get in touch if there's any further information you require or that you might provide me. Obviously, I hope this is diet-related and can be reversed.</p>
	Date Problem Started:	10/25/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown
Product Information:	Product Name:	Orijen Regional Red Dry Dog Food Fromm Beef Frittata A La Veg Dry Dog Food From Duck & Sweet Potato Dry Dog Food Purina Fortiflora
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	13 Pound
	Possess Unopened Product:	Yes
	Possess Opened Product:	No
Product Use Information:	Description:	I can provide a description of how I mixed this food with two others for part of B6's diet. Please let me know if you'd like me to send that. He was also fed scrambled eggs,

	yogurt, cottage cheese, and meats.
First Exposure Date:	12/03/2017
Last Exposure Date:	09/15/2018
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:	Possibly related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:

Purchase Location Information: Name: Chewy.com

Animal Information:

Name: **B6**

Type Of Species: Dog

Type Of Breed: Retriever - Golden

Gender: Male

Reproductive Status: Neutered

Weight: 80 Pound

Age: 3 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**
 Email: **B6**

Address: **B6**
 United States

Type of Veterinarian: Referred veterinarian

Date First Seen: 10/31/2018

Permission to Release Records to FDA: Yes

Practice Name: **B6**

		Contact:	Name:	B6
			Phone:	
			Other Phone:	
			Email:	
		Address:	B6	
				United States
		Type of Veterinarian:	Primary/regular veterinarian	
		Date First Seen:	11/08/2018	
		Permission to Release Records to FDA:	Yes	

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

Additional Documents:	Attachment:	B6 20181025 225133.pdf
	Description:	B6 echocardiogram report from 10/31/2018
	Type:	Echocardiogram

Report Details - EON-381027

ICSR: 2063277
 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: 2019-02-27 12:36:52 EST

Reported Problem:
Problem Description: On [B6] presented to her pcDVM for a two-week history of lethargy and an intermittent cough since Christmas; they thought she might have ingested some pillow foam due to her distended abdomen. On presentation, she was tachycardia at [B6] bpm with a new Grade I-II/VI heart murmur with a distended abdomen with a fluid wave present. Thoracic radiographs showed a large, globoid hear with mild pulmonary edema, and abdominal radiographs showed loss serosal detail. She was referred to the [B6] where an echocardiogram was performed that showed DCM, and it was noted at that time that she was being fed a grain-free diet. An ECG confirmed atrial fibrillation. She was started on [B6] and hospitalized overnight before being discharged on [B6] and Taurine.
Date Problem Started: [B6]
Concurrent Medical Problem: No
Outcome to Date: Died Euthanized
Date of Death: [B6]

Product Information:
Product Name: Orijen
Product Type: Pet Food
Lot Number:
Package Type: BAG
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: Taste of the Wild Whole Prey
Product Type: Pet Food
Lot Number:
Package Type: BAG
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: Great Dane

Gender: Female

Reproductive Status: Neutered

Weight: 53.6 Kilogram

Age: 3 Years

Assessment of Prior Health: Good

Number of Animals Given the Product: 2

Number of Animals Reacted: 2

Owner Information:

Owner Information provided: Yes

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

Address: **B6**
 United States

Healthcare Professional Information:

Practice Name: **B6**

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

Address: **B6**
 United States

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	Medical Records.pdf
Description:	B6	medical records (SOAPs, labwork, Echo report)
Type:	Medical Records	
Attachment:	B6	Medical Records.pdf
Description:	B6	surviving housemate) medical records (client communication, SOAP, and Echo report)
Type:	Medical Records	

Report Details - EON-363941

ICSR:	2054512
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-08-31 07:31:38 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 has been fed Wellness Core Grain Free food for several years. A few months ago she started seeming a little run down. This was about the time that I learned about low taurine levels and the relationship to dilated cardiomyopathy. I had B6 taurine level tested (at B6 lab) and it came back as B6 . Normal is 250. I had changed her food once I knew about this - actually in December to Precise Weight Management. She has not had an echo yet, but I will be scheduling that. She still seems a little off but exam last week showed no murmur.
	Date Problem Started:	06/13/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Wellness Core Weight Management Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	12/01/2017	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in air tight plastic container.	
	Product Use Information:	Description:	B6 was given a cup and a half of food AM and PM
		First Exposure Date:	12/20/2017
		Last Exposure Date:	03/01/2018
		Time Interval between Product Use and Adverse Event:	3 Years
		Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:		Unknown	
Product Use Started Again:		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:

Name:

Petsmart

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Retriever - Golden

Gender: Female

Reproductive Status: Neutered

Weight: 64 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:

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-366017

ICSR:	2055095
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:	2018-09-19 09:38:33 EDT
Initial Report Date:	08/31/2018
Reporter is the Animal Owner:	Yes
Parent ICSR:	2054512
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	B6 has been fed Wellness Core Grain Free food for several years. A few months ago she started seeming a little run down. This was about the time that I learned about low taurine levels and the relationship to dilated cardiomyopathy. I had B6 taurine level tested (at B6 lab) and it came back as B6 . Normal is 250. I had changed her food once I knew about this - actually in December to Precise Weight Management. She has not had an echo yet, but I will be scheduling that. She still seems a little off but exam last week showed no murmur. Addendum: B6 had a cardiac echo on 9/5/18 which was normal
	Date Problem Started:	06/13/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Wellness Core Weight Management Grain Free
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	30 Pound
	Purchase Date:	12/01/2017
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Stored in air tight plastic container.

Product Use Information:	Description:	B6 was given a cup and a half of food AM and PM
	First Exposure Date:	12/20/2017
	Last Exposure Date:	03/01/2018
	Time Interval between Product Use and Adverse Event:	3 Years
	Product Use Stopped After the Onset of the Adverse Event:	Yes
	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:	Petsmart
		Address:	B6
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	64 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:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	B6
		Email:	B6
		Address:	B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	09/05/2018
		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:	c470127 (1) B6 Cardiac Echo.pdf
	Description:	Cardiac Echo report
	Type:	Medical Records

Report Details - EON-366010

ICSR:	2055094
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:	2018-09-19 09:32:37 EDT
Initial Report Date:	08/31/2018
Reporter is the Animal Owner:	Yes
Parent ICSR:	2054512
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	B6 has been fed Wellness Core Grain Free food for several years. A few months ago she started seeming a little run down. This was about the time that I learned about low taurine levels and the relationship to dilated cardiomyopathy. I had B6 taurine level tested (at B6 lab) and it came back as B6 . Normal is 250. I had changed her food once I knew about this - actually in December to Precise Weight Management. She has not had an echo yet, but I will be scheduling that. She still seems a little off but exam last week showed no murmur. Addendum: B6 had a cardiac echo of B6 which was normal
	Date Problem Started:	06/13/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Wellness Core Weight Management Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	12/01/2017	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in air tight plastic container.	
	Product Use Information:	Description:	B6 was given a cup and a half of food AM and PM
		First Exposure Date:	12/20/2017
		Last Exposure Date:	03/01/2018
Time Interval between Product Use and Adverse Event:		3 Years	
Product Use Stopped After the Onset of the Adverse Event:		Yes	
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:	Petsmart
		Address:	B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	64 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:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	B6
		Email:	B6
		Address:	B6 United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	09/05/2018
		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-363873	
ICSR:	2054481
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 13:34:55 EDT
Reported Problem:	Problem Description: Developed congestive heart failure, and she was subsequently diagnosed with dilated cardiomyopathy; she was started on cardiac medications [B6] [B6] supplementation, including Taurine and L-Carnitine.
	Date Problem Started: 03/07/2017
	Date of Recovery: 07/19/2017
	Concurrent Medical Problem: No
	Outcome to Date: Stable
Product Information:	Product Name: Fromm Pork and Pea
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Product Use Information:
	Description: Fed due to housemate's allergy to chicken.
	Last Exposure Date: 08/30/2018
	Product Use Stopped After the Onset of the Adverse Event: 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: No	
Manufacturer /Distributor Information:	
Purchase Location Information:	
Animal Information:	Name: [B6]
	Type Of Species: Dog
	Type Of Breed: Shepherd Dog - Australian
	Gender: Female
	Reproductive Status: Neutered
	Weight: 23.6 Kilogram
	Age: 6 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:	
			Email:	
	Address:	B6 United States		
	Healthcare Professional Information:	Practice Name:	B6	
		Contact:	Name: B6	
			Phone:	
			Email:	
	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:	Email		
	Reported to Other Parties:	None		
Additional Documents:				

Report Details - EON-381033

ICSR:	2063285
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-27 13:15:32 EST
Initial Report Date:	08/29/2018
Parent ICSR:	2054439
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	On Zignature Kangaroo/lentil diet x 3.5 years. Developed severe dilated cardiomyopathy with congestive heart failure
	Date Problem Started:	03/15/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Zignature Kangaroo and Lentil
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Unknown

Product Use Information:	Description:	Patient was fed this diet for 3.5 years due to responsive to restrictive diet	B6
	First Exposure Date:	10/20/2014	
	Last Exposure Date:	03/20/2018	
	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:	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:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Bulldog - American		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	31.6 Kilogram		
	Age:	4.5 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:	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 01302019 SOAP.pdf		
	Description:	B6 most recent cardiac recheck		
	Type:	Medical Records		

Report Details - EON-363773		
ICSR:	2054439	
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:	2018-08-29 15:35:07 EDT	
Reported Problem:	Problem Description: On Zignature Kangaroo/lentil diet x 3.5 years. Developed severe dilated cardiomyopathy with congestive heart failure	
	Date Problem Started: 03/15/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: Zignature Kangaroo and Lentil	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Unknown	
	Product Use Information:	Description: Patient was fed this diet for 3.5 years due to B6
		First Exposure Date: 10/20/2014
		Last Exposure Date: 03/20/2018
		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: 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:		
Animal Information:	Name: B6	
	Type Of Species: Dog	

	Type Of Breed: Bulldog - American
	Gender: Female
	Reproductive Status: Neutered
	Weight: 31.6 Kilogram
	Age: 4.5 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information:
	Owner Information provided: Yes
	Contact: Name: B6
	Phone: B6
	Email: B6
	Address: B6
	United States
	Healthcare Professional Information:
	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	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-366960

ICSR: 2055381
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: 2018-09-26 19:14:01 EDT
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Suspected cardiomyopathy, fluid in lungs, on [B6] chronic cough with flem. Has been on grain free diet all his life
Date Problem Started: 09/01/2013
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Numerous grain free foods, Earthborn, Iams, Taste of the Wild
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Perceived Relatedness to Adverse Event:** Probably related
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: [B6]
Type Of Species: Dog
Type Of Breed: Spaniel - Cocker American
Gender: Male
Reproductive Status: Neutered
Weight: 35 Pound
Age: 13 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 8
Number of Animals Reacted: 2
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-366961

ICSR: 2055382
 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: 2018-09-26 19:23:36 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
 Problem Description: Suspected cardiomyopathy, taking **B6** very congested rattling lungs, no cough, fluid in lungs
 Date Problem Started: 07/26/2018
 Concurrent Medical Problem: No
 Outcome to Date: Worse/Declining/Deteriorating

Product Information:
 Product Name: Numerous grain free foods, Earthborn, Call of the Wild, Iams
 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: Spaniel - Cocker American
 Gender: Female
 Reproductive Status: Neutered
 Weight: 35 Pound
 Age: 9 Years
 Assessment of Prior Health: Excellent
 Number of Animals Given the Product: 8
 Number of Animals Reacted: 2
 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: Yes

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

Additional Documents:

Report Details - EON-367142		
ICSR:	2055483	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-09-28 14:51:18 EDT	
Reported Problem:	Problem Description: Low taurine levels, concern for cardiomyopathy.	
	Date Problem Started: 09/08/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: The Honest Kitchen Grain Free Chicken Recipe	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BOX	
	Package Size: 10 Pound	
	Possess Unopened Product: Yes	
	Possess Opened Product: Yes	
	Product Use Information:	Description: Fed as main diet for years.
		Product Use Stopped After the Onset of the Adverse Event: Yes
		Adverse Event Abate After Product Stop: Unknown
		Product Use Started Again: No
		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: Retriever - Golden	
	Gender: Male	
	Reproductive Status: Intact	
	Weight: 82.4 Pound	
	Age: 5 Years	
	Assessment of Prior Health: Excellent	
	Number of Animals Given the Product: 4	
	Number of Animals Reacted: 4	
Owner Information: Owner Yes		

		Information provided:	
		Contact:	Name: B6 Phone: B6
		Address:	B6 United States
		Healthcare Professional Information:	
Sender Information:	Name:		
	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-367443

ICSR:	2055606
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:	2018-10-02 18:30:07 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was recently diagnosed with a heart murmur. We completed a heart ultrasound with the following results: Left Ventricle There is severe eccentric hypertrophy. LV systolic function is low normal. Diastolic filling appears normal. LV hypokinesis (mild) given the presence/extent of MR in this patient. Left Atrium Left Atrium chamber is mildly to moderately dilated. Mitral Valve There is mild mitral valve prolapse, anterior leaflet. There is mild thickening of mitral valve anterior and posterior leaflets. There is moderate mitral regurgitation. Mildly thickened valve leaflet margins. Tricuspid Valve Tricuspid valve is structurally normal. There is mild tricuspid regurgitation. Pulmonary Valve There is normal pulmonic valve structure and function. There is trivial pulmonic regurgitation. Myxomatous mitral valve degeneration resulting in moderate mitral regurgitation and subsequent moderate to marked dilation of the LV and moderate dilation of the LA. There is mild systolic dysfunction evident given the extent of mitral regurgitation present.
	Date Problem Started:	09/01/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	GO! Sensitivity and Shine Pollock Recipe		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	In an enclosed bag.		
	Product Use Information:	Description:	Fed	
		First Exposure Date:	05/01/2018	
		Last Exposure Date:	10/02/2018	
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:	Yes			

	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Flat-coated	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	45 Pound	
	Age:	9.5 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
Type of Veterinarian:		Primary/regular veterinarian	
Sender Information:	Name:	B6	
	Address:	B6	
		Canada	
	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-368130

ICSR: 2055919
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: 2018-10-11 09:07:45 EDT

Reported Problem:
Problem Description: Presented for exercise intolerance, cough, murmur. Echo diagnosis - dilated cardiomyopathy
Date Problem Started: 09/11/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:
Product Name: Blue Buffalo Wilderness
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information: **First Exposure Date:** 12/01/2013
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: 67 Pound
Age: 6 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** Yes
Contact: **Name:** B6
Phone:
Email:
Address: B6
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:	Taurine - B6 .pdf
	Description:	taurine results
	Type:	Medical Records
	Attachment:	Medical History - B6 .pdf
	Description:	medical records
	Type:	Medical Records
	Attachment:	1 - B6 .11.18.pdf
	Description:	echo report
	Type:	Medical Records

Report Details - EON-367981

ICSR:	2055876
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:	2018-10-10 00:17:01 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Our almost 8 year old male Weimaraner, B6 was diagnosed with Dilated Cardiomyopathy after being brought into the vet for gurgling noises when he slept at night (he was otherwise perfectly healthy. Our vet almost missed it.) He was already in heart failure when diagnosed and given 4-6 months to live. We made the decision to euthanize him just after his 8th birthday, 4 months later, after he collapsed and had a hard time breathing. B6 had some skin allergies around the age of 2. At that time we switched his food to California Naturals Grain-Free Salmon and Peas food at the advice of our vet. His allergy ended up being unrelated to food but we kept his food the same due to claims that the food was a high quality diet. We fed B6 that diet for the remainder of his life, approximately 6 years. After much research, I believe that the grain free food may possibly have caused our dogs DCM and Heart Failure,
	Date Problem Started:	06/15/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	California Natural Limited Ingredient Diet Salmon Meal and Peas Recipe		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	06/01/2017		
	Number Purchased:	4		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	Yes		
	Storage Conditions:	Bags stored indoors before opening and poured into an Innova dog food storage container.		
	Product Use Information:	Description:	4 cups scooped into dog bowl. 1 cup Frozen green beans added for fiber.	
		First Exposure Date:	06/01/2017	
		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:		Possibly related		
Other Foods or		Yes		

		Products Given to the Animal During This Time Period:		
	Manufacturer /Distributor Information:			
	Purchase Location Information:	Name:	B6	
		Address:		
			United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Weimaraner		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	110 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:				
Email:				
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:	06/15/2017			
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:	None			
Additional Documents:				

Report Details - EON-368134

ICSR: 2055920
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: 2018-10-11 09:39:03 EDT

Reported Problem:
Problem Description: Dilated cardiomyopathy, atrial fibrillation, biventricular congestive heart failure
Date Problem Started: 08/23/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Dr. Gary Best Choice
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
First Exposure Date: 06/01/2018
Perceived Relatedness to Adverse Event: Probably related
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Mastiff
Gender: Male
Reproductive Status: Neutered
Weight: 162 Pound
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: B6
Other Phone: B6
Email: 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:	Attachment:	146595	B6	24.18.pdf
	Description:	echo report		
	Type:	Medical Records		
	Attachment:	Taurine	B6	pdf
	Description:	taurine results		
	Type:	Medical Records		
	Attachment:	Medical History	B6	pdf
	Description:	medical history		
	Type:	Medical Records		

Report Details - EON-367977

ICSR:	2055874
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-10-09 21:53:47 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	The night of October 3, B6 was standing and started acting funny, she fell to her side and became tense and her eyes rolled back (the vet believes she was having a seizure or fainted). After about a minute she relaxed and just laid there she had very minimal motivation to do anything and was breathing hard. She slept the rest of the night and next morning and didn't want to eat anything. I called the vet and they were able to see her in between their scheduled surgeries and run many tests. Most of the tests came back normal except her white blood cell count was off which they gave her antibiotics to treat for infection and her heart measured larger than normal. They diagnosed her with heart disease. She is now on heart medicine twice a day which seems to be helping her. She still breaths heavy at times and they said that will happen due to her heart being bigger and can push on her lungs. She still wont eat her dog food that she was on before (Blue Freedom Chicken Recipe Grain Free Senior Dog food). I began reading online trying to find the best dog food that would help her with her heart health. I came across a article that described how the FDA is investigating a possible connection with heart disease and grain free diets and wanted to report our recent situation with our golden retriever. B6
	Date Problem Started:	10/03/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	She tested positive for B6 but never had any problems with it.
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Blue Freedom Grain Free Senior Recipe with Chicken Potatoes and Peas	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	24 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	When I would get the dog food I would put it in a plastic bin that is sealed shut until I needed to add more to B6 dog dish.	
	Product Use Information:	Description:	I keep the dog food in a closed bin and fill the self feeding dish as it empties (there is a timer that lets down the food three times a day).
		Last Exposure Date:	10/03/2018
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:		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:	Unknown
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Petco
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	65 Pound	
	Age:	8 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 (I talked to two different drs)
		Phone:	B6
		Address:	United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	10/04/2018
		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-368135

ICSR: 2055921
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: 2018-10-11 09:49:00 EDT

Reported Problem:
Problem Description: Dilated cardiomyopathy
Date Problem Started: 08/30/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Victor Performance
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information: Product Use Stopped After the Onset of the Adverse Event: Yes
Perceived Relatedness to Adverse Event: Possibly related
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Shepherd Dog - German
Gender: Male
Reproductive Status: Intact
Weight: 22.6 Pound
Age: 5 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:
Other Phone:
Email:
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:	Attachment:	Medical History B6 .pdf
	Description:	medical records
	Type:	Medical Records
	Attachment:	Taurine B6 (1).pdf
	Description:	taurine results
	Type:	Medical Records
	Attachment:	B6 30.18.pdf
	Description:	echo report
	Type:	Medical Records
	Attachment:	Taurine B6 (2).pdf
	Description:	repeat taurine results
	Type:	Medical Records

Report Details - EON-368140

ICSR: 2055924
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: 2018-10-11 10:21:54 EDT

Reported Problem:
Problem Description: Dilated cardiomyopathy, ventricular arrhythmias
Date Problem Started: 10/02/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: **B6**
Outcome to Date: Stable

Product Information:
Product Name: Origin Fit and Trim
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
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: Ridgeback - Rhodesian
Gender: Male
Reproductive Status: Unknown
Weight: 126 Pound
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:
			Phone:
			Email:
		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:	Medical History	B6 .pdf
	Description:	Medical history	
	Type:	Medical Records	
	Attachment:	B6	.2.18 .pdf
	Description:	Echo report	
	Type:	Medical Records	
	Attachment:	Taurine	B6 .pdf
	Description:	Taurine results	
	Type:	Laboratory Report	

Report Details - EON-368175

ICSR:	2055936
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:	2018-10-11 14:49:45 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Dog was eating grain-free food for approximately 4-5 years. In July a heart murmur was detected and sent for an echocardiogram and was diagnosed with Dilated Cardiomyopathy.
	Date Problem Started:	07/30/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Nutrisource Grain-Free Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	35 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In bag or container		
	Product Use Information:	Description:	Fed twice a day to dogs	
		Last Exposure Date:	07/30/2018	
		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 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:	Female		
	Reproductive Status:	Intact		
	Pregnancy Status:	Not Pregnant		
	Lactation Status:	Not Applicable		
	Weight:	53 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:	
		Address:	B6	
			United States	
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	07/30/2018	
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:	Other			
Additional Documents:				

Report Details - EON-368495

ICSR: 2056139
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: 2018-10-16 11:02:00 EDT

Reported Problem:
Problem Description: B6 presents to B6 today for evaluation of cardiomegaly and suspected early cardiogenic edema. B6 was seen through B6 on B6 for a four day history of coughing. The client reports that the coughing episodes last between 15 to 20 minutes. At that time bloodwork and radiographs were taken. B6 was started on a trial dose of B6 at 50 mgs by mouth every 12 hours. The client reports that initially, for about three days, the cough was improved after starting the B6. However, the client reports that over the last day and a half the cough is worse again. B6 has no history of a heart murmur and has no other medical conditions at this time. B6 has not been on heartworm prevention for over a year at this point. B6 currently eats V-dog brand vegan dry dog food and has been eating this diet since 2014 or 2015 and prior to this diet he ate Fromm. The client reports that prior to starting the B6 had a great appetite, but since starting the B6 he is not eating and they are having to mix canned pumpkin in his food to get him to eat anything. The client also reports a decrease in B6 energy level since starting the B6.
Date Problem Started: B6
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: V-dog Vegan dry dog food
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: Collie (unspecified)
Gender: Male
Reproductive Status: Neutered
Weight: 25.5 Kilogram
Age: 11 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: Owner Information provided: Yes
Contact: Name: B6
Phone:
Other Phone:
Email:

		Address:	B6
			United States
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	
		Other Phone:	
		Email:	
		Address:	B6
			United States
Sender Information:	Name:		
	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-369318

ICSR: 2057922
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: 2018-10-25 03:58:49 EDT
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Healthy 1.75 year old female Golden Retriever died on **B6** suddenly due to Dialated Cardiomyopathy due to a grain free diet. There were no signs of heart disease or any medical problems with the Golden Retriever prior to this incident.
Date Problem Started: **B6**

Product Information:
Product Name: Blue Buffalo - Blue Wilderness Chicken Adult Food
Product Type: Pet Food
Lot Number:
UPC: 859610002719
Package Type: BAG
Package Size: 24 Pound
Purchase Date: 10/07/2018
Number Purchased: 2
Possess Unopened Product: No
Possess Opened Product: Yes
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information: Name: **B6**
Address: **B6**
United States

Animal Information:
Name:
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-369595

ICSR: 2058159
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-10-29 09:30:49 EDT

Reported Problem:

Problem Description: B6 was presented on emergency for a progressive cough of one week duration and exercise intolerance, lethargy and anorexia for the last several days. Radiographs taken by the referring veterinarian showed severe cardiomegaly and pulmonary infiltrates consistent with congestive heart failure. He was started on B6 twice daily prior to referral. He has a history of B6 for which he has been seen by the dermatologist at B6. He has been eating Zignature Kangaroo and Lentil diet for at least about 2 years.

Date Problem Started: 10/18/2018

Concurrent Medical Problem: No

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: Zignature Kangaroo and Lentil

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: Setter - English

Gender: Male

Reproductive Status: Neutered

Weight: 26.6 Kilogram

Age: 7 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 Information: Practice Name: B6

Contact: Name: B6
 Phone: B6
 Other Phone:

			Email: B6
		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-369442

ICSR:	2058098
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-10-26 12:51:48 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Without any prior warning signs- our 4 1/2 yr old Great Dane B6 started coughing on B6 just before midnight he developed difficulty breathing. We took him to our local B6 emergency facility and he was diagnosed with dilated cardiomyopathy which was confirmed by X-ray. B6 was given to him by injection at the time of the visit, and we were also prescribed two additional heart medications- he was never able to take them. We consulted with our primary veterinarian on B6 and he was euthanized. I was concerned about the link between grain free diets and DCM and wanted the FDA to be aware B6 was purchased from a reputable breeder, AKC registered with champion blood lines. He had both seller guarantees against heart disease and hip dysplasia at the time of purchase. I would have expected this condition later in his life, but not at the age of 4 1/2. B6 has been eating NutriSource Seafood Select grain free for approximately 1.5 years.
	Date Problem Started:	B6
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	NutriSource Seafood Select grain free dog food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	33 Pound		
	Purchase Date:	10/05/2018		
	Number Purchased:	2		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	Yes		
	Storage Conditions:	In a plastic bin		
	Product Use Information:	Description:	Canine has eaten this food daily for approximately 1 1/2 years.	
		Last Exposure Date:	B6	
		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		Possibly related		

		Relatedness to Adverse Event:	
		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:	Great Dane	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	138 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:		
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-370913

ICSR:	2058764
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:	2018-11-13 09:27:47 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 has been on a grain free diet for the past 4.5 years (3.5 years of Earthborn Meadow Feast and Fromm Hasen Duckenpfeffer for the past 1 year leading up to his diagnosis on 9/27/2018. Had this issue not been alerted to by the FDA this Spring on the media I might not have perceived the symptoms of DCM unfolding before my eyes and gone to the vet so quickly. B6 symptoms came on gradually late Spring of 2018 and worsened through the summer to the point of being clearly DCM. These symptoms include exercise intolerance, heat intolerance, heavy breathing and some congestion of the lungs in the hours following exercise and difficulty going up to high elevation. My echo report from the cardiologist states: dilated cardiomyopathy with moderate mitral regurgitation and a mild tricuspid regurgitation. Fractional shortening and ejection fraction are very low. Left atrium is enlarged and left ventricle is enlarged in systole and diastole. EPSS is enlarged. LA-AO ratio is increased. Mitral forward flow is elevated but not to the point that congestive heart failure is present. Mild tricuspid regurgitation.
	Date Problem Started:	05/01/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Fromm Hasen Duckenpfeffer		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	7270511460		
	Package Type:	BAG		
	Package Size:	26 Pound		
	Purchase Date:	07/17/2017		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	In pantry in air tight container		
	Product Use Information:	Description:	1.5 cups 2x per day	
		First Exposure Date:	07/27/2017	
	Last Exposure Date:	07/27/2018		
	Time Interval between Product Use and Adverse Event:	12 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:	Name:	B6	
		Address:		
			United States	
Animal Information:	Name: B6			
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	74 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:	Practice Name:	B6	
		Contact:	Name:	B6
Phone:				
Email:				
Address:		B6		
		United States		
Type of Veterinarian:	Referred veterinarian			
Date First Seen:	09/27/2018			
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:	Store/Place of Purchase Manufacturer			
Additional Documents:	Attachment: IMG_2857.JPG			

Description: Cardiologist report 9/27/2018

Type: Echocardiogram

Report Details - EON-359622

ICSR:	2052295
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:	2018-07-18 08:17:06 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 (6 year old Catahoula Leopard mix) had seen the vet end of June 2017 no heart murmur detected. September 15, 2017 rushed to the vet and was diagnosed with Dilated Cardiomyopathy, and end stage heart failure. She passed away B6 January 25th, 2018 our other dog B6 (7 year old German Shepherd Collie mix) was diagnosed with DCM and mild heart failure. He is still alive at this time B6 had a food allergy and therefore this was one of the foods that he could tolerate.) The cardiologist and our vet had no explanation how these two dogs not related were diagnosed with the same thing a few months apart. They were convinced it was just 'bad luck'.
	Date Problem Started:	09/15/2017
	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 Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	11/30/2012		
	Number Purchased:	5		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In a container but still in the bag.		
	Product Use Information:	Description:	Used to feed both dogs twice daily.	
		First Exposure Date:	12/31/2012	
		Last Exposure Date:	02/28/2018	
		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 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:	Mixed (Dog)
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	48 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:	
Sender Information:	Name:	
	Address:	B6
		United States
	Contact:	Phone:
		Other 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-378456

ICSR:	2062088
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:	2019-02-02 19:58:37 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Our 4Y old dog, B6 (Husky mix) started experiencing severe GI upset on B6. Mostly watery and mucousy diarrhea with undigested food and some vomiting. She had often had cycles of GI upset over the last year, but we were always told by our vet to feed bland food and were never asked about her food or brand. Everyone seemed to think she had a "sensitive stomach." This time, the GI upset did not resolve and progressed to hemorrhagic diarrhea with frank blood, noticed by her owners of B6. She was taken to the ER at B6 the same day and was found to be severely anemic and her blood was found to be markedly hemolyzed (see attached records). She presented with a fever. She was transferred to B6 and required 2 blood transfusions that night. By the following evening she was starting to decline again, with liver and kidney values rising and extreme lethargy. She also developed very red skin, eyes, and gums were injected which doctors found curious given her severe anemia and previous hemorrhagic state. Ultrasound findings suggestive of hepatitis, nephritis, and GI bloating/distention. COOMBS test came back negative. Her third night in the ICU she developed tachypnea, bradycardia, and severe edema in lungs and abdomen. It was hard for her to breathe and the decision was made to hasten death by euthanasia. With such an aggressive disease process and no diagnosis yet found, doctors at B6 recommended B6 be taken to B6 for a necropsy. Necropsy results found extensive liver and kidney damage and also moderate dilated cardiomyopathy (see report for reference). Case coordinator, B6 PhD, DACVP, writes in the necropsy report: "With the marked dilated ventricles of the heart and a history of being on a grain free diet for 3.5 years a dilated cardiomyopathy must be considered." B6 regular dog food was a Earthborn Holistic, a grain-free dog food high in legumes that the owners fed. B6 upon recommendation from a local 'natural' pet food store. Because of these startling findings underlying such an aggressive disease process in a young dog, and because of the recent warnings issued by the FDA in summer 2018 about connections between grain-free food and DCM, it was thought that this report would provide helpful data to the government.
	Date Problem Started:	01/21/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Earthborn Holistic Western Feast
	Product Type:	Pet Food
	Lot Number:	Lot Number: M1L1B2OE1326
		Expiration Date: 02/29/2020
	UPC:	3483471942
	Package Type:	BAG
	Package Size:	28 Pound
	Purchase Date:	12/01/2018
	Number Purchased:	1
	Possess Unopened Product:	No

	Possess Opened Product:	Yes
	Storage Conditions:	Stored at room temperature in kitchen cupboard.
	Product Use Information:	<p>Description: Note: We have been feeding her this brand almost exclusively for a little over 3 years. Information below pertains to the particular bag of food which was the last bag we bought. During the past year, [B6] was typically eating 2 cups of this food per day, supplemented occasionally with home cooked rice, eggs, carrots, kale, and plain beef or chicken. The bag of food is about 1/4 full currently; [B6] consumed about 3/4ths of the contents; [B6] seemed to be less interested in the food for the past 8-12 months, and we were preparing to switch her to another brand when the acute portion of her illness occurred. [B6] occasionally spent time outside unsupervised to use the bathroom.</p> <p>First Exposure Date: 12/01/2018</p> <p>Last Exposure Date: 01/20/2019</p> <p>Time Interval between Product Use and Adverse Event: 3 Years</p> <p>Product Use Stopped After the Onset of the Adverse Event: Yes</p> <p>Adverse Event Abate After Product Stop: No</p> <p>Product Use Started Again: No</p> <p>Perceived Relatedness to Adverse Event: Possibly related</p> <p>Other Foods or Products Given to the Animal During This Time Period: Yes</p>
	Manufacturer /Distributor Information:	<p>Name: Midwestern Pet Foods, Inc.</p> <p>Type(s): Manufacturer</p> <p>Address: Evansville Indiana 47725 United States</p> <p>Contact: Phone: 1-800-474-4163 Web Address: earthbornholisticpetfood.com</p> <p>Possess One or More Labels from This Product: Yes</p>
	Purchase Location Information:	<p>Name: [B6]</p> <p>Address: [B6] United States</p>
Animal Information:	Name:	[B6]
	Type Of Species:	Dog

Type Of Breed:	Other Canine/dog			
Gender:	Female			
Reproductive Status:	Neutered			
Weight:	26 Kilogram			
Age:	4 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:		
		Email:		
	Address:	B6		
		United States		
	Type of Veterinarian:	Referred veterinarian		
	Date First Seen:	B6		
	Permission to Release Records to FDA:	Yes		
	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		
Healthcare Professional Information:		Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
			Email:	
		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:	Other	

Additional Documents:	Attachment:	F19-0007705Interim B6 20190131-214032.pdf
	Description:	Interim Necropsy Report from B6
	Type:	Necropsy Report
	Attachment:	clinicalSummary_AN310182_S10676.pdf
	Description:	Clinical Summary of B6
	Type:	Medical Records
	Attachment:	B6 Bloodwork and rad report.pdf
	Description:	Initial Diagnostics from referring hospital B6 Emergency Center. This hospital referred B6 for further treatment.
	Type:	Medical Records
	Attachment:	HistopathologyInterim B6 0190201-204214.pdf
	Description:	Interim Necropsy Report with Slide Descriptions from B6
	Type:	Necropsy Report

Report Details - EON-367421

ICSR: 2055596
 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: 2018-10-02 15:42:01 EDT

Reported Problem:

Problem Description: Spontaneous episode of collapse - diagnosed with mitral and tricuspid insufficiencies and systolic dysfunction consistent with dilated cardiomyopathy, and rapidly coupled ventricular premature contractions; started on [B6] [B6] Taurine, and fish oils. He developed a thrombocytosis and needed to be started on [B6] His [B6] was able to be discontinued, but not his [B6]

Date Problem Started: 01/03/2018
Date of Recovery: 06/05/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:

Product Name: Nature's Variety Chicken and Beef
Product Type: Pet Food
Lot Number:
Package Type: CAN

Product Use Information:

First Exposure Date:	01/01/2018
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: Nutro Chicken and Brown Rice
Product Type: Pet Food
Lot Number:
Package Type: BAG

Product Use Information:

First Exposure Date:	05/01/2013
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:	Nature's Variety Chicken Formula Patties														
	Product Type:	Pet Food														
	Lot Number:															
	Package Type:	BAG														
	Product Use Information:	<table border="1"> <tr> <td>First Exposure Date:</td> <td>02/01/2017</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>Possibly related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	First Exposure Date:	02/01/2017	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						
First Exposure Date:	02/01/2017															
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:	Bulldog - American														
	Gender:	Male														
	Reproductive Status:	Neutered														
	Weight:	41.9 Kilogram														
	Age:	12 Years														
	Assessment of Prior Health:	Good														
	Number of Animals Given the Product:	1														
	Number of Animals Reacted:	1														
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact:</td> <td> <table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td> <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:										
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Phone:																
Email:																
Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States													
B6																
United States																
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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:	B6															

B6
United States

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:

None

Additional Documents:

Attachment:

B6 Medical Records.pdf

Description:

B6 SOAPs, phone communications, labwork, echo reports, and Holter monitor reports.

Type:

Medical Records

Report Details - EON-381032

ICSR:	2063281
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-27 13:09:28 EST
Initial Report Date:	10/02/2018
Parent ICSR:	2055596
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Spontaneous episode of collapse - diagnosed with mitral and tricuspid insufficiencies and systolic dysfunction consistent with dilated cardiomyopathy, and rapidly coupled ventricular premature contractions; started on [B6] [B6] Taurine, and fish oils. He developed a [B6] and needed to be started on [B6]. His [B6] was able to be discontinued, but not his [B6]	
	Date Problem Started:	01/03/2018	
	Date of Recovery:	06/05/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	

Product Information:	Product Name:	Nature's Variety Chicken and Beef		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	CAN		
	Product Use Information:	First Exposure Date:	01/01/2018	
		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:	Nutro Chicken and Brown Rice		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	First Exposure Date:	05/01/2013	
Perceived Relatedness to Adverse Event:		Unrelated		
Other Foods or Products Given		Yes		

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location
Information:

Product Name: Nature's Variety Chicken Formula Patties

Product Type: Pet Food

Lot Number:

Package Type: BAG

Product Use Information: First Exposure Date: 02/01/2017

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: Bulldog - American

Gender: Male

Reproductive Status: Neutered

Weight: 41.9 Kilogram

Age: 12 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:

Phone:

Email:

B6

Address:

B6

United States

Healthcare Professional Information:

Practice Name: B6

Contact: Name:

Phone:

B6

			Email: B6
		Address: B6	United States
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:	None		
Additional Documents:	Attachment:	B6	01302019 SOAP.pdf
	Description:	B6	most recent cardiac recheck
	Type:	Medical Records	

Report Details - EON-378515

ICSR:	2062098
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:	2019-02-03 19:28:43 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dogs hair had seemed to stop growing on her face. I took her to vet on the Jan 18th. It was discovered that she had a murmur in addition, B6 I took her back Jan 22nd because she was having diarrhea and vomiting. He took xray to see if she had blockage. He also took image of heart. Her heart was enlarged. On the 25th, took her back for another blood test to confirm Hypo. On 2/1 took her to get echo cardiogram. She was diagnosed with Advanced DCM, Afib, muscle wasn't contracting well and it was deemed due to age, grain free food. The dog came from a reputable breeder(double doodle) and there is no known heart disease in the family or with offspring. Parents are still alive. They said my dog has less than a year to live. She is on many medications, can go into congestive heart failure at any time. I have contacted Taste of the Wild because that is the last food I was feeding her for months.
	Date Problem Started:	01/18/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Taste of the Wild - PREY Angus Beef		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	unknown		
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	06/04/2018		
	Number Purchased:	2		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	I took out of bag and put in air tight container for pet food.		
	Product Use Information:	Description:	every day, 2 x a day for BOTH my dogs. PS - I tried to put the last date I purchased the food which was 11/29/2018 and it wouldn't allow me to be after the date I FIRST gave the food to the dog. Makes no sense. I also took the food back to the pet store and gave it to him, it was not in the original bag, it was in trash bag.	
		First Exposure Date:	06/04/2018	
	Last Exposure Date:	01/18/2019		
	Time Interval between Product Use and Adverse Event:	6 Months		
	Product Use Stopped After the Onset of the Adverse Event:	Yes		
	Adverse Event	Not Applicable		

Abate After Product Stop:	
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:	Other Canine/dog
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	64 Pound
	Age:	5 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	1

Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	
		Email:	
	Address:	B6	
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	02/01/2019	
	Permission to Release Records to FDA:	Yes	
	Practice Name:	B6	
Contact:		Name:	B6
		Phone:	
		Email:	
Address:	B6		

			B6
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	01/18/2019
		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:	Store/Place of Purchase Manufacturer	
Additional Documents:			

Report Details - EON-378640		
ICSR:	2062128	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2019-02-04 15:48:42 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: I have been feeding my dog FROMM Gold Grain Free. When I saw the reports of DCM rising in grain free fed dogs I contacted by vet and scheduled a echo. I had an echo one week later and my dog was diagnosed with Left Ventricular Systolic Dysfunction from grain free diet.	
	Date Problem Started: 02/01/2019	
	Concurrent Medical Problem: No	
	Outcome to Date: Not Applicable	
Product Information:	Product Name: FROMM Four Star Nutritionals	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 26 Pound	
	Purchase Date: 12/26/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: In the bag it came in, closed tightly to keep it fresh.	
	Product Use Information:	Description: I do have a package of this food from a previous purchase that has not been opened. It was fed daily as my dogs main source of nutrition based on the label for my dogs size.
		First Exposure Date: 12/26/2018
		Last Exposure Date: 01/02/2019
		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: Definitely 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: Other Canine/dog

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:

Email:

B6

Address:

B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: 02/01/2019

Permission to
Release Records
to FDA: Yes

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: Phone

Reported to Other: None

Parties:

Additional Documents:

Report Details - EON-382212

ICSR: 2063904
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: 2019-03-12 17:53:04 EDT
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Diagnosed with mitral valve endocardiosis and has Dilated Cardiomyopathy
Date Problem Started: 03/02/2019
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Acana Heritage - Red Meat
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 25 Pound
Storage Conditions: In bag or sealed container
Product Use Information:
Description: We have fed this dog food to our dogs for a few years and recently learned that unfortunately hundreds of dog owners have experienced the same problem and life threatening heart condition. Something in or lacking in this dog food is causing Dilated Cardiomyopathy in susceptible dogs. The suspicion is Taurine-Deficient (Nutritional) Dilated Cardiomyopathy
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Terrier (unspecified)
Gender: Female
Reproductive Status: Neutered
Weight: 50 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:
Address: B6
United States

		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	02/07/2018	
		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:	Manufacturer Store/Place of Purchase Distributor			
Additional Documents:	Attachment:	B6	mitral valve endocardiosis.pdf	
	Description:	Diagnosis of heart condition		
	Type:	Echocardiogram		

Report Details - EON-379837					
ICSR:	2062726				
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 09:59:19 EST				
Reported Problem:	Problem Description: B6 a 4 Yrs. 7 Mos. Female, Cattle Dog, Australian, owned by B6 was presented on B6 for cardiac evaluation following presentation to our ER service for abdominal distension. She had a c-section 4 weeks ago and had 4 puppies. Owners have noticed progressive abdominal distension, panting, and inappetance. She has been fed Taste of the Wild since puppyhood. There is moderate to severe generalized cardiomegaly and severe left ventricular myocardial failure consistent with dilated cardiomyopathy. There is mild low velocity mitral regurgitation and moderate tricuspid regurgitation with normal velocities. A moderate volume of peritoneal effusion was present on exam. Diagnosis: Dilated cardiomyopathy leading to congestive heart failure				
	Date Problem Started: B6				
	Concurrent Medical Problem: Yes				
	Pre Existing Conditions: B6 by her regular veterinarian after having 4 puppies about four weeks prior to presentation to ER at our facility. Her veterinarian had taken radiographs (cardiomegaly noted) and performed a thoracocentesis just hours prior to presentation at our facility and had started B6				
	Outcome to Date: Unknown				
Product Information:	Product Name: Taste of The Wild (unkown variety)				
	Product Type: Pet Food				
	Lot Number:				
	Product Use Information: <table border="1"> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>4 Years</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Probably related</td> </tr> </table>	Time Interval between Product Use and Adverse Event:	4 Years	Perceived Relatedness to Adverse Event:	Probably related
	Time Interval between Product Use and Adverse Event:	4 Years			
	Perceived Relatedness to Adverse Event:	Probably related			
Manufacturer /Distributor Information:					
Purchase Location Information:					
Animal Information:	Name: B6				
	Type Of Species: Dog				
	Type Of Breed: Cattle Dog - Australian (blue heeler, red heeler, Queensland cattledog)				
	Gender: Female				
	Reproductive Status: Intact				
	Pregnancy Status: Not Pregnant				
	Lactation Status: Lactating				
	Weight: 21.4 Kilogram				
	Age: 4 Years				
	Assessment of Prior Health: Good				
	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:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	
	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:	Phone		
Reported to Other Parties:	None		
Additional Documents:			

Report Details - EON-379442

ICSR: 2062530
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 10:04:17 EST

Reported Problem:

Problem Description:	Originally submitted as RFR EON-379406. 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 7/25/2018. He was being fed a suspect food high in legume ingredients. An irregular heart rhythm and gallop were noted on physical exam. history of decreased energy. Sinus tachycardia with a right bundle branch block; occasional polymorphic single ventricular premature complexes ~ 10 per minute. severe left and right ventricular dilation and severe ventricular hypokinesia. The right atrium appears mildly dilated, the left atrium appears mild to moderately dilated. There is mild low velocity mitral regurgitation and mild tricuspid regurgitation with normal velocities likely attributable to annular dilation. Diagnosis: Dilated cardiomyopathy, Supraventricular tachycardia with occasional ventricular arrhythmia.
Date Problem Started:	07/25/2018
Concurrent Medical Problem:	Unknown
Outcome to Date:	Unknown

Product Information:

Product Name:	Blue Buffalo Life Protection Chicken and Brown Rice Adult Formula
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:	Unknown		
Gender:	Male		
Reproductive Status:	Unknown		
Assessment of Prior Health:	Unknown		
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:			

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>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-379449

ICSR: 2062533
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 10:31:17 EST

Reported Problem:

Problem Description:	Originally submitted as RFR EON-379413. 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 10/3/2018. He was being fed a suspect food high in legume ingredients. severe generalized cardiac dilation and left ventricular myocardial failure consistent with dilated cardiomyopathy. There is mild pleural effusion and scant peritoneal effusion. There is mild mitral and tricuspid valve thickening with mild low velocity mitral regurgitation and mild tricuspid regurgitation with mildly increased velocities. Diagnosis: Dilated cardiomyopathy leading to suspect congestive heart failure (bicavitary effusion)
Date Problem Started:	10/03/2018
Concurrent Medical Problem:	Unknown
Outcome to Date:	Unknown

Product Information:

Product Name:	4Health Untamed (Lamb and Lentil)
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:	Unknown		
Gender:	Male		
Reproductive Status:	Unknown		
Assessment of Prior Health:	Unknown		
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:			

Sender Information:

Name:	B6				
Address:	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				
Reporter Wants to Remain Anonymous:	No				

	Permission To Contact Sender:	No
	Reported to Other Parties:	Unknown

Additional Documents:

Report Details - EON-379843

ICSR: 2062727
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 10:18:11 EST

Reported Problem:
Problem Description: B6 a 6 Yrs. 2 Mos., Neutered Male, Sheepdog, Shetland, owned by B6 B6 was presented on 10/26/2018 for a cardiac evaluation. Poor contractility with severely enlarged left ventricular end systolic and end diastolic dimensions, thin left ventricular free wall and intraventricular septal wall; consistent with DCM. Small amount of mitral regurgitation with decreased velocities and a small amount of tricuspid regurgitation with mild to moderately elevated velocities. Moderate biatrial dilation. Diagnosis: Dilated cardiomyopathy with poor contractility and moderate biatrial dilation, R/O Dietary induced vs idiopathic
Date Problem Started: 10/26/2018
Concurrent Medical Problem: Unknown
Outcome to Date: Unknown

Product Information:
Product Name: Acana (unknown variety) Grain Free
Product Type: Pet Food
Lot Number:
Product Use Information: Perceived Relatedness to Adverse Event: Probably related
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: 16.54 Kilogram
Age: 6 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:
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		
	Reported to Other Parties:	None		

Additional Documents:

Report Details - EON-380789

ICSR:	2063157
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 12:56:43 EST

Reported Problem: **Problem Description:** HISTORY [B6] a 9 Yrs. 1 Mos., Spayed Female, Terrier, Soft-Coated Wheaten, was presented on 2/11/2019 for cardiac evaluation [B6] had a slow heart rate noted on physical exam and heart enlargement was noted on radiographs [B6] has had heavy breathing/panting and always seems sluggish. No collapse is noted. No unusual coughing, sneezing, vomiting or diarrhea. No polyuria/polydipsia. Appetite and activity level normal [B6] was evaluated by [B6] [B6] has [B6] She has a history of allergies. She is not on heartworm prevention and is due for vaccines [B6] is fed Instinct Grain Free Raw diet and has been on a grain free diet for life. Current Medications: [B6] Physical Exam HR: 80; RR: 24 Weight: 29.5 lb/13.4 kg Pertinent PE Findings: enucleated OS; mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, no murmur, no arrhythmias, lungs clear, pulses good. Diagnostics Doppler

B6

Chamber size: moderately increased end-diastolic dimensions; severely increased end-systolic dimensions - Free wall thickness: decreased - IVS thickness: decreased - Shortening fraction: moderately to severely decreased - Ejection fraction: depressed - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: normal Right ventricle: - Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: normal 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: scant - Mitral inflows: normal - Mitral annulus motion (TDI): normal - Tricuspid regurgitation: scant - LVOT: normal flow pattern and velocities. - Aortic insufficiency: mild with normal velocities - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none Diagnosis: Dilated cardiomyopathy - rule out diet-related vs. idiopathic Treatment/Medications Discussed whole blood/plasma Taurine testing- owner declined at this time. Recommended transitioning off the grain-free diet to Royal Canin, Science diet, Purina or Iams. Owner is concerned that transitioning off the grain-free diet may cause problems as [B6] has allergies. Gave owner a sample of Science Diet d/d (grain-free but has not been implicated in any cases to date of diet-associated DCM) [B6] tabs- 1 tab PO am, 1/2 tab PO pm Start Taurine 500 mg PO BID and L-carnitine 750 mg PO TID with food A repeat echocardiogram is recommended in 3 months or earlier if clinically indicated.

Date Problem Started:	02/11/2019
Concurrent Medical Problem:	Unknown
Outcome to Date:	Unknown

Product Information:	Product Name:	Instinct Original Grain Free Recipe (unkown 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 - Irish Soft-coated Wheaten	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Age:	9 Years	
	Assessment of Prior Health:	Unknown	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided: No	
	Healthcare Professional Information:	Practice Name:	B6
Contact:		Name:	B6
		Phone:	
Address:		B6	
		United States	
Type of Veterinarian:	Primary/regular veterinarian		
Sender Information:	Name:	B6	
	Contact:	Phone: B6	
	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-381663

ICSR: 2063611
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2019-03-06 10:51:56 EST

Reported Problem:
Problem Description: B6 was presented to B6 emergency for a 3-4 week duration of funny breathing while sleeping. Initially the regular vet thought maybe snoring and also discussed a possible upper respiratory obstruction. The owners report progressive symptoms. Currently, B6 wakes up with a cough-like choke. The owners describes a distended abdomen and a decrease in appetite. He has been sleeping more the past few days but is still playful. He is currently being fed Redford Naturals grain free LID dry and canned food. He has been receiving furosemide twice daily since the weekend and the owners feel that B6 abdominal distention has improved with the diuretic.
Date Problem Started: 01/18/2019
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Redford Naturals LID
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: Intact
Weight: 38.6 Kilogram
Age: 1 Years
Number of Animals Reacted: 1
Owner Information:
 Owner Information provided: Yes
 Contact: Name: B6
 Phone: B6
 Address: B6
 United States
Healthcare Professional Information:
Practice Name: B6
 Contact: Name: B6
 Phone: B6
 Other Phone: B6
 Email: B6
 Address: B6

B6

United States

Sender Information:

Name:

Address:

B6

United States

Contact:

Phone:

Other Phone:

Email:

B6

Permission To Contact Sender: Yes

Preferred Method Of Contact: Email

Additional Documents:

Report Details - EON-378741		
ICSR:	2062177	
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:	2019-02-05 16:03:23 EST	
Reported Problem:	Problem Description: Owner was concerned because pet had been on a grain free diet for several years brought pet to us for exam and blood work, pet has been diagnosed with early DCM and taurine deficiency	
	Date Problem Started: 11/12/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: sportmix, wholesome, lamb and rice, grain free	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Product Use Information:	Description: pet was fed product twice daily
		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
Manufacturer /Distributor Information:		
Purchase Location Information:		
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Collie - Rough-haired	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 51 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 Yes		

		provided:	
		Contact: Name:	B6
		Phone:	
		Address:	B6
			United States
	Healthcare Professional Information:		
Sender Information:	Name:		
	Address:	B6	
		United States	
	Contact:		
	Reporter Wants to Remain Anonymous:	Yes	
	Reported to Other Parties:	Unknown	
Additional Documents:			

Report Details - EON-378349	
ICSR:	2062056
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:	2019-02-01 14:04:13 EST
Reported Problem:	Problem Description: Submitted as RFR EON-376956. CVM resubmitting as PFR. 3 yo patient presented for weight loss and respiratory problems. Found to have dilated cardiomyopathy. Patient has been eating a grain free diet and treats its entire life. Grain free diets have recently been linked to taurine deficiency leading to DCM in dogs. Diet is called Acana Heritage (multiple flavors) Treats are prime nuggets 1 /19/19 Development of dilated cardiomyopathy - respiratory distress, cough, weight loss leading up to date Taurine levels pending
	Date Problem Started: 01/19/2019
	Concurrent Medical Problem: Unknown
	Outcome to Date: Unknown
Product Information:	Product Name: Prime nuggets grain free dog treats
	Product Type: Pet Food
	Lot Number:
	Package Type: POUCH
	Possess Unopened Product: Unknown
	Possess Opened Product: Unknown
	Product Use Information:
	Manufacturer /Distributor Information:
	Purchase Location Information:
	Product Name: Acana Heritage dog food
	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: Unknown
	Reproductive Status: Unknown
	Age: 3 Years
	Assessment of Prior Health: Unknown
	Number of Animals 1

	Reacted:	
	Owner Information:	Owner Information provided: No
	Healthcare Professional Information:	
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact:	B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
Additional Documents:		

Report Details - EON-381165

ICSR:	2063372
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:	2019-02-28 17:45:20 EST

Reported Problem: **Problem Description:** HISTORY: **B6** a 7 Yrs. 2 Mos., Neutered Male, Papillon was presented on 8/9/2017 for cardiac evaluation. He presented to our **B6** service 2 days ago for abdominal ultrasound. **B6** has a ~2 year history of presumed **B6** **B6**. He had been doing fairly well on EOD **B6** therapy and a novel protein:carbohydrate diet. Approximately 1 week ago **B6** seemed to be getting worse and the owner increased the **B6** to once daily therapy; owner has since decreased to EOD again. **B6** continued to deteriorate. Hyporexia has progressed to anorexia. He is lethargic and not interactive with the other dogs. One episode of emesis noted. No history of dietary indiscretion. Labored breathing was noted 2 nights ago. **B6**

B6

B6 The remainder of the abdominal ultrasound was relatively unremarkable. Directed thoracic ultrasound revealed cardiomegaly with right/left heart enlargement. Poor cardiac contractility. Left atrial enlargement. Smoke. Thoracic radiographs: Cardiomegaly with right/left heart enlargement. Left atrial enlargement (bulge). Scalloping of lung lobes on the lateral projection suggestive pleural effusion or chronic pulmonary parenchymal changes. Cardiac silhouette takes up more that 50% of the chest cavity on the VD projection. Increased interstitial infiltrates to the caudal lung lobes. Medications **B6**

B6 Diet: Acana - lamb and apple
Physical Exam Weight: 14.19 lb (6.45 kg) HR- 150; RR- 80 Pertinent PE Findings: Lethargic; mm pale pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, no murmur; muffled heart and lung sounds; mildly increased respiratory effort, no arrhythmias, pulses poor. Abdominal distension, no overt fluid wave. **B6** Normal peripheral lymph nodes Diagnostics ECG:normal sinus rhythm on lead II ECG during echocardiogram with average heart rate of 150 bpm Doppler blood pressure: 140

B6

Comments: There is severe generalized cardiac dilation and severe generalized hypokinesis. All cardiac valves appear normal. There is moderate mitral regurgitation and mild tricuspid regurgitation likely secondary to annular dilation. There is scant pericardial, pleural and mild peritoneal effusion. No cardiac tumors or masses were visualized on exam. Mild spontaneous echocontrast was noted throughout the heart. 2D/M-MODE: Left ventricle: Chamber size: severely dilated - Free wall thickness: normal - IVS thickness: normal - Shortening fraction: normal - Global wall movement: normal - E point to septal separation: normal Left atrial size: normal Right ventricle: Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: normal 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: moderate with decreased velocities - Mitral inflows: restrictive filling pattern - Mitral annulus motion (TDI): normal - Tricuspid regurgitation: mild with mildly increased velocities - LVOT: normal flow pattern with decreased velocities. - Aortic insufficiency: none - RVOT: normal flow pattern with decreased velocities. - Pulmonic insufficiency: none Diagnosis: Dilated cardiomyopathy Suspect right-sided heart failure (peritoneal, pleural, pericardial effusion) Possible pancreatitis

B6 treatment/Medications Start the following: **B6**

B6

BID L-Carnitine 1 gm PO BID - continue **B6** as previously prescribed - add

		B6	if appetite does not improve in the next couple days. - recheck blood work (renal values/lytes) and effusion volume in 1-2 weeks. - a repeat echocardiogram is recommended in 3 months or earlier if clinically indicated.	
	Date Problem Started:	08/09/2017		
	Date of Recovery:	11/09/2017		
	Outcome to Date:	Better/Improved/Recovering		
Product Information:	Product Name:	Acana		
	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:	Papillon - Spaniel - Continental Toy (with erect ears or with dropped ears (Phaléne))		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	6.45 Kilogram		
	Age:	7 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:	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-363214

ICSR: 2054139
 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: 2018-08-23 12:06:06 EDT

Reported Problem:

Problem Description: The patient was diagnosed with congestive heart failure and dilated cardiomyopathy on 7/20/18. B6 has been eating a kangaroo grain free diet. Taurine levels performed the time of diagnosis of the CHF showed low taurine levels.

Date Problem Started: 07/20/2018

Concurrent Medical Problem: No

Outcome to Date: Stable

Product Information:

Product Name: Zignature Kangaroo Formula (Limited Ingredient Formula)

Product Type: Pet Food

Lot Number: Lot Number: 7M12P 1347 3
 Expiration Date: 06/12/2019

UPC: 8 88641 13132 7

Package Type: BAG

Package Size: 27 Pound

Purchase Date: 06/25/2018

Number Purchased: 1

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Storage Conditions: Stored partially in plastic containers, remaining food stays in bag (closed).

Product Use Information:

Description: Served in a dog bowl.

Last Exposure Date: 08/23/2018

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: Unknown

Manufacturer /Distributor Information:

Purchase Location Information: Name: [Redacted] Address: [Redacted]

B6

			B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Spaniel - Cocker American		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	15 Kilogram		
	Age:	2 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:	B6	
Address:	B6 United States			
Healthcare Professional Information:				
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:	Attachment:	B6	145-1 8-23-18 (2).doc	
	Description:	Echocardiogram Report		
	Type:	Letter		

Report Details - EON-363894

ICSR:	2054490		
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 16:11:23 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	B6 was eating grain-free lamb and rice food for the last two years. She began collapsing when running hard at the end of May. I took her to the vet and he suspected DCM. Vet said she was not yet in congestive heart failure. I took her to a specialist for an echo cardiogram and chest x-ray and the diagnosis was confirmed. Consulted with a cardiologist and he put her on three heart medications and suggested a taurine level test. That test confirmed very low plasma taurine levels. We added a taurine supplement to her meds. Two weeks later and EKG showed marked improvement. She seems to have recovered her energy. She will have a follow-up echo cardiogram in November to see if the DCM has improved.	
	Date Problem Started:	05/13/2018	
	Date of Recovery:	08/30/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	Product Name:	Castor and Pollux Grain Free Lamb and Rice	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	I don't have this	
	Package Type:	BAG	
	Package Size:	22 Pound	
	Purchase Date:	05/01/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In a sealed container	
	Product Use Information:	Description:	Fed two cups twice a day
		First Exposure Date:	05/01/2018
		Last Exposure Date:	05/31/2018
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	Definitely related		

		Relatedness to Adverse Event:	
		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:	Retriever - Labrador	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	94 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:		
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:			

Report Details - EON-364590

ICSR:	2054752		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date:	2018-09-07 18:56:17 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	B6 began coughing so went to vet. Was diagnosed with bronchitis but owner was asked if we wanted to do an x-ray to be safe to which we opted to do. Radiologist noticed enlarged heart. Was sent to B6 for Echo and testing. Results confirmed Taurine Deficient DCM with a whole blood Taurine level of 28. B6 has eaten Acana Lamb and Apple for the last 6 years.	
	Date Problem Started:	08/27/2018	
	Date of Recovery:	09/07/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Acana Lamb and Apple Singles Formula with Grass - Fed Kentucky Lamb & Red Delicious Apples	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	6499251025	
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	08/01/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Stored in an air tight plastic dog food container in the bag	
	Product Use Information:	Description:	Given 1c/2X daily
		Last Exposure Date:	08/27/2018
		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:		Unknown	
Product Use Started Again:		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:

Name:

Address:

B6

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Retriever - Golden

Gender: Male

Reproductive Status: Neutered

Weight: 88 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:

Address:

B6

United States

Type of
Veterinarian: Primary/regular veterinarian

Date First Seen: 08/21/2018

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: 08/27/2018

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:	Phone	
Reported to Other Parties:	Other Store/Place of Purchase Manufacturer		

Additional Documents:

Report Details - EON-364718		
ICSR:	2054783	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-09-09 16:21:16 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: [B6] was coughing frequently. I took her into her primary vet [B6] Hospital, on [B6]. He mis-diagnosed her with Kennel Cough. On 08/21/2018, I had to take her into another veterinary establishment. We were out of town visiting family, and I had [B6] with me. Her symptoms included: shallow breathing, coughing, loss of appetite, one eye dilated more than the other, and lethargy. The coughing did not go away, and her overall health declined rapidly. I had x-rays and blood work performed at [B6] Hospital, and the results of the x-rays determined she had an enlarged heart, and water build-up in her lungs. During the same day, she was referred to [B6] [B6] to have an echocardiogram performed. They also performed a Taurine test during this time. The Taurine test shown her to be taurine deficient. They had prescribed her various medications and was diagnosed with Congestive Heart Failure DCM. She is continuing her follow-up visits & tests with her primary vet for DCM, and also has an appointment with [B6] to visit an optometrist for her eye dilation issue. Her echocardiogram report states the grain free diet is quite suspect, and recommended changing her diet immediately.	
	Date Problem Started: 07/26/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: DIAMOND NATURALS GRAIN-FREE WILD-CAUGHT WHITEFISH & SWEET POTATO FORMULA FOR DOGS	
	Product Type: Pet Food	
	Lot Number: Lot Number: 8178 ONW0603 LGM 03:38 337 Expiration Date: 06/27/2019	
	UPC: 074198611553	
	Package Type: BAG	
	Package Size: 28 Pound	
	Purchase Date: 08/18/2018	
	Number Purchased: 4	
	Possess Unopened Product: Yes	
	Possess Opened Product: Yes	
	Storage Conditions: Sealed bags stored at room temperature next to food bin. Opened bag stored in food bin at room temperature.	
	Product Use Information:	Description: 1 Cup in the morning & 1 Cup in the evening by mouth.
		Last Exposure Date: 08/21/2018
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: 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: [Redacted] Address: [Redacted] United States

Animal Information:

Name: [Redacted]

Type Of Species: Dog

Type Of Breed: Pit Bull

Gender: Female

Reproductive Status: Neutered

Weight: 64.5 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: [Redacted]

Contact: Name: [Redacted] Phone: [Redacted] Email: [Redacted]

Address: [Redacted] United States

Type of Veterinarian: Primary/regular veterinarian

Date First Seen: 07/30/2018

Permission to Release Records to FDA: Yes

Practice Name: [Redacted]

Contact: Name: [Redacted] Phone: [Redacted] Email: [Redacted]

Address: [Redacted]

			B6
		United States	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	08/21/2018	
	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:	08/21/2018	
	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:	None	
Additional Documents:	Attachment:	B6	DCM Medical Record 011.jpg
	Description:	B6	X-RAY
	Type:	Radiographs	
	Attachment:	B6	DCM Medical Record 006.jpg
	Description:	B6	REPORT
	Type:	Analysis	
	Attachment:	B6	DCM Medical Record 019.jpg
	Description:	B6	TAURINE TEST
	Type:	Laboratory Report	
	Attachment:	B6	DCM Medical Record 018.jpg
	Description:	B6	REPORT
	Type:	Echocardiogram	
	Attachment:	B6	DCM Medical Record 004.jpg
	Description:	B6	
	Type:	Laboratory Report	

Report Details - EON-365076

ICSR:	2054879
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-09-12 14:20:11 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 had developed Cardiomyopathy due to her Grain-Free Dog Food Diet. She had fluid build up which made it very difficult for to breath, eventually eat or drink water. Original symptoms were coughing which at first was thought by our Veterenarian she had an irritant in her throat area and was treated. Within a few days of not getting better and medicine administered made her sick, tried another medicine for a few days which did not improve her breathing and then was quickly brought to B6 for further treatment and eventually could not save her. She had been fed Grain-Free Dog Food since 2014.
	Date Problem Started:	08/05/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Earthborn Holistic Coastal Grain Free Natural Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	Do not have it		
	Package Type:	BAG		
	Package Size:	28 Pound		
	Purchase Date:	08/15/2016		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Large Plastic Container in closet		
	Product Use Information:	Description:	Dry Dog Food 1 Cup Morning, 1 Cup Night	
		Last Exposure Date:	09/24/2016	
		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:		Yes		
Manufacturer /Distributor Information:				

	Purchase Location Information:	Name:	Chewy.com
		Address:	3251 Hollywood Blvd Set 401 Hollywood Florida 33021 United States
	Product Name:	Weruva Caloric Melody Chicken, Turkey & Salmon Dinner with Lentils Gran-Free Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	Threw bag away	
	Package Type:	BAG	
	Package Size:	24 Pound	
	Purchase Date:	07/22/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Product Use Information:		
	Manufacturer /Distributor Information:		
Purchase Location Information:	Name:	Chewy.com	
	Address:	3251 Hollywood Blvd Set 401 Hollywood Florida 33021 United States	
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	65 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:			
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 Distributor

Additional Documents:

Report Details - EON-359175

ICSR:	2052003
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 22:22:02 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Dog developed Dilated Cardiomyopathy and was in congestive heart failure.
	Date Problem Started:	03/16/2017
	Date of Recovery:	07/13/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	ACANA Lamb and Apple singles Formula		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	03/16/2017		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in original package		
	Product Use Information:	Description:	1 cup fed twice per day.	
		First Exposure Date:	03/16/2017	
		Last Exposure Date:	03/16/2017	
		Time Interval between Product Use and Adverse Event:	1 Years	
		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		
	Address:			United States

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	85 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:		03/17/2017		
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6		
	Address:	B6		
		United States		
	Contact:	Phone:	B6	
	Reporter Wants to Remain Anonymous:	No		
Permission To Contact Sender:	Yes			
Preferred Method Of Contact:	Phone			
Reported to Other Parties:	Store/Place of Purchase			
Additional Documents:				

Report Details - EON-365810

ICSR: 2055063
 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: 2018-09-18 14:27:58 EDT

Reported Problem:
 Problem Description: Diet Associated Dilated Cardiomyopathy
 Date Problem Started: 06/15/2017
 Outcome to Date: Worse/Declining/Deteriorating

Product Information:
 Product Name: Nutri Source Chicken and Pea Formula
 Product Type: Pet Food
 Lot Number:
 Product Use Information:
 Stopped After the Onset of the Adverse Event: Yes
 Product Use Started Again: No
 Perceived Relatedness to Adverse Event: Definitely related
 Manufacturer /Distributor Information:
 Purchase Location Information:

Animal Information:
 Name: **B6**
 Type Of Species: Dog
 Type Of Breed: Retriever - Golden
 Reproductive Status: Neutered
 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: **B6**
 Address: **B6**
 United States
 Healthcare Professional Information:
 Practice Name: **B6**
 Contact: Name: **B6**
 Phone: **B6**
 Email:
 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-361002

ICSR:	2053056
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:	2018-07-31 19:30:53 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was fed Fromm Heartland Gold large breed grain free dog food since she was a pup at roughly 12 weeks old. She has always been healthy and was seen by her vet in the spring of 2018, with a clean bill of health. In mid July, 2018, she began to stop eating all of her meals. She began to pant heavily, even at rest and she developed some coughing. We took her to the vet on July 27 where she was examined and placed on B6 for a 104 degree fever and slight white cell count. Her heart rate was in the 150s. When she did not improve over the weekend, we returned to the vet July 30 where they did xrays and an echocardiogram. The echo revealed an enlarged heart, fluid build up, heart rate in the 200s. She has been referred to cardiology for further testing. The vet sent to have her Taurine level tested. The vet believes this is induced from her grain free diet. B6 has no history of heart disease in her AKC family bloodline. She has no history of murmur or irregular heart sounds. She will begin Taurine supplements, was taken off grain free food, started B6 twice daily, placed on antibiotics and will begin additional cardiac meds per cardiology orders.
	Date Problem Started:	07/18/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Fromm Large Breed Heartland Gold Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	7270510410	
	Package Type:	BAG	
	Package Size:	26 Pound	
	Purchase Date:	07/11/2018	
	Number Purchased:	3	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	Yes	
	Storage Conditions:	Storage bin from Petco once open. 1 bag every 4-5 days.	
	Product Use Information:	Description:	Dry food fed orally twice daily
		First Exposure Date:	07/11/2018
Last Exposure Date:		07/29/2018	
Time Interval between Product Use and Adverse Event:		2 Weeks	
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:	Great Dane	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	150 Pound	
	Age:	2 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:	
		Other Phone:	
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	07/27/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:		
			United States
	Contact: Phone:	B6	
	Other Phone:		

Email

B6

Permission To Contact Sender: Yes

Preferred Method Of Contact: Phone

Reported to Other Parties: Other

Additional Documents:

Attachment: AD21632F-A283-4E10-B900-8740301E625A.jpeg

Description: Vet instructions

Type: Specification

Attachment: 641CB530-C4B3-4016-A2E2-BE6D11096C09.jpeg

Description: Vet receipt

Type: Record

Report Details - EON-361320		
ICSR:	2053222	
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:	2018-08-03 19:12:08 EDT	
Reported Problem:	Problem Description: Murmur was discovered as part of his annual physical exam and pre-dental procedure. B6 is examined on an annual basis. B6 is acting completely normally at home. He has an excellent appetite, no vomiting, no diarrhea, no coughing, no sneezing, no change in water intake nor urination. He is considered to be playful and active. B6 has not ever been winded or get tired during his activities on or walks. B6 has a history of allergic dermatitis and is managed with a kangaroo diet. Historically periodically treated with B6. One of two dogs in the home.	
	Date Problem Started: 02/15/2018	
	Date of Recovery: 02/15/2018	
	Concurrent Medical Problem: Unknown	
	Outcome to Date: Stable	
Product Information:	Product Name: Zignature (brand) Kangaroo Kibble Limited Ingredient Diet	
	Product Type: Pet Food	
	Lot Number:	
	Possess Unopened Product: Unknown	
	Possess Opened Product: Unknown	
	Product Use Information:	Description: Zignature Brand Kangaroo Kibble Limited Ingredient Diet for a relatively long time. *NOTE: I have asked the family to put several cups of this diet in a bag and keep in the fridge for the short term. It would also be worthwhile for the family to keep the original food packaging so that we can get the lot number and manufacturing information etc if needed.
		Last Exposure Date: 03/21/2018
		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		
Manufacturer /Distributor Information:		
Purchase Location Information:	Address: Canada	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Terrier - Yorkshire	
	Gender: Male	
	Reproductive Status: Neutered	

	Weight: 3.56 Kilogram
	Age: 6 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] Phone: [Redacted] Other Phone: [Redacted] Email: [Redacted]
	Address: [Redacted] Canada
Healthcare Professional Information:	Practice Name: [Redacted]
	Contact: Name: [Redacted] Phone: [Redacted]
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 02/15/2018
Sender Information:	Name: [Redacted]
	Address: [Redacted] Canada
	Contact: Phone: [Redacted] 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] Records.pdf
	Description: [Redacted] records from his referring veterinarian [Redacted]
	Type: Medical Records
	Attachment: [Redacted] Rads 03.jpg
	Description: Radiographs from referring veterinarian [Redacted]
	Type: Radiographs
	Attachment: [Redacted] Records.pdf
	Description: [Redacted] records and diagnostic reports from our hospital [Redacted]
	Type: Medical Records

Attachment:	B6	Rads 01.jpg
Description:	Radigraphs from referring veterinarian	B6
Type:	Radiographs	
Attachment:	B6	Rads 02.jpg
Description:	Radigraphs from referring veterinarian	B6
Type:	Radiographs	

Report Details - EON-359942

ICSR:	2052515
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:	2018-07-20 22:58:12 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	In October of 2017, B6 began wheezing and coughing. Went to vet who noted heart murmur and took chest x-rays on his lungs. B6 was treated for pneumonia, but was still hacking. He became a bit lethargic and tired easily, breathing became heavier. B6 was also constantly hungry and losing weight. Diagnosed with heart disease and given medication. He had what I suspected was a seizure (non-responsive). I shook him out of it. More recently he has been collapsing when stressed. Read FDA article on pet food and realized that this sounded like: B6
	Date Problem Started:	10/01/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Nutro Hearty Stews Senior canned		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	CAN		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	unopened in pantry/opened in fridge		
	Product Use Information:	Description:	This food was used as a substitute for Nutro Ultra on some days. Dog would be given 1/4 can morning and night.	
		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:	Pet Smart	
		Address:	B6 United States	
	Product Name:	Product Name:	Nutro Ultra Weight Management Adult canned food	
Product Type:		Pet Food		
Lot Number:				
Package Type:		CAN		
Possess Unopened Product:		No		

	Possess Opened Product:	No														
	Storage Conditions:	Unopened in the pantry. Opened in the refrigerator.														
	Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>1/2 can along with 1/4 cup of dry food morning and night.</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>Possibly related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	1/2 can along with 1/4 cup of dry food morning and night.	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						
Description:	1/2 can along with 1/4 cup of dry food morning and night.															
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:	<table border="1"> <tr> <td>Name:</td> <td>Pet Smart</td> </tr> <tr> <td>Address:</td> <td>B6 United States</td> </tr> </table>	Name:	Pet Smart	Address:	B6 United States										
Name:	Pet Smart															
Address:	B6 United States															
Animal Information:	Name:	B6														
	Type Of Species:	Dog														
	Type Of Breed:	Terrier - Rat														
	Gender:	Male														
	Reproductive Status:	Neutered														
	Weight:	20 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:	<table border="1"> <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>Other Phone:</td> <td></td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td>B6 United States</td> </tr> <tr> <td>Type of Veterinarian:</td> <td>Primary/regular veterinarian</td> </tr> <tr> <td>Permission to Release Records to FDA:</td> <td>Yes</td> </tr> </table>	Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Other Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Other Phone:		Address:	B6 United States	Type of Veterinarian:	Primary/regular veterinarian	Permission to Release Records to FDA:	Yes
Contact:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Other Phone:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Other Phone:										
Name:	B6															
Phone:																
Other Phone:																
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:	<table border="1"> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Other Phone:</td> <td></td> </tr> </table>	Phone:	B6	Other Phone:											
Phone:	B6															
Other Phone:																

Email:

B6

**Permission To Contact
Sender:** Yes

**Preferred Method Of
Contact:** Email

**Reported to Other
Parties:** Other

Additional Documents:

Report Details - EON-360871

ICSR:	2052960
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:	2018-07-30 19:50:24 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 has been fed rotating proteins of Zignature dry and canned food since he was a puppy. He was diagnosed with DCM on June 28 by Dr. B6 of B6. She informed us that dogs fed solely a grain-free diet where peas and legumes are included have been developing DCM. It was suggested by many parties that a report should be filed with your office.	
	Date Problem Started:	06/28/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6 We have since determined the cause to be B6 in the course of diagnosing the cause of his many symptoms, an internal medicine specialist determined that he had Dilated Cardiomyopathy June 28.	
	Outcome to Date:	Stable	

Product Information:	Product Name:	Zignature Canned (All protein formulas)		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	P7ZLPK7052A	
		Expiration Date:	07/01/2020	
	UPC:	886411316		
	Package Type:	CAN		
	Package Size:	13 Ounce		
	Purchase Date:	05/05/2018		
	Number Purchased:	12		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	No		
	Storage Conditions:	With lid in fridge.		
	Product Use Information:	Description:	Used as food topper. Fed approx 2 Tb per day.	
		Last Exposure Date:	06/28/2018	
		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:	Name:	Pets Global Inc
	Type(s):	Manufacturer
	Address:	28334 Industry Drive Valencia California 91355 United States
	Contact:	Phone: (888) 897-7207 Web Address: www.zignature.com
	Possess One or More Labels from This Product:	Yes
Purchase Location Information:	Name:	chewy.com
Product Name:	Zignature (various protein formulas fed)	
Product Type:	Pet Food	
Lot Number:		
UPC:	8864113110	
Package Type:	BAG	
Package Size:	27 Pound	
Purchase Date:	06/03/2018	
Number Purchased:	1	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Storage Conditions:	Stored in the bag with a clip to close.	
Product Use Information:	Description:	Fed twice daily as main source of nutrition.
	Last Exposure Date:	06/28/2018
	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:	Name:	chewy.com
Purchase Location Information:	Address:	United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	67 Pound
	Age:	4 Years

	Assessment of Prior Health:	Poor																																
	Number of Animals Reacted:	1																																
	Owner Information:																																	
	Healthcare Professional Information:	<table border="1"> <tr> <td data-bbox="665 247 885 291">Practice Name:</td> <td data-bbox="885 247 1554 291">B6</td> </tr> <tr> <td data-bbox="665 291 885 377">Contact:</td> <td data-bbox="885 291 1554 377"> <table border="1"> <tr> <td data-bbox="885 291 1047 334">Name:</td> <td data-bbox="1047 291 1554 334">B6</td> </tr> <tr> <td data-bbox="885 334 1047 377">Phone:</td> <td data-bbox="1047 334 1554 377"></td> </tr> </table> </td> </tr> <tr> <td data-bbox="665 377 885 506">Address:</td> <td data-bbox="885 377 1554 506">B6</td> </tr> <tr> <td data-bbox="665 506 885 571">Type of Veterinarian:</td> <td data-bbox="885 506 1554 571">Referred veterinarian</td> </tr> <tr> <td data-bbox="665 571 885 614">Date First Seen:</td> <td data-bbox="885 571 1554 614">06/28/2018</td> </tr> <tr> <td data-bbox="665 614 885 700">Permission to Release Records to FDA:</td> <td data-bbox="885 614 1554 700">Yes</td> </tr> <tr> <td data-bbox="665 700 885 743">Practice Name:</td> <td data-bbox="885 700 1554 743">B6</td> </tr> <tr> <td data-bbox="665 743 885 830">Contact:</td> <td data-bbox="885 743 1554 830"> <table border="1"> <tr> <td data-bbox="885 743 1047 786">Name:</td> <td data-bbox="1047 743 1554 786">B6</td> </tr> <tr> <td data-bbox="885 786 1047 830">Phone:</td> <td data-bbox="1047 786 1554 830"></td> </tr> </table> </td> </tr> <tr> <td data-bbox="665 830 885 980">Address:</td> <td data-bbox="885 830 1554 980">B6 United States</td> </tr> <tr> <td data-bbox="665 980 885 1045">Type of Veterinarian:</td> <td data-bbox="885 980 1554 1045">Referred veterinarian</td> </tr> <tr> <td data-bbox="665 1045 885 1088">Date First Seen:</td> <td data-bbox="885 1045 1554 1088">07/23/2018</td> </tr> <tr> <td data-bbox="665 1088 885 1196">Permission to Release Records to FDA:</td> <td data-bbox="885 1088 1554 1196">Yes</td> </tr> </table>	Practice Name:	B6	Contact:	<table border="1"> <tr> <td data-bbox="885 291 1047 334">Name:</td> <td data-bbox="1047 291 1554 334">B6</td> </tr> <tr> <td data-bbox="885 334 1047 377">Phone:</td> <td data-bbox="1047 334 1554 377"></td> </tr> </table>	Name:	B6	Phone:		Address:	B6	Type of Veterinarian:	Referred veterinarian	Date First Seen:	06/28/2018	Permission to Release Records to FDA:	Yes	Practice Name:	B6	Contact:	<table border="1"> <tr> <td data-bbox="885 743 1047 786">Name:</td> <td data-bbox="1047 743 1554 786">B6</td> </tr> <tr> <td data-bbox="885 786 1047 830">Phone:</td> <td data-bbox="1047 786 1554 830"></td> </tr> </table>	Name:	B6	Phone:		Address:	B6 United States	Type of Veterinarian:	Referred veterinarian	Date First Seen:	07/23/2018	Permission to Release Records to FDA:	Yes
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Date First Seen:	07/23/2018																																	
Permission to Release Records to FDA:	Yes																																	
	Sender Information:	<table border="1"> <tr> <td data-bbox="665 1196 1079 1239">Name:</td> <td data-bbox="1079 1196 1554 1239">B6</td> </tr> <tr> <td data-bbox="665 1239 1079 1390">Address:</td> <td data-bbox="1079 1239 1554 1390">B6 United States</td> </tr> <tr> <td data-bbox="665 1390 1079 1498">Contact:</td> <td data-bbox="1079 1390 1554 1498"> <table border="1"> <tr> <td data-bbox="1079 1390 1209 1433">Phone:</td> <td data-bbox="1209 1390 1554 1433"></td> </tr> <tr> <td data-bbox="1079 1433 1209 1498">Email:</td> <td data-bbox="1209 1433 1554 1498">B6</td> </tr> </table> </td> </tr> <tr> <td data-bbox="665 1498 1079 1563">Permission To Contact Sender:</td> <td data-bbox="1079 1498 1554 1563">Yes</td> </tr> <tr> <td data-bbox="665 1563 1079 1627">Preferred Method Of Contact:</td> <td data-bbox="1079 1563 1554 1627">Phone</td> </tr> <tr> <td data-bbox="665 1627 1079 1692">Reported to Other Parties:</td> <td data-bbox="1079 1627 1554 1692">Other</td> </tr> </table>	Name:	B6	Address:	B6 United States	Contact:	<table border="1"> <tr> <td data-bbox="1079 1390 1209 1433">Phone:</td> <td data-bbox="1209 1390 1554 1433"></td> </tr> <tr> <td data-bbox="1079 1433 1209 1498">Email:</td> <td data-bbox="1209 1433 1554 1498">B6</td> </tr> </table>	Phone:		Email:	B6	Permission To Contact Sender:	Yes	Preferred Method Of Contact:	Phone	Reported to Other Parties:	Other																
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Phone:																																		
Email:	B6																																	
Permission To Contact Sender:	Yes																																	
Preferred Method Of Contact:	Phone																																	
Reported to Other Parties:	Other																																	
	Additional Documents:																																	

Report Details - EON-362724

ICSR:	2053904
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:	2018-08-17 22:40:50 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My pet B6 was diagnosis (06/2018) with dilated cardiomyopathy.
	Date Problem Started:	06/08/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Other
	Date of Death:	B6

Product Information:	Product Name:	4health Grain-Free Large Breed Formula Adult Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	13 Pound		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Dog food container		
	Product Use Information:	Description:	1cup mixed	
		First Exposure Date:	02/01/2018	
		Last Exposure Date:	04/01/2018	
		Time Interval between Product Use and Adverse Event:	3 Months	
		Product Use Stopped After the Onset of the Adverse Event:	Yes	
		Adverse Event Abate After Product Stop:	Unknown	
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Probably related		
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	Tractor Supply		
	Address:	B6 United States		
Product Name:	Wellness Grain-Free Complete Health Large Breed Adult Deboned Chicken &			

	Chicken Meal Recipe Dry Dog Food, 24-lb bag	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Package Size:	24 Pound	
Number Purchased:	2	
Possess Unopened Product:	Yes	
Possess Opened Product:	Yes	
Storage Conditions:	Stored in dog food container	
Product Use Information:	Description:	2 cups morning/evening
	First Exposure Date:	04/03/2017
	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
	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:	Chewy website
	Address:	United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Mastiff
	Gender:	Male
	Reproductive Status:	Intact
	Weight:	167 Pound
	Age:	2 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:
		Phone:

		Email:	B6
	Address:	B6	
		United States	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	06/08/2018	
	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:	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-362482	
ICSR:	2053816
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:	2018-08-16 12:39:15 EDT
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: B6 Dog doing well then noticed poor appetite. After three days took her to the vet where tests showed liver numbers elevated. Given medication and sent home. Three days later tested again and numbers were good. 24 hours later she was extremely lethargic. We then took her to the emergency hospital. Admitted and given oxygen, tests done, 48 hours later determined her heart was not working properly, prognosis very poor, nothing else to be done. Euthanized later that day. Hospital records have been sent to Dr. Lauren Carey - Adverse Event Review Team - Lauren.Carey@fda.hhs.gov
	Date Problem Started: B6
	Concurrent Medical Problem: No
	Outcome to Date: Died Euthanized
	Date of Death: B6
Product Information:	Product Name: Fromm four star nutritional grain free dry food
	Product Type: Pet Food
	Lot Number:
	Possess Unopened Product: No
	Possess Opened Product: No
	Storage Conditions: sorted in fridge in air tight container.
	Product Use Information: Description: 1/4 cup twice a day
	Manufacturer /Distributor Information:
	Purchase Location Information: Name: B6
	Address: B6
Animal Information:	Name: B6
	Type Of Species: Dog
	Type Of Breed: Shih Tzu
	Gender: Female
	Reproductive Status: Neutered
	Weight: 13 Pound
	Age: 8 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
		Other Phone:	
	Address:	B6	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	B6	
	Permission to Release Records to FDA:	Yes	
	Practice Name:	B6	
	Contact: Name:	B6	
	Phone:		
	Other Phone:		
	Address:	B6	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	B6	
	Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	B6	
	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-361876

ICSR:	2053575	
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 21:19:19 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description:	<p>Regarding Nature's Domain Puppy Chicken and Pea Formula dog food. I have been breeding OFA health certified / International Champion Labrador Retrievers for eleven years now. I have been in the veterinary field for 22 years. I am also a certified dog trainer. In November 2016 I started feeding Costco's Nature's Domain Puppy Chicken and Pea Formula dog food to my whelping bitches and their puppies. I only changed to this puppy food after Costco quit carrying another brand I had used for over 20 years without issue. I recommended this Nature's Domain Puppy Chicken and Pea Formula dog food to my puppy's new owners. In March of this year a 10 ½ month old client's puppy died from congestive heart failure. In July of this year a puppy from the same litter, different owner, also died from congestive heart failure, this one at 14 ½ months old. I own both the sire and dam to this litter. They both have their OFA heart clearances done by a canine cardiac specialist. The dam to this litter has previously produced 28 healthy puppies for me and the sire has produced 88 healthy puppies for me, none with any sort of heart issue. The only thing that had changed for this litter was the puppy food! I also personally kept three young females that were on the Nature's Domain Puppy Chicken and Pea Formula dog food out of three different dams, three different litters, to hopefully add to my future breeding program. All three females that I have kept, one the full sister to the two that died from the aforementioned litter (she is now 15 months old), one that is 19 months old, and the other that is now 21 months old, are all ten pounds under the AKC breed standard size for being an adult Labrador Retriever show dog. Once again the only difference in raising these girls is that they were fed the Nature's Domain Puppy Chicken and Pea Formula dog food! I had suspected the Nature's Domain Puppy Chicken and Pea Formula dog food after reading several articles about dangers of peas in dog food and the fact that peas are high in lectins. Apparently, lectins line the intestine as well as stomach and interfere with the absorption of nutrients. The Nature's Domain Puppy Chicken and Pea Formula dog food's main ingredients are listed in this order: Chicken, chicken meal, peas, garbanzo beans, lentils, fava beans, sweet potatoes. Five of the seven main ingredients high in lectins. I then promptly contacted all of my clients and recommended they change puppy food immediately, attaching articles to validate my concerns. I was able to go back to my original puppy food in April of this year when I discovered that I could order it from Costco online. In May I contacted Costco Customer Service who then contacted [B6] DVM, Kirkland Signature Pet Foods Customer Support Team, with no acknowledgment of my concerns. I have spoken to my veterinarian and he agrees with my assessment and the correlation between the Costco's Nature's Domain Puppy Chicken and Pea Formula, the heart issues and deaths of my client's puppies, as well as the three small undersized adult dogs that I now have. I have asked him to write a letter for [B6] I was very pleased to see the July 12 statement of the FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease. It brought credibility to my concerns. I have copies of veterinary records for my client's deceased puppies. I currently still have my three young adult females. I also have a client that recently lost their unrelated almost eight year dog from DCM out of a different OFA heart cleared sire, that was feed the grain free Taste of the Wild for the past six years. I'd certainly appreciate continued research into this matter as we are doing a great disservice to the public letting them believe they are loving their beloved pets while they are unknowingly actually killing them with grain free foods.</p>
	Date Problem Started:	11/01/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Not Applicable
Product Information:	Product Name:	Nature's Domain Puppy Chicken and Pea Formula

	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Package Size: 40 Pound
	Possess Unopened Product: No
	Possess Opened Product: No
	Storage Conditions: Stored in the garage unopened. Once opened stored in secure plastic dog food bins.
	Product Use Information:
	Description: Fed dry to my dogs twice daily
	First Exposure Date: 11/01/2016
	Last Exposure Date: 04/01/2018
	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 - Labrador
	Gender: Female
	Reproductive Status: Intact
	Pregnancy Status: Not pregnant
	Lactation Status: Not lactating
	Weight: 55 Pound
	Age: 1 Years
	Assessment of Prior Health: Excellent
	Number of Animals Reacted: 5
	Owner Information:
	Healthcare Professional Information:
	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Address: B6

			B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		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:	Other Manufacturer Distributor Store/Place of Purchase	
Additional Documents:			

Report Details - EON-361866

ICSR:	2053572
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-08-10 19:05:30 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I had 2 golden retrievers and had both dogs on nature's domain from costco, the grain free food. I initially started them on the salmon and sweet potato formula years ago and then discovered they had an organic version and wanted to the right thing for my dogs so started to feed them that. 15 months ago B6 was diagnosed with dilated cardio myopathy. she is on a cocktail of medication and now I have discovered that this possibly was caused due to the lack of taurine in the diet. the orange food in particular contains a large amount of pea protein which has been found to be one of the culprits among other things for DCM developing. After changing her food and supplements there has been a small improvement in her cardiac activity. she has seen had another echo so three in all and she has plateaued
	Date Problem Started:	04/04/2017
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Stable

Product Information:	Product Name:	Nature's domain Organic chicken and Pea purchased at costco		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	04/01/2017		
	Number Purchased:	1		
	Possess Unopened Product:	Unknown		
	Possess Opened Product:	No		
	Storage Conditions:	food was stored in a pantry in the kitchen		
	Product Use Information:	Description:	i fed both my retrievers one cup of food twice a day	
		First Exposure Date:	04/01/2017	
		Last Exposure Date:	06/14/2017	
		Product Use Stopped After the Onset of the Adverse Event:	Unknown	
		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 Address: B6 United States
Animal Information:	Name: B6	olden retriever
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	82 Pound
	Age:	6 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: 04/01/2017
Sender Information:	Name:	
	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:	Distributor
Additional Documents:		

Report Details - EON-361855		
ICSR:	2053566	
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 16:47:18 EDT	
Reported Problem:	Problem Description: Taurine deficiency found on whole blood testing.	
	Date Problem Started: 07/12/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Not Applicable	
Product Information:	Product Name: Royal Canin, Ultamino	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Storage Conditions: Product was stored in the bag from the manufacturer in our laundry room up to one week then after opening was placed in a dog food bin with a lid.	
	Product Use Information:	First Exposure Date: 11/16/2017
		Last Exposure Date: 01/24/2018
		Time Interval between Product Use and Adverse Event: 3 Months
		Product Use Stopped After the Onset of the Adverse Event: No
		Other Foods or Products Given to the Animal During This Time Period: Unknown
		Manufacturer /Distributor Information:
	Purchase Location Information:	
	Product Information:	Product Name: Fromm Grain Free Heartland Gold, large breed puppy formula.
		Product Type: Pet Food
Lot Number:		
Package Type: BAG		
Storage Conditions: Product was stored in the bag from the manufacturer in our laundry room up to one week then after opening was placed in a dog food bin with a lid.		
Product Use Information:		Description: [B6] age 2 [B6] from 9 weeks to 1 year was on Fromm Grain Free Heartland Gold, large breed puppy formula. He was fed this kibble twice daily. The first 5 ingredients in this formula are: Beef, Pork meat meal, PEAS, LENTILS, CHICKPEAS and POTATOES. At one year I transitioned [B6] to Zignature grain free diet that my other Golden [B6] was on [B6] has been on Zignature grain free since then, 13 months.
		First Exposure Date: 09/01/2016
		Last Exposure Date: 06/30/2017

		Date:	
		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:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	Zignature Salmon Formula Limited ingredient formula	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Storage Conditions:	Product was stored in the bag from the manufacturer in our laundry room up to one week then after opening was placed in a dog food bin with a lid.	
	Product Use Information:	First Exposure Date:	09/01/2014
		Last Exposure Date:	07/29/2018
		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:	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:	64 Pound	
	Age:	2 Years	

Assessment of Prior Health:	Excellent														
Number of Animals Given the Product:	2														
Number of Animals Reacted:	2														
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
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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:								
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United States															
Type of Veterinarian:	Referred veterinarian														
Date First Seen:	11/16/2017														
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></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	Name:	B6	Phone:		Email:									
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B6															
United States															
Type of Veterinarian:	Referred veterinarian														
Date First Seen:	07/31/2018														
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		
Additional Documents:	Attachment:	B6	2018-07-10-1618.pdf
	Description:	Taurine bloodwork	
	Type:	Analysis	

Report Details - EON-361857

ICSR: 2053567
 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 16:48:35 EDT

Reported Problem:
Problem Description: Taurine deficiency found on whole blood testing.
Date Problem Started: 07/12/2018
Concurrent Medical Problem: No
Outcome to Date: Not Applicable

Product Information:
Product Name: Royal Canin, Ultamino
Product Type: Pet Food
Lot Number:
Package Type: BAG
Storage Conditions: Product was stored in the bag from the manufacturer in our laundry room up to one week then after opening was placed in a dog food bin with a lid.
Product Use Information:
First Exposure Date: 11/16/2017
Last Exposure Date: 01/24/2018
Time Interval between Product Use and Adverse Event: 3 Months
Product Use Stopped After the Onset of the Adverse Event: No
Other Foods or Products Given to the Animal During This Time Period: Unknown

Manufacturer /Distributor Information:
Purchase Location Information:

Product Name: Fromm Grain Free Heartland Gold, large breed puppy formula.
Product Type: Pet Food
Lot Number:
Package Type: BAG
Storage Conditions: Product was stored in the bag from the manufacturer in our laundry room up to one week then after opening was placed in a dog food bin with a lid.

Product Use Information:
Description: [B6] age 2 [B6] from 9 weeks to 1 year was on Fromm Grain Free Heartland Gold, large breed puppy formula. He was fed this kibble twice daily. The first 5 ingredients in this formula are: Beef, Pork meat meal, PEAS, LENTILS, CHICKPEAS and POTATOES. At one year I transitioned [B6] to Zignature grain free diet that my other Golden [B6] was on [B6] has been on Zignature grain free since then, 13 months.
First Exposure Date: 09/01/2016
Last Exposure Date: 06/30/2017

		Date:	
		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:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
	Product Name:	Zignature Salmon Formula Limited ingredient formula	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Storage Conditions:	Product was stored in the bag from the manufacturer in our laundry room up to one week then after opening was placed in a dog food bin with a lid.	
	Product Use Information:	First Exposure Date:	09/01/2014
		Last Exposure Date:	07/29/2018
		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:	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:	65 Pound	
	Age:	4 Years	

Assessment of Prior Health:	Excellent														
Number of Animals Given the Product:	2														
Number of Animals Reacted:	2														
Owner Information:	<table border="1"> <tr> <td data-bbox="667 267 878 375">Owner Information provided:</td> <td data-bbox="878 267 1554 375">Yes</td> </tr> <tr> <td data-bbox="667 375 878 504">Contact:</td> <td data-bbox="878 375 1554 504"> <table border="1"> <tr> <td data-bbox="878 375 1040 418">Name:</td> <td data-bbox="1040 375 1554 504" rowspan="3">B6</td> </tr> <tr> <td data-bbox="878 418 1040 461">Phone:</td> </tr> <tr> <td data-bbox="878 461 1040 504">Email:</td> </tr> </table> </td> </tr> <tr> <td data-bbox="667 504 878 655">Address:</td> <td data-bbox="878 504 1554 655"> <table border="1"> <tr> <td data-bbox="878 504 1203 612">B6</td> <td data-bbox="1203 504 1554 655"></td> </tr> <tr> <td colspan="2" data-bbox="878 612 1554 655">United States</td> </tr> </table> </td> </tr> </table>	Owner Information provided:	Yes	Contact:	<table border="1"> <tr> <td data-bbox="878 375 1040 418">Name:</td> <td data-bbox="1040 375 1554 504" rowspan="3">B6</td> </tr> <tr> <td data-bbox="878 418 1040 461">Phone:</td> </tr> <tr> <td data-bbox="878 461 1040 504">Email:</td> </tr> </table>	Name:	B6	Phone:	Email:	Address:	<table border="1"> <tr> <td data-bbox="878 504 1203 612">B6</td> <td data-bbox="1203 504 1554 655"></td> </tr> <tr> <td colspan="2" data-bbox="878 612 1554 655">United States</td> </tr> </table>	B6		United States	
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Type of Veterinarian:	Referred veterinarian														
	<table border="1"> <tr> <td data-bbox="667 1323 878 1366">Date First Seen:</td> <td data-bbox="878 1323 1554 1366">11/16/2017</td> </tr> </table>	Date First Seen:	11/16/2017												
Date First Seen:	11/16/2017														
	<table border="1"> <tr> <td data-bbox="667 1366 878 1453">Permission to Release Records to FDA:</td> <td data-bbox="878 1366 1554 1453">Yes</td> </tr> </table>	Permission to Release Records to FDA:	Yes												
Permission to Release Records to FDA:	Yes														
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	<table border="1"> <tr> <td data-bbox="667 1841 878 1884">Date First Seen:</td> <td data-bbox="878 1841 1554 1884">07/31/2018</td> </tr> </table>	Date First Seen:	07/31/2018												
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	<table border="1"> <tr> <td data-bbox="667 1884 878 1970">Permission to Release Records to FDA:</td> <td data-bbox="878 1884 1554 1970">Yes</td> </tr> </table>	Permission to Release Records to FDA:	Yes												
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		
Additional Documents:	Attachment:	B6	2018-07-10-1618.pdf
	Description:	Taurine bloodwork	
	Type:	Analysis	

Report Details - EON-361674	
ICSR:	2053460
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 14:27:38 EDT
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: Prior to November 2014, B6 was a relatively healthy 6 year old intact male golden retriever. He had been fed a grain free diet his entire life. I had changed brands on occasion but I mostly stuck to Earthborn Lamb and Rice formula. B6 had a history of mild valvular aortic stenosis and a possible prostate infection. B6 was diagnosed with DCM 11/3/14 after I noticed coughing and increased respiratory rate. Radiographs confirmed fluid in lungs and enlarged heart. Echocardiogram confirmed diagnosis of DCM. Medication treatment was started. B6 was being treated with antibiotics for a potential infection in the prostate at the time of diagnosis. Taurine levels were not tested because at that time, we weren't aware of the possible link to grain free diet. B6 passed away unexpectedly in B6 (due to his DCM). A year and half later, our other dog B6 was also diagnosed with DCM. I have submitted a separate report for him. B6 was also fed the same diet that B6 was. Earthborn Holistic Meadow Feast (lamb). Because both of my dogs, both golden retrievers, both being fed the exact same diet, developed DCM (and they are not genetically related), I believe 100% that this disease was caused by the food I was feeding.
	Date Problem Started: 11/03/2014
	Concurrent Medical Problem: Yes
	Pre Existing Conditions: B6
	Outcome to Date: Died Other
	Date of Death: B6
	Product Information:
Product Name: Earthborn Holistic Meadow Feast Lamb Blend	
Product Type: Pet Food	
Lot Number:	
Package Type: BAG	
Storage Conditions: stored in a dog food container	
Product Use Information:	
Description: fed twice a day	
Perceived Relatedness to Adverse Event: Definitely related	
Manufacturer /Distributor Information:	
Purchase Location Information:	
Name:	
Address: B6	
Animal Information:	
Name: B6	
Type Of Species: Dog	
Type Of Breed: Retriever - Golden	
Gender: Male	
Reproductive Status: Intact	
Weight: 80 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:	B6
	Address:	B6
		United States
	Type of Veterinarian:	Primary/regular veterinarian
	Date First Seen:	11/03/2014
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:	Med Recs B6.pdf
	Description:	Medical records for B6 since his DCM diagnosis
	Type:	Medical Records

Report Details - EON-361661

ICSR: 2053453
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 12:44:28 EDT
Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: Prior to December 2017, [B6] was a healthy 6 year old neutered male golden retriever. He had been fed a grain free diet his entire life. I had changed brands on occasion but I mostly stuck to Earthborn Lamb and Rice formula. [B6] lived in a home with another dog, [B6] who had DCM. They are not related. I will submit a separate report for [B6] who was diagnosed with DCM 12/29/17 after I noticed coughing and labored breathing. Radiographs confirmed fluid in lungs and enlarged heart. Echocardiogram confirmed decreased heart function. Medication treatment was started [B6]. Since this was my second dog diagnosed with DCM, which is usually unheard of, I started doing my own research on DCM. I read that DCM might be linked to grain free dog food. This made sense to me since both of my dogs were fed a grain free diet and now both were diagnosed with DCM. I asked my veterinarian if we could check his Taurine level and that was submitted on 4/21/18. His level was [B6] (normal range is 60-120), so significantly low. Taurine supplementation was started. Since then, I have also changed his diet to a food that is NOT grain free and have continued all of his medications. He has not had a recheck echo. He is doing well but the DCM has not resolved completely.

Date Problem Started: 12/29/2017
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
Storage Conditions: Stored in a dog food container

Product Use Information:

Description: 1 cup twice a day
Perceived Relatedness to Adverse Event: Definitely related

Manufacturer /Distributor Information:

Purchase Location Information:

Name: [B6]
Address: [B6]
United States

Animal Information:

Name: [B6]
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Male
Reproductive Status: Neutered
Weight: 73 Pound
Age: 6.5 Years
Assessment of Prior Health: Excellent
Number of Animals: 2

	Given the Product:	
	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:	12/29/2017
	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:	Email
Additional Documents:	Attachment:	Med Recs B6 pdf
	Description:	Medical records as of 12/29/17. Does not include echo results but that can be obtained if needed.
	Type:	Medical Records

Report Details - EON-361659

ICSR:	2053451		
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 12:26:09 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	B6 a German Shepherd Dog stopped eating and was diagnosed with dilated cardiomyopathy. He did not respond to treatment including taurine supplementation and died 5 weeks later. He was treated by cardiologist B6 . According to Dr. B6 taurine levels were not abnormally low but just at the low end of normal. B6 along with a female GSD about the same age and his son who was 4 years at the time of B6 death were on the same grain free diet for 4 to 5 years. At first various varieties of Merricks then for the last 2 years various varieties of Kirkland Natures Domain (Diamond). Specifically 70% Salmon, 15% Beef and 15% Turkey. The other 2 dogs have not shown any adverse effects.	
	Date Problem Started:	08/01/2014	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Died Naturally	
	Date of Death:	B6	
Product Information:	Product Name:	Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	35 Pound	
	Purchase Date:	08/01/2011	
	Number Purchased:	3	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	in bag or pet food container	
	Product Use Information:	Description:	3 cups daily moistened and a very small amount of all meat canned dog food added.
		First Exposure Date:	09/01/2011
		Last Exposure Date:	07/30/2014
Time Interval between Product Use and Adverse Event:		3 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:	Name: Costco		
		Address:	B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Shepherd Dog - German		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	108 Pound		
	Age:	10 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:	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 Parties:	Store/Place of Purchase			
Additional Documents:				

Report Details - EON-361577

ICSR:	2053386		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date:	2018-08-07 13:39:45 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	I actually had two dogs involved. My ten year old male dog had slight heart murmur but his breathing was labored. I became aware of the taurine issue and was concerned he might have DCM. As a precaution, I also had the 6 year old female tested. Both came back considerably below the "normal" standard. The male was at B6 and the female was at B6 . Both had been eating Acana Lamb /Apple Singles for the past 1.5 - 2.0 years. I did take them for Echoc and neither showed DCM at that point. However, the cardiologist recommending a change of food and supplementing with taurine to avoid DCM.	
	Date Problem Started:	07/01/2017	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	Product Name:	Acana Singles Limited Ingredient Diet Lamb and Okanagan Apple Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	07/01/2015	
	Number Purchased:	1	
	Possess Opened Product:	No	
	Storage Conditions:	Airtight plastic container	
	Product Use Information:	Description:	Feed 2x daily
		First Exposure Date:	12/01/2015
		Last Exposure Date:	07/20/2017
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After Product Stop:	Yes
Product Use Started Again:		No	
Other Foods or Products Given to the Animal During This Time Period:		No	
Manufacturer /Distributor Information:			
Purchase Location Information:	Name:	PetFlow Online	
	Address:	United States	
Animal Information:	Name:	B6	

	Type Of Species: Dog
	Type Of Breed: Retriever - Golden
	Gender: Female
	Reproductive Status: Neutered
	Age: 6 Years
	Assessment of Prior Health: Excellent
	Number of Animals Reacted: 2
	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: 07/01/2017
	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: 07/24/2017	
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: Manufacturer	

Additional Documents:

Attachment:	B6	Second Taurine Test.pdf
Description:	B6	2017 Taurine Test Results from UC Davis
Type:		Laboratory Report
Attachment:	B6	Echo.pdf
Description:		Cardiologist Report
Type:		Record
Attachment:	B6	Taurine Test Results UC Davis.pdf
Description:	B6	s Initial Taurine Test Results from UC Davis 2017
Type:		Laboratory Report
Attachment:	B6	- Echo August 2017.pdf
Description:		Cardiologist Report B6
Type:		Record

Report Details - EON-361406

ICSR:	2053246
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:	2018-08-05 19:26:34 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	About 3 years ago I switched to a grain-free dog food because it was suggested that it would help with winter time dry skin. We used Hill's Ideal Balance Chicken and Brown Rice Adult Dry food. @ years ago, our dog, B6 was diagnosed with a slightly enlarged heart. Nothing to worry about but told to watch he weight, exercise level and report any new symptoms. This May, B6 started with a persistent cough. I brought him to the vet. They did and X-ray and ultrasound and said he was in heart failure. His heart was in grave condition. Put him on 4 different antibiotics, but, B6 died 5 days later. He is from a litter of 11 pups and his parents and ten other pups are all healthy and without any history of heart disease. I just read that grain free dog food could be linked in some way and wanted to report immediately, since everyone is stumped as to how his heart got so bad and so quickly.
	Date Problem Started:	06/11/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Hill's Ideal Balance Natural Chicken & Brown Rice Recipe Adult Dry Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	06/04/2018		
	Number Purchased:	1		
	Possess Opened Product:	No		
	Storage Conditions:	We stored our dry food inside a sealed rubber/tupperware type container.		
	Product Use Information:	Description:	We measured 1-¾ cups of dry food each morning and put in clean, dog bowl.	
		Last Exposure Date:	06/15/2018	
		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:		Probably related		
Other Foods or Products Given to the Animal During This Time Period:		Yes		
	Manufacturer:			

	/Distributor Information:		
	Purchase Location Information:	Name:	Chewy's Online and PetCo
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Portuguese Water Dog	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	55 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:	B6
	Address:	B6	
		United States	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	06/11/2018	
	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-361242

ICSR:	2053158		
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:	2018-08-03 05:16:27 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Was on a grain free diet from 3 mos. of age to 3 years of age. Had Taurine level checked: B6 Switched to a grain food: Fromm Duck & Sweet Potato @ 2 years of age. Taurine level checked 11 mos. later (7/2018): B6 Food immediately switched (per Vet. advice). Blood test soon thereafter to check proBNP level: result was within range. Recent echocardiogram suggestive but not diagnosed with early onset of Dilated Cardiomyopathy. He is now on Taurine supplements, started 24 hours ago. Continues on new kibble: Royal Canin Adult Golden Retriever with topper (organ and/or muscle meat) to add in additional Taurine to diet.	
	Date Problem Started:	08/17/2017	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Worse/Declining/Deteriorating	
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	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Airtight container	
	Product Use Information:	Description:	Kibble with small amount of warm water, topped with high protein meat source or egg. Fed 1 cup three times per day.
		First Exposure Date:	09/05/2015
		Time Interval between Product Use and Adverse Event:	21 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:		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;"> <h1>B6</h1> </div>	
	Animal Information: Type Of Species: Dog Type Of Breed: Retriever - Golden Gender: Male Reproductive Status: Intact Weight: 63 Pound Age: 3 Years Assessment of Prior Health: Excellent Number of Animals Given the Product: 2 Number of Animals Reacted: 2 Owner Information:	Name: B6 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: 08/17/2017 Permission to Release Records to FDA: Yes	
	Sender Information:	Name: Address:	<div style="border: 1px dashed black; padding: 10px; text-align: center;"> <h1>B6</h1> </div>	United States Contact: Phone: B6 Other Phone: Email:
	Additional Documents:			

Report Details - EON-361243

ICSR:	2053157
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:	2018-08-03 05:15:27 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Was on a grain free diet from 4 mos. of age to 5.4 years of age. Had Taurine level checked: B6 ; Switched to a grain food: Fromm Duck & Sweet Potato @ 5.4 years of age. Taurine level checked 11 mos. later (7/2018): B6 ; Food immediately switched (per Vet. advice). Blood test soon thereafter to check proBNP level: almost double the high end of normal range suggesting heart muscle dysfunction. Recent echocardiogram confirmed early onset of Dilated Cardiomyopathy. He is now on cardiac medication, Taurine supplements started 24 hours ago. Continues on new kibble: Royal Canin Adult Golden Retriever with topper (organ and/or muscle meat) to add in additional Taurine to diet.
	Date Problem Started:	08/17/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

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
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Air tight container

Product Use Information:	Description:	Given as kibble with small amount of warm water, topped with meat source of protein or egg. Fed 1 cup serving three times a day.
	First Exposure Date:	08/10/2012
	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:	Probably related
	Other Foods or Products Given to the Animal	Yes

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: Retriever - Golden

Gender: Male

Reproductive Status: Neutered

Weight: 68 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:

Phone:

Other Phone:

B6

Address:

B6

United States

Type of
Veterinarian: Primary/regular veterinarian

Date First Seen: 08/17/2017

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
Parties: Store/Place of Purchase
Other

Additional Documents:

Report Details - EON-361042		
ICSR:	2053073	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-08-01 09:40:07 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Fed my dog grain free food since she was 6 months old. She died of Hypertrophic cardiomyopathy. Suspect grain free food is the possible issue. Autopsy showed that her left ventricle walls were severely thickened (3 cm).	
	Date Problem Started: B6	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Other	
	Date of Death: B6	
Product Information:	Product Name: Pure Balance Grain Free Salmon and Pea	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 24 Pound	
	Purchase Date: 12/30/2015	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Plastic sealed dog food container	
	Product Use Information:	Description: Fed daily starting January 2016
		First Exposure Date: 01/01/2016
		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: No		
Manufacturer /Distributor Information:		
Purchase Location Information:	Name: Walmart	
	Address: B6	

		B6 United States
Product Name:	Nature's Recipe Grain Free Dry Dog Food - Salmon, Sweet Potato, and pumpkin	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Package Size:	24 Pound	
Purchase Date:	01/01/2013	
Number Purchased:	1	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Storage Conditions:	Plastic container (sealed)	
Product Use Information:	Description:	Fed daily from 2013 until mid 2016.
	First Exposure Date:	01/01/2013
	Last Exposure Date:	01/01/2016
	Time Interval between Product Use and Adverse Event:	5 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:	No
	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 - Belgian Malinois
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	65 Pound
	Age:	6 Years
	Assessment of Prior Health:	Unknown
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:	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
	Permission To Contact Sender:	Yes	
Preferred Method Of Contact:	Email		
Reported to Other Parties:	Other		

Additional Documents:	Attachment:	IMG_1760001.jpg
	Description:	B6 heart after removal during autopsy. Note the severe thickening of the left ventricle walls.
	Type:	Photograph

Report Details - EON-359190

ICSR:	2052010
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 08:09:38 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Dog developed cough so I took him to our vet. He was diagnosed with dilated cardiomyopathy. He was prescribed: B6 I learned at this time through internet articles, some scientific, that there is a correlation between grain free dog foods that contain legumes and DCM. We first started feeding this food 6 years ago.
	Date Problem Started:	07/02/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Earthborn holistics coastal catch		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	28 Pound		
	Purchase Date:	06/27/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Product is stored in an airtight container.		
	Product Use Information:	Description:	This is my dogs primary food source. They eat it daily.	
		First Exposure Date:	06/28/2018	
		Last Exposure Date:	07/12/2018	
		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:		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:	No			

	Manufacturer /Distributor Information:																			
	Purchase Location Information:	<table border="1"> <tr> <td>Name:</td> <td>B6</td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Name:	B6	Address:	B6		United States												
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Address:	B6																			
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Animal Information:	Name:	B6																		
	Type Of Species:	Dog																		
	Type Of Breed:	Poodle - Standard																		
	Gender:	Male																		
	Reproductive Status:	Neutered																		
	Weight:	70 Pound																		
	Age:	8 Years																		
	Assessment of Prior Health:	Excellent																		
	Number of Animals Given the Product:	3																		
	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> </table> </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>07/10/2018</td> </tr> <tr> <td>Permission to Release Records to FDA:</td> <td>Yes</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> </table>	Name:	B6	Phone:	B6	Address:	B6		United States	Type of Veterinarian:	Primary/regular veterinarian	Date First Seen:	07/10/2018	Permission to Release Records to FDA:	Yes
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Phone:	B6																			
Email:	B6																			
	Permission To Contact Sender:	Yes																		
	Preferred Method Of Contact:	Email																		
	Reported to Other Parties:	None																		
Additional Documents:	Attachment:	A209ACA3-BE96-43FB-A501-9E28509ED847.png																		
	Description:	This is a screenshot of an article stating that the fda is looking a correlation between canine dilated cardiomyopathy and foods that contain legumes. I believe my dog may be affected by this as the above mentioned food contains																		

legumes.

Type: Article

Report Details - EON-359276

ICSR:	2052050
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-07-15 17:02:16 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	4 year old Golden Retriever had been eating "4 Health Beef & Potato" dry, grain free dog food since birth (per Breeders recommendation) and suddenly contracted a cough and died 48 hours later from Dilated Cardiomyopathy (enlarged heart). Hospital Vet submitted blood to UCAL Davis and Dog had low taurine blood levels pointing to dog food as reason for heart failure. Also sibling died one month later, also from eating the SAME brand of 4 Health Dog food. No heart murmur was detected at annual checks ups.
	Date Problem Started:	B6
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Naturally
	Date of Death:	B6

Product Information:	Product Name:	4 Health Grain Free Beef & Potato Formula	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Product was stored in clean plastic container in kitchen closet with other human food items.	
	Product Use Information:	Description:	Dry Dog food given to my Golden retriever three times a day since birth. My Dog died at 4 years 7 month old on B6. My dog never had a heart murmur detected by the vet. He suddenly contracted a cough and within 48 hours he died of heart failure.
		First Exposure Date:	08/09/2013
		Last Exposure Date:	B6
		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:		Yes	
Manufacturer			

	/Distributor Information:	<table border="1"> <tr> <td data-bbox="667 116 889 297">Purchase Location Information:</td> <td data-bbox="889 116 1539 297"> <table border="1"> <tr> <td data-bbox="889 116 1073 157">Name:</td> <td data-bbox="1073 116 1539 157">Tractor Supply</td> </tr> <tr> <td data-bbox="889 157 1073 297">Address:</td> <td data-bbox="1073 157 1539 297"> <table border="1"> <tr> <td data-bbox="1073 157 1154 245">B6</td> <td data-bbox="1154 157 1539 245"></td> </tr> <tr> <td data-bbox="1073 245 1154 297">United States</td> <td data-bbox="1154 245 1539 297"></td> </tr> </table> </td> </tr> </table> </td> </tr> </table>	Purchase Location Information:	<table border="1"> <tr> <td data-bbox="889 116 1073 157">Name:</td> <td data-bbox="1073 116 1539 157">Tractor Supply</td> </tr> <tr> <td data-bbox="889 157 1073 297">Address:</td> <td data-bbox="1073 157 1539 297"> <table border="1"> <tr> <td data-bbox="1073 157 1154 245">B6</td> <td data-bbox="1154 157 1539 245"></td> </tr> <tr> <td data-bbox="1073 245 1154 297">United States</td> <td data-bbox="1154 245 1539 297"></td> </tr> </table> </td> </tr> </table>	Name:	Tractor Supply	Address:	<table border="1"> <tr> <td data-bbox="1073 157 1154 245">B6</td> <td data-bbox="1154 157 1539 245"></td> </tr> <tr> <td data-bbox="1073 245 1154 297">United States</td> <td data-bbox="1154 245 1539 297"></td> </tr> </table>	B6		United States																																																										
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Animal Information:	<table border="1"> <tr> <td data-bbox="375 297 667 338">Name:</td> <td data-bbox="667 297 1539 338">B6</td> </tr> <tr> <td data-bbox="375 338 667 379">Type Of Species:</td> <td data-bbox="667 338 1539 379">Dog</td> </tr> <tr> <td data-bbox="375 379 667 420">Type Of Breed:</td> <td data-bbox="667 379 1539 420">Retriever - Golden</td> </tr> <tr> <td data-bbox="375 420 667 461">Gender:</td> <td data-bbox="667 420 1539 461">Male</td> </tr> <tr> <td data-bbox="375 461 667 502">Reproductive Status:</td> <td data-bbox="667 461 1539 502">Neutered</td> </tr> <tr> <td data-bbox="375 502 667 543">Weight:</td> <td data-bbox="667 502 1539 543">65 Pound</td> </tr> <tr> <td data-bbox="375 543 667 584">Age:</td> <td data-bbox="667 543 1539 584">4 Years</td> </tr> <tr> <td data-bbox="375 584 667 625">Assessment of Prior Health:</td> <td data-bbox="667 584 1539 625">Good</td> </tr> <tr> <td data-bbox="375 625 667 709">Number of Animals Reacted:</td> <td data-bbox="667 625 1539 709">1</td> </tr> <tr> <td data-bbox="375 709 667 750">Owner Information:</td> <td data-bbox="667 709 1539 750"></td> </tr> <tr> <td data-bbox="375 750 667 1235">Healthcare Professional Information:</td> <td data-bbox="667 750 1539 1235"> <table border="1"> <tr> <td data-bbox="667 750 889 791">Practice Name:</td> <td data-bbox="889 750 1539 791">B6</td> </tr> <tr> <td data-bbox="667 791 889 875">Contact:</td> <td data-bbox="889 791 1539 875"> <table border="1"> <tr> <td data-bbox="889 791 1073 832">Name:</td> <td data-bbox="1073 791 1539 832">B6</td> </tr> <tr> <td data-bbox="889 832 1073 875">Phone:</td> <td data-bbox="1073 832 1539 875"></td> </tr> </table> </td> </tr> <tr> <td data-bbox="667 875 889 1024">Address:</td> <td data-bbox="889 875 1539 1024"> <table border="1"> <tr> <td data-bbox="889 875 1073 985">B6</td> <td data-bbox="1073 875 1539 985"></td> </tr> <tr> <td data-bbox="889 985 1073 1024">United States</td> <td data-bbox="1073 985 1539 1024"></td> </tr> </table> </td> </tr> <tr> <td data-bbox="667 1024 889 1086">Type of Veterinarian:</td> <td data-bbox="889 1024 1539 1086">Referred veterinarian</td> </tr> <tr> <td data-bbox="667 1086 889 1127">Date First Seen:</td> <td data-bbox="889 1086 1539 1127">B6</td> </tr> <tr> <td data-bbox="667 1127 889 1235">Permission to Release Records to FDA:</td> <td data-bbox="889 1127 1539 1235">Yes</td> </tr> </table> </td> </tr> <tr> <td data-bbox="77 1235 375 1795">Sender Information:</td> <td data-bbox="375 1235 667 1795"> <table border="1"> <tr> <td data-bbox="375 1235 667 1276">Name:</td> <td data-bbox="667 1235 1539 1276"></td> </tr> <tr> <td data-bbox="375 1276 667 1425">Address:</td> <td data-bbox="667 1276 1539 1425"> <table border="1"> <tr> <td data-bbox="667 1276 961 1386">B6</td> <td data-bbox="961 1276 1539 1386"></td> </tr> <tr> <td data-bbox="667 1386 961 1425">United States</td> <td data-bbox="961 1386 1539 1425"></td> </tr> </table> </td> </tr> <tr> <td data-bbox="375 1425 667 1530">Contact:</td> <td data-bbox="667 1425 1539 1530"> <table border="1"> <tr> <td data-bbox="667 1425 889 1466">Phone:</td> <td data-bbox="889 1425 1539 1466"></td> </tr> <tr> <td data-bbox="667 1466 889 1530">Email:</td> <td data-bbox="889 1466 1539 1530">B6</td> </tr> </table> </td> </tr> <tr> <td data-bbox="375 1530 667 1593">Reporter Wants to Remain Anonymous:</td> <td data-bbox="667 1530 1539 1593">No</td> </tr> <tr> <td data-bbox="375 1593 667 1655">Permission To Contact Sender:</td> <td data-bbox="667 1593 1539 1655">Yes</td> </tr> <tr> <td data-bbox="375 1655 667 1718">Preferred Method Of Contact:</td> <td data-bbox="667 1655 1539 1718">Email</td> </tr> <tr> <td data-bbox="375 1718 667 1795">Reported to Other Parties:</td> <td data-bbox="667 1718 1539 1795">Other</td> </tr> </table> </td> </tr> <tr> <td data-bbox="77 1795 375 2028">Additional Documents:</td> <td data-bbox="375 1795 1539 2028"></td> </tr> </table>	Name:	B6	Type Of Species:	Dog	Type Of Breed:	Retriever - 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Type of Veterinarian:	Referred veterinarian																																																																				
Date First Seen:	B6																																																																				
Permission to Release Records to FDA:	Yes																																																																				
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Preferred Method Of Contact:	Email																																																																				
Reported to Other Parties:	Other																																																																				
Additional Documents:																																																																					

Report Details - EON-359494

ICSR:	2052236
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 11:12:48 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My Black Lab was only six years old and had no history of heart disease. I fed him Natures Domain grain free from Costco for an extended period of time. Last week out of nowhere a dog that was so full of energy and life died of Cardiomyopathy at age 6. I spent thousands of dollars at Doctors and specialists to no avail, to be told he had Congestive heart failure and had 6 months to live. I humanely had him put down and was devastated.
	Date Problem Started:	06/20/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Natures Domain
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	40 Pound
	Purchase Date:	11/01/2017
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Stored in a plastic container.

Product Use Information:	Description:	Fed my Labradors twice a day.
	Last Exposure Date:	11/10/2017
	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: Costco
	Address: B6

			B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Labrador		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	65 Pound		
	Age:	6 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
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		06/20/2018		
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:	B6 5850.pdf		
	Description:	Report from B6		
	Type:	Medical Records		

Report Details - EON-359524

ICSR:	2052249
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 13:46:30 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dog was fed Fromm's Surf and Turf kibble all his life. He developed distal cardiomyopathy at age 7 and died at age 8 after being treated for 9 months. His kibble was grain-free and contained potatoes, pea flour, sweet potatoes among other main ingredients. I am seeing reports that this type of diet is linked to the heart condition that caused the death of my dog. His breed is not typical at risk for this heart condition. My dog had to be euthanized due to his severe heart condition and difficulty breathing. I have the cardiologist reports and medical file.
	Date Problem Started:	02/10/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Fromm Surf & Turf
	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 - Irish
	Gender:	Male
	Reproductive Status:	Neutered
	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:	Practice Name: B6
		Contact: Name: B6 Phone: B6 Other Phone: B6 Email: B6
	Address: B6 Canada	
	Type of Referred veterinarian	

		Veterinarian:	
		Date First Seen:	02/10/2017
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:		
		Canada	
	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:	Attachment:	clinicalSummary_AN170926_CN665265_S114.pdf	
	Description:	Clinical Summary from Cardiologist	
	Type:	Medical Records	

Report Details - EON-359838		
ICSR:	2052447	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-07-19 23:34:11 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Started B6 on 4 Health Beef and Potato Grain Free dog food you get st B6 in January 2017, in January 2018 I took B6 in for his annual check up and told the vet he had been having a slight cough. Vet listened to his chest repeatedly and told me B6 was in the mid stages of CHD or Congestive Heart Disease. Started him on 3 medications and had to Switch him to a lower sodium food.	
	Date Problem Started: 12/17/2017	
	Concurrent Medical Problem: No	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: 4 Health Beef and Potato Dog Food Grain Free 30 pounds	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 30 Pound	
	Purchase Date: 12/01/2017	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Air tight container	
	Product Use Information:	Description: Serving size according to bag in bowl each day. He grazes but eventually eats all by end of day
		First Exposure Date: 12/01/2017
		Last Exposure Date: 01/15/2018
		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:

Address:

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Terrier - Boston

Gender: Male

Reproductive Status: Neutered

Weight: 20 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:

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: None

Additional Documents:

Report Details - EON-360891

ICSR: 2053003
 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: 2018-07-31 09:52:53 EDT

Reported Problem:

Problem Description: Presented to ER service for collapse episode while on a run with owner. Additional collapse episode while on regular run two weeks ago. Diagnosed with Dilated Cardiomyopathy on echocardiogram (severe left ventricular dilation with severe global decrease in contractility). Began medical therapy with [B6] and taurine supplementation on discharge [B6].

Date Problem Started: [B6]

Date of Recovery: 07/30/2018

Concurrent Medical Problem: No

Outcome to Date: Stable

Product Information:

Product Name: Pedigree Dentistix

Product Type: Pet Food

Lot Number:

Package Type: POUCH

Possess Unopened Product: No

Possess Opened Product: Yes

Product Use Information:

Description: Given 1/3 stick twice a day since January 2013

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: 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.T. Sweet Potato & Venison, Brown Rice & Lamb, and Sweet Potato & Fish

Product Type: Pet Food

Lot Number:

Package Type: POUCH

Purchase Date: 06/05/2018

Possess Unopened Product: Unknown

Possess Opened Product:	Yes	
Product Use Information:	Description:	Given 2-4 small treats twice a day
	Last Exposure Date:	B6
	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:	Name:	Amazon
Product Name:	Earthborn Holistic Meadow Grain Free Great Plains Feast	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Package Size:	48 Pound	
Purchase Date:	06/20/2018	
Number Purchased:	4	
Possess Unopened Product:	Yes	
Possess Opened Product:	Yes	
Storage Conditions:	Stored in original bag	
Product Use Information:	Description:	Gave 1.75 cups twice a day since August 2014 up to current date
	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:	Unknown
	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: Amazon	
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Boxer (German Boxer)	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	44.1 Kilogram	
	Age:	6 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided: Yes	
	Contact:	Name: B6	
		Phone: B6	
	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: Other

Additional Documents:

Report Details - EON-358119											
ICSR:	2051190										
Type Of Submission:	Initial										
Report Version:	FPSR.FDA.PETF.V.V1										
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)										
Reporting Type:	Voluntary										
Report Submission Date:	2018-07-02 14:28:07 EDT										
Reported Problem:	Problem Description: Presented 6/18/18 for heart murmur evaluation, which was first documented 3 years ago. Murmur is now progressive and B6 has also developed a cough in March. Diagnosed with tracheal collapse at that time due to radiographs. B6 has good energy levels and the owner is restricting her activity since March. B6 has a history of food allergies and was placed on Zignature Kangaroo and Lentil diet about 2 years ago.										
	Date Problem Started: 06/18/2018										
	Concurrent Medical Problem: Yes										
	Pre Existing Conditions: Heart murmur documented 1 year prior to diet. Medications include B6 70mg SID and B6 9mg SID B6										
	Outcome to Date: Better/Improved/Recovering										
Product Information:	Product Name: Zignature Kangaroo and Lentil										
	Product Type: Pet Food										
	Lot Number:										
	Package Type: BAG										
	Possess Unopened Product: No										
	Possess Opened Product: Yes										
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>1/3 cup BID since 2016.</td> </tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>1 Years</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>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:	1/3 cup BID since 2016.	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
	Description:	1/3 cup BID since 2016.									
	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: <table border="1"> <tr> <td>Address:</td> <td>B6 United States</td> </tr> </table>	Address:	B6 United States									
Address:	B6 United States										
Name: B6											
Type Of Species: Dog											
Type Of Breed: Maltese											
Gender: Female											
Reproductive Status: Neutered											
Weight: 4.9 Kilogram											
Age: 12 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></td> </tr> <tr> <td>Other 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>Other Phone:</td> <td></td> </tr> <tr> <td>Email:</td> <td></td> </tr> </table>	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
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Other Phone:																		
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	Phone:	B6																
Other Phone:																		
Email:																		
Permission To Contact Sender:	Yes																	
Preferred Method Of Contact:	Email																	
Reported to Other Parties:	None																	
Additional Documents:	Attachment:	cardio0009.pdf																
	Description:	echo report, taurine level, diet history																
	Type:	Medical Records																

Report Details - EON-359257

ICSR: 2052024
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 11:11:43 EDT
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: We were feeding [B6] our Sheepadoodle (Old English Sheepdog + Poodle Mix), grain-free food from 8 weeks old until time of diagnosis (12 months). He was eating Victor Hi Pro Plus and Victor Salmon + Sweet Potato, both grain-free and high in legumes. At 12 months, [B6] was having an irregular heart rhythm during a vet appointment and underwent testing (EKG, echocardiogram). His whole blood taurine levels were [B6] (unfasted), which we were told is just below normal range. He was diagnosed with Dilated Cardiomyopathy in the beginning of February 2018 and started on 3000mg of Taurine supplements per day, [B6]. We also switched his food to Hills Science Diet Chicken & Barley. [B6] had a repeat echo several weeks ago, 5 months into treatment, and (thankfully) the DCM is improving but not yet normal. We are continuing treatment and very hopeful.
Date Problem Started: 02/01/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Victor Hi-Pro Plus
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: 61 Pound
Age: 17 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]

		B6 United States
	Type of Veterinarian:	Primary/regular veterinarian
	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
	Contact:	Phone: B6 Email: B6
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	None

Additional Documents:	Attachment:	B6 362614.pdf
	Description:	Initial DCM Diagnosis (Echocardiogram Report)
	Type:	Echocardiogram
	Attachment:	B6 Echo 2-1-18.pdf
	Description:	Repeat Echocardiogram Report
	Type:	Echocardiogram

Report Details - EON-359337

ICSR:	2052111
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 11:09:54 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I fed my pure breed Lab grain free dog food for years without incident and considered grain-free dog food the better, healthier choice overall. Now I'm wondering if it might be the cause for my German Shepherd Mix heart disease. She was diagnosed with DCM 03/2018 at just 4.5yrs old when I rushed her to emergency in heart failure. She's been on Grain Free dog-food since I rescued her from a shelter Sept 2016. Instinct by Nature's Variety Raw Boost Healthy Weight Grain-Free Chicken Recipe and Lotus Oven-Baked Fish Recipe Grain-Free Dry Dog Food. She's currently being treated for DCM with the following medications: B6 B6 500mg Taurine 2x Day. Based on the recent FDA announcement about grain free dog food and DCM, I will be switching her diet right away.
	Date Problem Started:	03/02/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Instinct by Nature's Variety Raw Boost Healthy Weight Grain-Free Chicken Recipe Dry Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	20 Pound		
	Purchase Date:	08/31/2017		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in original packaging		
	Product Use Information:	Description:	1 cup 2x Day	
		First Exposure Date:	09/01/2017	
		Last Exposure Date:	07/16/2018	
		Time Interval between Product Use and Adverse Event:	18 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:	Name: Chewy.com
	Product Name:	Lotus Oven-Baked Fish Recipe Grain-Free Dry Dog Food,
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	10 Pound
	Purchase Date:	09/01/2016
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Remained in original packaging
	Product Use Information:	Description: 1 cup 2x Day
		First Exposure Date: 09/05/2016
		Last Exposure Date: 03/31/2018
		Time Interval between Product Use and Adverse Event: 18 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: 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:	48 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: B6
		Phone: B6
	Address:	B6
		United States
	Type of Veterinarian:	Referred veterinarian
	Date First Seen:	03/14/2018
	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-359724

ICSR:	2052359
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-07-18 22:08:38 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I started B6 on Hi-Tek Naturals Grain free Lamb and sweet Potato dog food around 1 year old. It was supposed to be a five star dog food on Dogfoodadvisor.com. Last winter (March 2018) I noticed he was acting different. My playful pup didn't run around and didn't want to play. He also started breathing at a high rate (50-80) at rest. Then I started to notice his tongue turning a bluish color during exercise and he refused to go on our normal snow shoe hike one day. I was going to have his teeth cleaned so I called the vet to see if they would do a heart test before they put him under. They thought I was nuts but low and behold he had an elevated ProBNP. He also showed enlarged heart upon X-ray. My bet asked about his diet because she had just heard about grain free foods causing DCM in dogs. I immediately switched his diet and added taurine supplements to his food. (His taurine levels were normal at this time). Within a week or so my husband and I started to notice B6 had more energy. We thought we were imagining it. I took B6 to a cardiologist vet and she drew his blood again in May. His ProBNP were half the amount into the normal range! I believe from B6 He didn't show an enlarged heart during the EKG. So all has been reversed!
	Date Problem Started:	03/01/2018
	Date of Recovery:	05/18/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Recovered Completely

Product Information:	Product Name:	Hi-Tek Rations Naturals Grain free lamb and sweet potato dog food		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	X0014BLX9R		
	Package Type:	BAG		
	Package Size:	5 Pound		
	Purchase Date:	02/02/2018		
	Number Purchased:	1		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	No		
	Storage Conditions:	In bag in food storage container		
	Product Use Information:	Description:	1/2 cup twice of day	
		First Exposure Date:	02/03/2018	
	Last Exposure Date:	03/18/2018		
	Time Interval between Product Use and Adverse Event:	1 Years		
	Product Use Stopped After the Onset of the Adverse Event:	Yes		
	Adverse Event	Yes		

	Abate After Product Stop:	
	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:	Amazon.com
	Address:	Online <div style="border: 1px dashed black; padding: 5px; display: inline-block;">B6</div> United States
Product Name:	Hi-Tek Rations Naturals Grain Free Lamb and Sweet Potato dog food	
Product Type:	Pet Food	
Lot Number:		
UPC:	X00114BL9R	
Package Type:	BAG	
Package Size:	5 Pound	
Purchase Date:	02/01/2018	
Number Purchased:	1	
Possess Unopened Product:	Yes	
Possess Opened Product:	No	
Storage Conditions:	In bag and bag put in dog food storage container	
Product Use Information:	Description:	Gave 1/2 cup twice daily
	Last Exposure Date:	03/30/2018
	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:	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:	<table border="1"> <tr> <td data-bbox="672 120 889 157">Name:</td> <td data-bbox="894 120 1534 157">Amazon</td> </tr> <tr> <td data-bbox="672 163 889 228">Address:</td> <td data-bbox="894 163 1534 228"> <table border="1"> <tr> <td data-bbox="899 163 1170 189">B6</td> </tr> <tr> <td data-bbox="899 196 1529 222">United States</td> </tr> </table> </td> </tr> </table>	Name:	Amazon	Address:	<table border="1"> <tr> <td data-bbox="899 163 1170 189">B6</td> </tr> <tr> <td data-bbox="899 196 1529 222">United States</td> </tr> </table>	B6	United States																																																												
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Shetland	Gender:	Male	Reproductive Status:	Neutered	Weight:	25 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:	<table border="1"> <tr> <td data-bbox="899 776 1170 804">Practice Name:</td> <td data-bbox="1175 776 1529 804">B6</td> </tr> <tr> <td data-bbox="899 810 1040 847">Contact: Name:</td> <td data-bbox="1045 810 1534 847">B6</td> </tr> <tr> <td data-bbox="899 853 1040 890">Phone:</td> <td data-bbox="1045 853 1534 890"></td> </tr> <tr> <td data-bbox="899 896 889 1047">Address:</td> <td data-bbox="894 896 1534 1047"> <table border="1"> <tr> <td data-bbox="899 896 1170 1004">B6</td> </tr> <tr> <td data-bbox="899 1011 1529 1037">United States</td> </tr> </table> </td> </tr> <tr> <td data-bbox="899 1054 1040 1118">Type of Veterinarian:</td> <td data-bbox="1045 1054 1534 1118">Primary/regular veterinarian</td> </tr> <tr> <td data-bbox="899 1125 1040 1162">Date First Seen:</td> <td data-bbox="1045 1125 1534 1162">03/18/2018</td> </tr> <tr> <td data-bbox="899 1168 1040 1233">Permission to Release Records to FDA:</td> <td data-bbox="1045 1168 1534 1233">Yes</td> </tr> </table>	Practice Name:	B6	Contact: Name:	B6	Phone:		Address:	<table border="1"> <tr> <td data-bbox="899 896 1170 1004">B6</td> </tr> <tr> <td data-bbox="899 1011 1529 1037">United States</td> </tr> </table>	B6	United States	Type of Veterinarian:	Primary/regular veterinarian	Date First Seen:	03/18/2018	Permission to Release Records to FDA:	Yes	Sender Information:		<table border="1"> <tr> <td data-bbox="672 1252 889 1310">Name:</td> <td data-bbox="894 1252 1534 1310">B6</td> </tr> <tr> <td data-bbox="672 1317 889 1446">Address:</td> <td data-bbox="894 1317 1534 1446"> <table border="1"> <tr> <td data-bbox="899 1317 1170 1425">B6</td> </tr> <tr> <td data-bbox="899 1431 1529 1457">United States</td> </tr> </table> </td> </tr> <tr> <td data-bbox="672 1453 889 1539">Contact: Phone:</td> <td data-bbox="894 1453 1534 1539">B6</td> </tr> <tr> <td data-bbox="672 1545 889 1582">Email:</td> <td data-bbox="894 1545 1534 1582"></td> </tr> <tr> <td data-bbox="672 1588 889 1653">Reporter Wants to Remain Anonymous:</td> <td data-bbox="894 1588 1534 1653">No</td> </tr> <tr> <td data-bbox="672 1660 889 1696">Permission To Contact Sender:</td> <td data-bbox="894 1660 1534 1696">Yes</td> </tr> <tr> <td data-bbox="672 1703 889 1761">Preferred Method Of Contact:</td> <td data-bbox="894 1703 1534 1761">Phone</td> </tr> <tr> <td data-bbox="672 1767 889 1813">Reported to Other Parties:</td> <td data-bbox="894 1767 1534 1813"> <table border="1"> <tr> <td data-bbox="899 1767 1040 1795">Manufacturer</td> </tr> <tr> <td data-bbox="899 1802 1529 1828">Other</td> </tr> </table> </td> </tr> </table>	Name:	B6	Address:	<table border="1"> <tr> <td data-bbox="899 1317 1170 1425">B6</td> </tr> <tr> <td data-bbox="899 1431 1529 1457">United States</td> </tr> </table>	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:	<table border="1"> <tr> <td data-bbox="899 1767 1040 1795">Manufacturer</td> </tr> <tr> <td data-bbox="899 1802 1529 1828">Other</td> </tr> </table>	Manufacturer	Other	Additional Documents:		
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Additional Documents:																																																																				

Report Details - EON-359956

ICSR:	2052521		
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:	2018-07-21 12:06:50 EDT		
Initial Report Date:	07/21/2018		
Reporter is the Animal Owner:	Yes		
Parent ICSR:	2052520		
Follow-up Report to FDA Request:	Yes		
Reported Problem:	Problem Description:	sudden onset of coughing- new found heart murmur. heart significantly enlarged on chest xrays. echo of heart shows DCM	
	Date Problem Started:	07/09/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Worse/Declining/Deteriorating	
Product Information:	Product Name:	WholeHearted Grain Free All Life Stages Lamb and Lentil Formula Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	07/02/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Stored on shelf at store. once home- store in air tight contained with a twist on top	
	Product Use Information:	Description:	Fed twice daily to dogs as directed based off weight
		Last Exposure Date:	07/19/2018
		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:	No
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

United States

Animal Information:

Name:

Type Of Species: Dog

Type Of Breed: Terrier - Boston

Gender: Male

Reproductive Status: Neutered

Weight: 30 Pound

Age: 7 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:

Phone:

Other Phone:

B6

Address:

B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: 07/19/2018

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: Phone

Reported to Other Parties: Other

Additional Documents:

Report Details - EON-359955		
ICSR:	2052520	
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:	2018-07-21 11:55:35 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: sudden onset of coughing- new found heart murmur. heart significantly enlarged on chest xrays. echo of heart shows DCM	
	Date Problem Started: 07/09/2018	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6	
	Outcome to Date: Worse/Declining/Deteriorating	
Product Information:	Product Name: WholeHearted Grain Free All Life Stages Lamb and Lentil Formula Dry Dog Food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 25 Pound	
	Purchase Date: 07/02/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: Yes	
	Storage Conditions: Stored on shelf at store. once home- store in air tight contained with a twist on top	
	Product Use Information:	Description: Fed twice daily to dogs as directed based off weight
		Last Exposure Date: 07/19/2018
		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: 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;"> <h1 style="margin: 0;">B6</h1> </div>	
		United States		
Animal Information:	Name:			
		Type Of Species:	Dog	
		Type Of Breed:	Terrier - Boston	
		Gender:	Male	
		Reproductive Status:	Neutered	
		Weight:	30 Pound	
		Age:	7 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:	<div style="border: 1px dashed black; padding: 5px; text-align: center;"> <h1 style="margin: 0;">B6</h1> </div>	
		United States		
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	07/19/2018	
		Permission to Release Records to FDA:	Yes	
Sender Information:	Name:			
		Address:	<div style="border: 1px dashed black; padding: 5px; text-align: center;"> <h1 style="margin: 0;">B6</h1> </div>	
		United States		
		Contact:		
		Reporter Wants to Remain Anonymous:	Yes	
		Reported to Other Parties:	Other	
Additional Documents:				

Report Details - EON-360887

ICSR:	2053000
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:	2018-07-31 09:28:52 EDT
Initial Report Date:	07/25/2018
Parent ICSR:	2052746
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Present 7/19/18 for labored breathing. Radiographs revealed cardiomegaly with mild pleural effusion and moderate pulmonary edema. Pet has responded to B6 Taurine levels B6 (200-350). Started taurine 500 mg daily.
	Date Problem Started:	07/08/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Acana Lamb and apple single formula		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Product Use Information:	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:	Samoyed
	Gender:	Female
	Reproductive Status:	Intact
	Pregnancy Status:	Not Pregnant
	Lactation Status:	Not lactating
	Weight:	42.4 Pound
	Age:	4 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	2
	Number of Animals	1

	Reacted:	
	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
		Other Phone: B6
		Email: B6
	Address: B6 United States	
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact: Phone:	B6
		Other Phone: B6
		Email: B6
	Permission To Contact Sender: Yes	
	Preferred Method Of Contact: Email	
	Reported to Other Parties: None	
Additional Documents:	Attachment:	B6 2018-07-30-1548.pdf
	Description:	taurine levels
	Type:	Laboratory Report

Report Details - EON-360449

ICSR: 2052746
 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: 2018-07-25 20:19:00 EDT

Reported Problem:
Problem Description: Present 7/19/18 for labored breathing. Radiographs revealed cardiomegaly with mild pleural effusion and moderate pulmonary edema. Pet has responded to B6
Date Problem Started: 07/08/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Acana Lamb and apple single formula
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
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: Samoyed
Gender: Female
Reproductive Status: Intact
Pregnancy Status: Not Pregnant
Lactation Status: Not lactating
Weight: 42.4 Pound
Age: 4 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 2
Number of Animals Reacted: 1
Owner Information:
Owner Information provided: Yes
Contact: Name: B6
 Phone:

		Address:	B6		
				United States	
Healthcare Professional Information:	Practice Name:		B6		
	Contact:	Name:	B6		
		Phone:	B6		
		Other Phone:	B6		
	Email:				
	Address:		B6		
				United States	
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:	None				
Additional Documents:					

Report Details - EON-361105

ICSR:	2053104
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:	2018-08-01 18:58:49 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 collapsed after a walk of B6 and was rushed immediately to his local vet who took x-rays and then advised that he should be taken immediately to the local animal emergency clinic. B6 B6 After meeting with the admitting vet, he was given a sonogram and the initial diagnosis was dilated cardiomyopathy (DCM). We were asked to bring B6 back the following day to see cardiologist. B6 B6 underwent a number of tests. B6 was diagnosed with dilated cardiomyopathy, right sided. This appears to be caused by low levels of taurine in his blood which the cardiologist suspects resulted from feeding him a holistic grain free diet for the last 6+ years. As of 7/17, B6 taurine level is B6 micromoles/liter (I think is the reported concentration). They were only B6 in the first analysis on 6/30. The average range is 200-350, with a target goal of 250. So the cardiologist increased the taurine supplement dosage from 500 mg twice a day to 1,000 mg twice a day. See attached reports for additional information.
	Date Problem Started:	B6
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Earthborn Holistic Coastal Catch Grain Free	
	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:	Rubbermaid container	
	Product Use Information:	Description:	2 cups of kibble, twice a day. B6 was fed this food for 1 year as we had read it was a good idea to change proteins every now and then.
	First Exposure Date:	07/01/2015	
	Last Exposure Date:	07/31/2016	
	Time Interval between Product Use and Adverse Event:	2 Years	
	Product Use Stopped After the Onset of the Adverse Event:	Yes	
	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:

Product Name: Earthborn Holistic Meadow Feast Grain Free

Product Type: Pet Food

Lot Number:

UPC: 034846719123

Package Type: BAG

Package Size: 28 Pound

Number Purchased: 1

Possess Unopened
Product: Yes

Possess Opened
Product: Yes

Storage Conditions: Stored in sealed Rubber Maid container. After opened, stored in sealed dog food container.

Product Use
Information:

Description:

B6 was fed 2 cups of the kibble twice a day. **B6** was fed this product all of his adult life, except for one year where he was fed Earthborn Holistic Coastal Catch Grain Free.

First Exposure
Date: 07/01/2012

Last Exposure
Date: **B6**

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: Probably 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: Retriever - Golden
	Gender: Male
	Reproductive Status: Neutered
	Weight: 75 Pound
	Age: 6.7 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: 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: 07/01/2018
	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: Other	
Additional Documents:	

Attachment:	7-23-18 Cardiologist Update.pdf
Description:	Taurine results from 7-17 Cardiologist appointment
Type:	Medical Records
Attachment:	Emergency Record B6 .pdf
Description:	Emergency Room Visit Record
Type:	Medical Records
Attachment:	Diet History_Taurine Study-4.pdf
Description:	UC Davis Diet History Taurine Study information
Type:	Record
Attachment:	B6 Discharge Instructions 7-2-18.pdf
Description:	Discharge Information and Instructions from 7-2-18 Cardiologist Appointment
Type:	Medical Records

Report Details - EON-361244		
ICSR:	2053160	
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:	2018-08-03 06:31:39 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: After becoming aware that dogs eating grain free diets could have low taurine levels, with a result of DCM, I decided to have B6 tested. Her plasma taurine level came back at B6 . (critical level is less than 40, normal range is 60-120.) I had her heart checked by Echocardiogram and it was noted that she has a small amount of mitral valve and tricuspid valve regurgitation.	
	Date Problem Started: 07/16/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Unknown	
Product Information:	Product Name: Acana Singles Ingredient Diet Lamb & Apple Formula	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 25 Pound	
	Purchase Date: 06/01/2015	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: The product was stored in a Simple Human, BPA free, dogfood storage container.	
	Product Use Information:	Description: B6 was feed this dog food from age 15 months to current (4.3 years). She received 3.5 cups per day as her primary source of food.
		First Exposure Date: 06/01/2015
		Last Exposure Date: 08/03/2018
		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: Definitely related		
Other Foods or Products Given to the Animal During This Time Period: Yes		
Manufacturer /Distributor Information:		
Purchase Location Name:		
<div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 24px; font-weight: bold;">B6</div>		

	Information:	Address:	B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	33.3 Kilogram		
	Age:	4.3 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:	B6
Other Phone:			B6	
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:	07/16/2018			
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:	Other			
Additional Documents:	Attachment:	Taurine Plasma Results.pdf		
	Description:	Results of plasma taurine test		
	Type:	Laboratory Report		

Attachment:	scan0008.pdf
Description:	B6 Echocardiogram Results
Type:	Echocardiogram

Report Details - EON-361347

ICSR: 2053230
 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: 2018-08-04 11:49:14 EDT

Reported Problem:
Problem Description: Dog developed a grade **B6** left apical systolic murmur, which was evaluated by a cardiologist via echocardiogram, which revealed concern for occult dilated cardiomyopathy, possibly taurine deficiency. A taurine level was sent to the lab and her level was **B6** normal is 200-350, critically low is less than 150).
Date Problem Started: 07/10/2018
Concurrent Medical Problem: No
Outcome to Date: Unknown

Product Information:
Product Name: V-Dog Kinder Kibble
Product Type: Pet Food
Lot Number:
Product Use Information:
Description: This food was fed as the majority of the diet for all of 2017 through June 2018. The dog was also intermittently fed small portions of Natural Balance Vegetarian for no more than 1 month of 2017, and in June 2018 the dog was switched to Halo Vegan.
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: Pit Bull
Gender: Female
Reproductive Status: Neutered
Weight: 55 Pound
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**
Phone:
Email:

		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
	Date First Seen:	07/10/2018
	Permission to Release Records to FDA:	Yes
	Practice Name:	B6
	Contact: Name:	B6
Phone:	B6	
Type of Veterinarian:	Referred veterinarian	
Date First Seen:	07/20/2018	
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:	B6 17984839.pdf
	Description:	Taurine level
	Type:	Laboratory Report
	Attachment:	B6 -20-18.pdf
	Description:	Echocardiogram report
	Type:	Echocardiogram

Report Details - EON-361412

ICSR:	2053251
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-08-05 20:48:31 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	In February, 2018, B6 started coughing when he was playing, been excited or was doing excensises, for example, when digging snow. He became lethargic, lost appetite, he started breathing hard. During the walk he was making several stops for rest. We contacted our vet. He made an X-Ray. On X-Ray the left half of the heart been enlarged. Our vet recommended us to see a cardiologist. The cardiologist made the ultrasonic exam of the heart and diagnosed DCM. The cardiologist made blood tests for infections and taurine. Tests didn't show any problems. After all exams cardiologist told that the only guess he has is genetic. He also noticed that miniature schnauzers don't have genetic predisposition to DCM and our case is exceptional. July 13th, 2018 we found an article on the NBC News website called "Dog heart disease linked to food, FDA says". According to this article, FDA reports that dogs fed "grain-free" food based on peas, lentils or potatoes are developing an unusual condition that can cause dilated cardiomyopathy. At this point we remembered that we fed B6 with such a dog food, a grain-free food containing peas, lentils and potatoes, exactly the same, as FDA has been reported.
	Date Problem Started:	02/20/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
Outcome to Date:		Stable

Product Information:	Product Name:	Instinct by Nature's Variety Raw Boost Healthy Weight Grain-Free Chicken Recipe Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	4 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Before and after opening the product was stored in the room temperature condition. Before opening in the original bag. After opening in the stainless steel canisters with acrylic tops.	
	Product Use Information:	Description:	We fed B6 twice per day. In the morning and in the evening. This dog food contains peas.
		Product Use Stopped After the Onset of the Adverse Event:	Yes
Adverse Event Abate After Product Stop:		No	
Product Use		No	

		Started Again:	
		Perceived Relatedness to Adverse Event:	Possibly related
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	
			United States
	Product Name:	CANIDAE Grain-Free PURE Fields with Chicken Small Breed Limited Ingredient Diet Adult Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	4 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Before and after opening the product was stored in the room temperature condition. Before opening in the original bag. After opening in the stainless steel canisters with acrylic tops.	
	Product Use Information:	Description:	We fed B6 twice per day. In the morning and in the evening. After 6 month B6 stopped eating this food. He was protesting and running away when see this food. This food contains peas, lentils and potatoes as one of main ingredients. Exactly the same list was reported by FDA as ingredients that may cause DCM (dilated cardiomyopathy).
		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
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	B6
		Address:	
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Schnauzer - Miniature	
	Gender:	Male	
	Reproductive Status:	Intact	
	Weight:	20 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
	Address: B6
	United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 04/05/2018
	Permission to Release Records to FDA: Yes
	Practice Name: B6
	Contact: Name: B6
Phone: B6	
Address: B6	
United States	
Type of Veterinarian: Referred veterinarian	
Permission to Release Records to FDA: Yes	
Practice Name: B6	
Contact: Name: B6	
Phone: B6	
Address: B6	
United States	
Type of Veterinarian: Referred veterinarian	
Sender Information:	Name:
Address: B6	
United States	
Contact: Phone: B6	
Email: B6	
Permission To Contact Sender: Yes	
Preferred Method Of: Email	

	Contact:	
	Reported to Other Parties:	Other
Additional Documents:	Attachment:	2018-04-21 X-RAY [B6] Series-3--Image-NaN).png
	Description:	X-RAY, Image 3
	Type:	Medical Records
	Attachment:	2018-04-21 X-RAY [B6] Series-1--Image-NaN).png
	Description:	X-RAY, Image 1
	Type:	Medical Records
	Attachment:	2018-04-21 X-RAY [B6] Series-2--Image-NaN).png
	Description:	X-RAY, Image 2
	Type:	Medical Records
	Attachment:	2018-04-21 ECHOCARDIOGRAPHY REPORT [B6].df
	Description:	ECHOCARDIOGRAPHY REPORT
	Type:	Medical Records
	Attachment:	2018-04-21 CARDIOLOGY REFERRAL REPORT [B6] 73447).pdf
	Description:	CARDIOLOGY REFERRAL REPORT
	Type:	Medical Records

Report Details - EON-361601

ICSR:	2053401
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 16:20:10 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Since B6 was a puppy, he's had B6 likely related to a B6 . Since he was 9 months old, he's been on Zignature kangaroo dry food in order to give him an exotic protein he and his ancestors had not been exposed to. So B6 has been on Zignature kangaroo for a little over 3 years, he's fed very few other treats (only bully sticks and bits of cheese for medicine), so Zignature kangaroo dry food is his main nutrition source. On B6 woke up incredibly lethargic, somewhat able to move around but totally exhausted and disinterested in food, which was very unlike him. I took him to the emergency clinic and he was diagnosed with dilated cardiomyopathy either related to a taurine deficiency in conjunction with grain free food or a possible genetic /ideopathic link. The emergency clinic took a blood sample to be sent off for taurine analysis. Yesterday, I saw a veterinary cardiologist who confirmed the dilated cardiomyopathy (DCM) diagnosis, noting that his left chamber was very enlarged but his left atrium was still normal, very in line with DCM. She suspected a link to taurine deficiency but the lab had not yet returned. Last night (8/6/2018), the emergency clinic called and said B6 blood test confirmed his taurine levels are EXTREMELY low and would absolutely be enough to cause taurine deficiency DCM. B6 now needs to take 6000 mg of a taurine supplement per day (2000mg 3x a day). He will also need to be moved to a dog food WITH grain because it's not yet understood if the grain free food itself is taurine deficient or something about the ingredients causes taurine deficiency. As per the FDA press release, I'm writing in to let you know about another case of grain free food and dilated cardiomyopathy in my 4 year old Golden Retriever. Both B6 parents (and their parents) were certified by a veterinary cardiologist prior to being bred and both passed with no signs of genetic DCM. I won't know 100% until I follow-up with the cardiologist in 6 months after he's gotten his taurine supplement, but at this point, it's very likely related to this food.
	Date Problem Started:	07/29/2018
	Date of Recovery:	08/06/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6 so he was prescribed an exotic /novel protein diet.
	Outcome to Date:	Stable

Product Information:	Product Name:	Zignature Kangaroo Formula Limited Ingredient Formula
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	27 Pound
	Purchase Date:	07/14/2018
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	Yes
	Storage Conditions:	Stored in an airtight container after opening
Product Use Information:	Description:	B6 ate 1.5 cups of Zignature kangaroo in the AM and 1.5 cups of Zignature kangaroo in the PM. Because of his B6 B6 was only fed this food and other, non-protein treats (cheese for medicine).

Manufacturer /Distributor Information:	Name:	Pets Global
	Type(s):	Manufacturer
	Address:	28334 Industry Dr Valencia California 91355 United States
	Contact:	Phone: (661) 309-1235 Web Address: www.zignature.com
	Possess One or More Labels from This Product:	Yes
Purchase Location Information:		
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	86 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
	Address:	B6 United States
	Type of Veterinarian:	Referred veterinarian
	Date First Seen:	07/29/2018
	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:	08/06/2018
	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:	08/07/2018
		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:	Attachment:	B6	vs_report.pdf
	Description:		emergency clinic report
	Type:		Medical Records
	Attachment:		20180806105046291.pdf
	Description:	B6	lab results for his taurine blood test
	Type:		Laboratory Report
	Attachment:	8_6_1	B6 240094_CARDIO_REPORT.pdf
	Description:	B6	report from the cardiologist
	Type:		Medical Records

Report Details - EON-361684

ICSR: 2053471
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-08 15:50:26 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: B6 is a 6 year old American Staffordshire Terrier. In Nov of 2017, he was taken to the ER. He was in Congestive Heart Failure. More recently, his cardiologist suggested there may be a link between a grain free diet and his heart problems. He has been on a grain free diet for most of his life.
Date Problem Started: 11/30/2017
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Kirkland Signature Nature's Domain Organic Chicken & Pea Formula Dog Food, 30 lb, Item 833170 at Costco
Product Type: Pet Food
Lot Number:
UPC: Item 833170
Package Type: BAG
Package Size: 30 Pound
Purchase Date: 07/25/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: dry closet in the bag

Product Use Information:
Description: 4 cups a day for the last 5-6 years
Last Exposure Date: 08/08/2018
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: 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		
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Terrier - Bull - Staffordshire		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	80 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:	
Address:		B6		
		United States		
Type of Veterinarian:		Referred veterinarian		
Date First Seen:		12/01/2017		
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-361723			
ICSR:	2053499		
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:	2018-08-09 09:08:03 EDT		
Reported Problem:	Problem Description:	This dog has been fed a grain-free diet since she was a puppy and has now developed dilated cardiomyopathy.	
	Date Problem Started:	08/08/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Zignature Kangaroo Limited Ingredient Formula Grain-Free Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Product Use Information:	Description:	According to the dog's owners, this dog has been on grain-free dog food since puppy hood.
		Last Exposure Date:	08/08/2018
		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:	Definitely related
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:	53 Pound	
	Age:	35 Months	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
Owner Information:	Owner Information	Yes	

		provided:															
		<table border="1"> <tr> <td rowspan="4">Contact:</td> <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>	Contact:	Name:	B6	Phone:	Other Phone:	Email:									
Contact:	Name:	B6															
	Phone:																
	Other Phone:																
	Email:																
		<table border="1"> <tr> <td rowspan="2">Address:</td> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	Address:	B6	United States												
Address:	B6																
	United States																
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td rowspan="4">Contact:</td> <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> <tr> <td rowspan="2">Address:</td> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	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																
Sender Information:	<table border="1"> <tr> <td rowspan="2">Name:</td> <td rowspan="2">B6</td> </tr> <tr> <td>Address:</td> </tr> <tr> <td></td> <td>United States</td> </tr> <tr> <td rowspan="3">Contact:</td> <td>Phone:</td> <td rowspan="3">B6</td> </tr> <tr> <td>Other Phone:</td> </tr> <tr> <td>Email:</td> </tr> <tr> <td>Permission To Contact Sender:</td> <td>Yes</td> </tr> <tr> <td>Preferred Method Of Contact:</td> <td>Email</td> </tr> <tr> <td>Reported to Other Parties:</td> <td>None</td> </tr> </table>	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
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-362172

ICSR:	2053687
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:	2018-08-14 09:20:28 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	We have two bluetick coonhounds, same parents, 3 years apart in age. B6 is 5 (neutered boy) and B6 is 2 (spayed girl). After our vet diagnosed B6 with D.C.M and told us he had a severely enlarged heart, we went to the B6 to confirm diagnosis with a canine cardiologist. Confirmed D.C.M and congestive heart failure with 25% of his heart was working with a year to live on medication. He was put on diuretics. B6 We did the blood test for taurine deficiency related D.C.M. with the wildcard hope that it was reversible since B6 was so young, not a breed that is predisposed to D.C.M. and has been an active, happy dog. While we waited for the results, we started Taurine and L-Carnitine supplements twice daily. After 1 week, his heart reduced in size by 15%, our vet sent us the NY Times article about D.C.M. and grain-free food. We switched B6 from Kirkland Nature's Domain Organic Chicken and Peas dry food to Hill's Science Diet Adult 1-5 years Chicken and Barley. We received B6 plasma taurine results. B6 We immediately tested and x-rayed B6 her plasma taurine level as B6 and her heart was slightly enlarged. We started supplementing her with Taurine upon vet confirmation. We love our dogs and are so sad that the "good" food we bought them potentially caused all this. We have one more week before the next milestone follow-up of x-rays and blood work at 1 month post diagnosis but B6 is up to 91lb from 78lbs.
	Date Problem Started:	07/19/2018
	Date of Recovery:	08/04/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6 had a cough and was hard breathing (fast breathing but not panting), he was diagnosed with a cold and was put on antibiotics. After 2 weeks, he still was not better and was put on another round of antibiotics. After the second round with no improvement, we brought him in for an x-ray and blood work. He was diagnosed with D.C.M.
Outcome to Date:	Better/Improved/Recovering	

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:	06/30/2018
	Number Purchased:	3
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	After their feeder is filled, the remaining product was put in a air tight plastic bin in our pantry. https://www.costco.com/Kirkland-Signature-Natures-Domain-Organic-Chicken-&-Pea-Dog-Food-30-lb..product.100155729.html and https://www.costco.com/Kirkland-Signature-Nature's-Domain-Turkey-Meal-and-Sweet-Potato-Dog-Food-35-lb..product.100343435.html
Product Use Information:	Description: B6 free feed in a self feeding dry food dispenser container. We were feeding B6 since age 1 Kirkland Signature Nature's Domain Turkey Meal and Sweet Potato Dog Food 35 lb. and switched to Kirkland Signature Nature's Domain Organic Chicken & Pea Dog Food 30 lb.	

		just before he turned 3. B6 has been on Kirkland Signature Nature's Domain Organic Chicken & Pea Dog Food 30 lb. her whole time with us since she was 14 weeks old to July 28, 2018.
	First Exposure Date:	07/01/2018
	Last Exposure Date:	07/28/2018
	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:	Yes
	Product Use Started Again:	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:	Name: Costco
		Address: B6 United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Coonhound - Bluetick
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	78.4 Pound
	Age:	5 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:
		Other Phone:
		Email:
		Address: B6

			B6
		United States	
	Type of Veterinarian:	Referred veterinarian	
	Date First Seen:	07/19/2018	
	Permission to Release Records to FDA:	Yes	
	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	
		Other Phone:	
		Email:	
	Address:	B6	
		United States	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	07/16/2018	
	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:	IMG_20180719_0002.pdf	
	Description:	B6 D.C.M and congestive heart failure diagnosis	
	Type:	Letter	
	Attachment:	B6 .pdf	
	Description:	Taurine test results for B6	
	Type:	Letter	
	Attachment:	[Untitled].pdf	
	Description:	B6 diet pre and post D.C.M. diagnosis	
	Type:	Other	

Report Details - EON-362327

ICSR: 2053755
 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 12:20:29 EDT

Reported Problem:
Problem Description: Diagnosed with dilated cardiomyopathy and congestive heart failure in October 2016
Date Problem Started: 10/20/2016
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Stable

Product Information:

Product Name:	Nature's Variety Instinct Limited Ingredient Diet - Lamb	
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:		
Product Name:	Nature's Variety Instinct Limited Ingredient Diet - Duck	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Product Use 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:	Unknown
Manufacturer /Distributor Information:		
Purchase Location Information:		
Product Name:	Zignature Kangaroo Formula	

	Product Type:	Pet Food								
	Lot Number:									
	Package Type:	CAN								
	Possess Unopened Product:	No								
	Possess Opened Product:	No								
	Product Use Information:	<table border="1"> <tr> <td>Last Exposure Date:</td> <td>06/01/2018</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>Possibly related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Unknown</td> </tr> </table>	Last Exposure Date:	06/01/2018	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:	Unknown
Last Exposure Date:	06/01/2018									
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:	Unknown									
	Manufacturer /Distributor Information:									
	Purchase Location Information:									
	Product Name:	Zignature Kangaroo Formula								
	Product Type:	Pet Food								
	Lot Number:									
	Package Type:	BAG								
	Possess Unopened Product:	No								
	Possess Opened Product:	No								
	Product Use Information:	<table border="1"> <tr> <td>Last Exposure Date:</td> <td>06/01/2018</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>Possibly related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Unknown</td> </tr> </table>	Last Exposure Date:	06/01/2018	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:	Unknown
Last Exposure Date:	06/01/2018									
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:	Unknown									
	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:	84 Pound								

	Age:	10 Years												
	Assessment of Prior Health:	Fair												
	Number of Animals Given the Product:	1												
	Number of Animals Reacted:	1												
	Owner Information:	<table border="1"> <tr> <td>Owner Information provided:</td> <td>Yes</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Owner Information provided:	Yes	Contact: Name:	B6	Phone:		Address:	B6		United States		
Owner Information provided:	Yes													
Contact: Name:	B6													
Phone:														
Address:	B6													
	United States													
	Healthcare Professional Information:	<table border="1"> <tr> <td>Practice Name:</td> <td>B6</td> </tr> <tr> <td>Contact: Name:</td> <td>B6</td> </tr> <tr> <td>Phone:</td> <td>B6</td> </tr> <tr> <td>Email:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> <tr> <td></td> <td>United States</td> </tr> </table>	Practice Name:	B6	Contact: Name:	B6	Phone:	B6	Email:		Address:	B6		United States
Practice Name:	B6													
Contact: Name:	B6													
Phone:	B6													
Email:														
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:	Email												
	Reported to Other Parties:	None												
Additional Documents:														

Report Details - EON-362347

ICSR: 2053764
 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 13:46:25 EDT

Reported Problem:
Problem Description: Pleural effusion diagnosed 8/14/18 Echocardiogram revealed biventricular DCM
Date Problem Started: 08/11/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: 4health Untamed Open Highland Lamb & Lentil
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
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: B6
Type Of Species: Dog
Type Of Breed: Mixed (Dog)
Gender: Female
Reproductive Status: Neutered
Weight: 31 Pound
Age: 4 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

			B6 United States	
Healthcare Professional Information:	Practice Name:	B6		
	Contact:	Name:	B6	
		Phone:		
	Email:			
	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:	Email		
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-361298

ICSR: 2053201
 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: 2018-08-03 15:17:36 EDT

Reported Problem:
Problem Description: Previously healthy dog [B6] presented to ER for acute, severe, productive coughing; Dx pneumonia vs kennel cough; Rx [B6] 7/16/2018 - presented to pcDVM for recheck - persistent coughing, now decreased appetite; Dx CHF; Rx [B6] 7/18/2018 - presented to [B6] for Pets for further evaluation of CHF; clinically improved with cardiac Rx; echo diagnosis of dilated cardiomyopathy. Taurine level submitted by pcDVM with a decreased result returned. Patient has been started on taurine and L-carnitine supplementation and diet had been changed to Natural Balance Synergy chicken (a non-grain-free formula). As of our last communication with the owner on 7/23 /2018, the dog is clinically doing well at home.
Date Problem Started: [B6]
Date of Recovery: 07/23/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: Dick Van Patten's Natural Balance Limited Ingredient Diets For Adult Dogs Complete and Balanced For All Breeds Sweet Potato and Fish Formula
Product Type: Pet Food
Lot Number:
UPC: 723633420365
Package Type: BAG
Package Size: 13 Pound
Possess Unopened Product: No
Possess Opened Product: Yes
Storage Conditions: Please contact owner for storage information.
Product Use Information:
Description: Please contact owner for feeding 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:	Dick Van Patten's Natiral Balance Limited Ingredient Diets with Chicken and Sweet Potatoes.	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	723633001700	
	Package Type:	CAN	
	Package Size:	13 Ounce	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	No	
	Storage Conditions:	Please contact owner for storage information.	
	Product Use Information:	Description:	Please contact owner for feeding 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:	Retriever - Golden	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	36.4 Kilogram	
	Age:	5 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name:
			Phone:
			Other Phone:
			Email:
		Address:	B6

		B6 United States	
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	
		Phone:	B6
		Other Phone:	
	Address:	B6	
		United States	
Type of Veterinarian:	Primary/regular veterinarian		
Date First Seen:	07/16/2018		
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:	Attachment:	B6 Echo Data 7.18.2018.pdf	
	Description:	Echo Data 7.18.2018	
	Type:	Medical Records	
	Attachment:	B6 Cardiac Evaluation Report 7.18.2018.pdf	
	Description:	Cardiac Evaluation Report 7.18.2018	
	Type:	Medical Records	

Report Details - EON-361314

ICSR: 2053218
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2018-08-03 18:21:31 EDT

Reported Problem:

Problem Description: [B6] was initially presented to the primary care vet 6/22/18 for loose stools and cough - they had prescribed a tapering [B6] dose, which seemed to help at first but then the cough recurred and on 7/3/18 they prescribed [B6] [B6] for anxiety. He presented to our ER and cardiology service on [B6] for persistent cough, anxiety, and heavy panting. Thoracic radiographs were performed and showed severe cardiomegaly and diffuse pulmonary changes most consistent with pulmonary edema; he was started on [B6] and supplemental oxygen pending cardiac evaluation. No weakness or collapse had been noted and [B6] continued to eat normally. Echocardiogram confirmed dilated cardiomyopathy with severe left atrial and left ventricular enlargement, profound decrease in systolic function, and moderate right atrial and ventricular enlargement. Supportive therapy for heart failure with [B6] and Oxygen were continued, but due to progressive decline the owners elected to have [B6] euthanized on [B6] [B6] had been on the Zignature brand Kangaroo and Lentil diet for several years; the owners changed the diet to Wellness Core Whitefish and Potato approximately 1 week prior to presentation.

Date Problem Started: 06/22/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: Chronic history of [B6] had chronically been on [B6] supplementation and was on the Kangaroo and Lentil Diet to try and help this. Due to the recurrence of loose stools ~2 weeks prior to presentation, the owner had switched the patient to a new diet (Wellness Core) to see if this would help.

Outcome to Date: Died Euthanized

Date of Death: [B6]

Product Information:

Product Name: Zignature Kangaroo and Lentil - Dry

Product Type: Pet Food

Lot Number:

Package Type: BAG

Possess Unopened Product: No

Possess Opened Product: No

Product Use Information:

Description:	Fed daily for several years
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: No

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Shepherd Dog - Australian

Gender: Male

Reproductive Status: Neutered

Weight: 27 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: B6
Phone: B6
Other Phone: B6
Email: B6

Address:

B6
United States

Healthcare Professional Information:

Practice Name: B6

Contact:

Name: Multiple Doctors Multiple Doctors
Phone: B6
Other Phone: B6

Address:

B6
United States

Type of Veterinarian:

Primary/regular veterinarian

Date First Seen:

06/22/2018

Permission to Release Records to FDA:

Yes

Practice Name:

B6

Contact:

Name: B6
Phone: B6
Other Phone: B6

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	
		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:	1.2.840.114387.905481555.32157.17982.37310.25855147266163.jpg		
	Description:	Left lateral radiograph at initial ER presentation		
	Type:	Radiographs		
	Attachment:	B6	Echo Report.pdf	
	Description:	Echo report		
	Type:	Medical Records		
	Attachment:	HX	B6 pdf	
	Description:	ER presenting history and referral form to cardiology service		
	Type:	Medical Records		
	Attachment:	Echo Data (13).pdf		
	Description:	Echocardiographic data		
	Type:	Echocardiogram		
	Attachment:	BW (CBC, CHEM, LYLES)	B6 pdf	
	Description:	ER labwork performed at initial presentation		
	Type:	Laboratory Report		

Report Details - EON-361315

ICSR:	2053219
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-08-03 18:25:46 EDT
Initial Report Date:	08/03/2018
Parent ICSR:	2053218
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	B6 was initially presented to the primary care vet 6/22/18 for loose stools and cough - they had prescribed a tapering B6 dose, which seemed to help at first but then the cough recurred and on 7/3/18 they prescribed B6 B6 as well as B6 for anxiety. He presented to our ER and cardiology service on B6 for persistent cough, anxiety, and heavy panting. Thoracic radiographs were performed and showed severe cardiomegaly and diffuse pulmonary changes most consistent with pulmonary edema; he was started on B6 and supplemental oxygen pending cardiac evaluation. No weakness or collapse had been noted and B6 continued to eat normally. Echocardiogram confirmed dilated cardiomyopathy with severe left atrial and left ventricular enlargement, profound decrease in systolic function, and moderate right atrial and ventricular enlargement. Supportive therapy for heart failure with B6 and Oxygen were continued but due to progressive decline the owners elected to have B6 euthanized on B6 had been on the Zignature brand Kangaroo and Lentil diet for several years; the owners changed the diet to Wellness Core Whitefish and Potato approximately 1 week prior to presentation. **It was also requested that I add to this report that I was encouraged by Vet-LIRN to submit this complaint**
	Date Problem Started:	06/22/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Chronic history of B6 had chronically been on B6 supplementation and was on the Kangaroo and Lentil Diet to try and help this. Due to the recurrence of loose stools ~2 weeks prior to presentation, the owner had switched the patient to a new diet (Wellness Core) to see if this would help.
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Zignature Kangaroo and Lentil - Dry		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Product Use Information:	Description:	Fed daily for several years	
		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:	No	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Shepherd Dog - Australian		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	27 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:	B6
			Phone:	
			Other Phone:	
	Email:			
Address:	B6			
	United States			
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:	06/22/2018		
Permission to Release Records to FDA:	Yes			
Practice Name:	B6			

	Contact:	Name: Multiple Doctors Multiple Doctors
		Phone: B6
		Other Phone:
	Address:	B6
		United States
	Type of Veterinarian:	Referred veterinarian
Date First Seen:	07/06/2018	
Permission to Release Records to FDA:	Yes	

Sender Information:	Name:	
	Address:	B6
		United States
	Contact:	Phone:
		Other 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-362158

ICSR: 2053655
 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: 2018-08-13 22:41:16 EDT

Reported Problem:

Problem Description: **** I spoke with Dr. Jennifer Jones regarding this patient and submitting necropsy tissue samples 8/13/18**** Patient was transferred from rDVM to the emergency service for further care for dyspnea and suspected CHF on 7/13/18. Patient severely dyspneic on presentation and not stable enough for echo until the next day. Patient treated for CHF and improved. Echocardiogram showed findings consistent with dilated cardiomyopathy with severe LV dilation and severe systolic dysfunction. The owner had been feeding Acana lamb and apple diet for years to both of her dogs. Taurine level was submitted and patient was placed on taurine supplementation with recommended diet change. Patient was able to be discharged from the hospital a few days later and had been doing pretty well at home but did present to ER for possible syncopal episodes on B6 owner declined most diagnostic tests recommended but patient clinically appeared stable and was diagnosed with a corneal ulcer at that time. Patient presented to the emergency service B6 DOA - patient was reportedly dyspneic and died during transport to the hospital.

Date Problem Started: 07/13/2018

Concurrent Medical Problem: No

Outcome to Date: Died Naturally

Date of Death: B6

Product Information:

Product Name: Acana Lamb and Apple Singles Formula

Product Type: Pet Food

Lot Number:

UPC: 6499251013

Package Type: BAG

Package Size: 13 Pound

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Product Use Information:

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: Pug

Gender: Male

Reproductive Status: Neutered

Weight: 8.75 Kilogram

Age: 5 Years

Assessment of Prior: Good

	Health:															
	Number of Animals Given the Product:	2														
	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:												
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Phone:																
Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States													
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	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> <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>	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:		Address:	<table border="1"> <tr> <td>B6</td> </tr> <tr> <td>United States</td> </tr> </table>	B6	United States
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:	B6														
	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:	Other														
Additional Documents:	Attachment:	B6 taurine level B6 pdf														
	Description:	taurine level														
	Type:	Laboratory Report														
	Attachment:	B6 echocardiogram B6 pdf														
	Description:	Echo report														
	Type:	Echocardiogram														

Report Details - EON-362883									
ICSR:	2053978								
Type Of Submission:	Initial								
Report Version:	FPSR.FDA.PETF.V.V1								
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)								
Reporting Type:	Voluntary								
Report Submission Date:	2018-08-20 16:54:22 EDT								
Reported Problem:	Problem Description: Reported as RFR EON-362877, ICSRHouse mate of [B6] case # 225069 (report filed 8/17/18). Came in for DCM screening. ACANA Dog Foods manufactured by Champion Petfoods USA: Chicken, Turkey and Nest Laid Eggs. NCSU Veterinary School has been following cases of Dilated Cardiomyopathy in dogs on grain free diets. [B6] 4 year old female, snayed Doberman Pinscher, was diagnosed and treated for DCM at [B6] in April 2018. It was originally assumed to be breed related, however it was noted that she had been eating ACANA grain free pet food. The owner changed the food to Orijen Regional Red Grain Free diet for 1 month, then changed again to Purina Pro Plan Bright Minds in May 2018. He was seen again August 14, 2018 and a significant improvement has been reported in both her clinical signs and diagnostic imaging.								
	Date Problem Started: 04/20/2018								
	Date of Recovery: 08/14/2018								
	Concurrent Medical Problem: Unknown								
	Outcome to Date: Better/Improved/Recovering								
Product Information:	Product Name: ACANA Grain Free Chicken, Turkey and Nest Laid Eggs Dry Dog Food								
	Product Type: Pet Food								
	Lot Number:								
	Package Type: BAG								
	Product Use Information:								
	Manufacturer /Distributor Information: <table border="1"> <tr> <td>Name:</td> <td>Champion Petfoods</td> </tr> <tr> <td>Type(s):</td> <td>Manufacturer</td> </tr> <tr> <td>Contact:</td> <td></td> </tr> <tr> <td>Possess One or More Labels from This Product:</td> <td>Yes</td> </tr> </table>	Name:	Champion Petfoods	Type(s):	Manufacturer	Contact:		Possess One or More Labels from This Product:	Yes
	Name:	Champion Petfoods							
Type(s):	Manufacturer								
Contact:									
Possess One or More Labels from This Product:	Yes								
Purchase Location Information:									
Animal Information:	Name: [B6]								
	Type Of Species: Dog								
	Type Of Breed: Doberman Pinscher								
	Gender: Female								
	Reproductive Status: Neutered								
	Age: 4 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>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> </table> </td> </tr> </table>	Practice Name:	[B6]	Contact:	<table border="1"> <tr> <td>Name:</td> <td>[B6]</td> </tr> </table>	Name:	[B6]			
Practice Name:	[B6]								
Contact:	<table border="1"> <tr> <td>Name:</td> <td>[B6]</td> </tr> </table>	Name:	[B6]						
Name:	[B6]								

			Phone	B6
			Email	B6
		Address:	B6	
			United States	
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	04/20/2018	
		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:	Attachment:	B6	14 Aug 2018.pdf	
	Description:	NCSU medical record - 4 mo recheck		
	Type:	Medical Records		
	Attachment:	B6	Apr 2018.pdf	
	Description:	NCSU Medical record 4.20.2018		
	Type:	Medical Records		

Report Details - EON-362958

ICSR: 2054015
 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: 2018-08-21 13:50:45 EDT

Reported Problem:
Problem Description: B6 presented to B6 ER for abdominal effusion and increased panting (referred by rDVM). She was diagnosed and treated for DCM and biventricular heart failure. Blood was submitted for taurine analysis and her results came back B6 nmol/ml (normal is 200-350). She was placed on B6 taurine. On her 10 day recheck she showed no signs of edema and her heart has decreased in size. She continues to have some arrhythmias.
Date Problem Started: 08/06/2018
Concurrent Medical Problem: No
Outcome to Date: Better/Improved/Recovering

Product Information:
Product Name: ACANA singles: Pork and Squash Lamb and Apple
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: No
Possess Opened Product: Unknown
Storage Conditions: Unsure - ok to contact owner
Product Use Information:
Description: Used as food
First Exposure Date: 01/01/2016
Last Exposure Date: 08/21/2018
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: 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:	31.4 Kilogram	
	Age:	9 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	1	
	Number of Animals Reacted:	1	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6 Phone: B6
		Address:	B6 United States
	Healthcare Professional Information:	Practice Name:	B6
Contact:		Name: B6 Phone: B6	
Address:		B6 United States	
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:	B6 06 Aug 2018.pdf	
	Description:	NCSU 1st visit	
	Type:	Medical Records	
	Attachment:	B6 16 Aug 2018.pdf	
	Description:	NCSU recheck visit	
	Type:	Medical Records	

Report Details - EON-363497			
ICSR:	2054299		
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:	2018-08-27 15:44:42 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	1. New 3/6 heart murmur on physical exam, Aug 2018 2. Referred to cardiologist who found DCM by echo and taurine deficiency 3. Other than murmur, dog is asymptomatic	
	Date Problem Started:	08/01/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	Heart Guard for heartworm prevention	
	Outcome to Date:	Stable	
Product Information:	Product Name:	NUTRO WHOLESOME ESSENTIALS Senior Farm-Raised Chicken, Brown Rice & Sweet Potato Recipe Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	08/08/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Before opening, stored in bag it came in. After opening, stored in airtight hard plastic dog food container.	
	Product Use Information:	Description:	I've been feeding both of my dogs this kibble for several years. The affected dog (flat-coated retriever) eats approx 3 cups per day. The unaffected dog (border collie) eats approximately 2 cups a day. I will have the unaffected dog's taurine level tested.
		Last Exposure Date:	08/27/2018
		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:	Amazon	
	Address:	United States	
Animal Information:	Name:	B6	

	Type Of Species: Dog
	Type Of Breed: Retriever - Flat-coated
	Gender: Male
	Reproductive Status: Intact
	Weight: 65 Pound
	Age: 8.5 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:
	Address: B6
	United States
	Type of Veterinarian: Referred veterinarian
	Date First Seen: 08/18/2018
	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
Additional Documents:	

Report Details - EON-363513

ICSR: 2054304
 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: 2018-08-27 17:44:54 EDT

Reported Problem:
Problem Description: Submitted as RFR EON-363503. FDA resubmitting as PFR. canine dilated cardiomyopathy with low blood taurine level Patient was a neutered male Samoyed dog 8 years old. Presented with acute collapse and was found to have a cardiac arrhythmia and heart failure caused by dilated cardiomyopathy. Owner reports he has been exclusively fed a premium grain free diet for several years. The diet is Blue Buffalo Wilderness Grain Free with Salmon dry dog food, along with other flavors of the same brand, but all grain-free. He was hospitalized and treated in consultation with a veterinary cardiologist but died two days later. Whole blood taurine levels drawn on admission were subsequently found to be low (B6 ;nmols/l).
Date Problem Started: B6
Concurrent Medical Problem: Unknown
Outcome to Date: Died Other
Date of Death: B6

Product Information:
Product Name: Blue Buffalo Wilderness High Protein grain Free dry dog food salmon flavor
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: Unknown
Possess Opened Product: Unknown
Product Use Information: **Description:** Owner reports he has been exclusively fed a premium grain free diet for several years.
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Samoyed
Gender: Male
Reproductive Status: Neutered
Age: 8 Years
Assessment of Prior Health: Unknown
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** No
Healthcare Professional Information: **Practice Name:** B6
Contact: **Name:** B6
Phone:
Email:
Address: B6

B6

United States

Type of Veterinarian: Primary/regular veterinarian

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-345822

ICSR: 2040525
 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: 2018-01-22 17:19:17 EST

Reported Problem:

Problem Description: B6 was presented for evaluation of cough, labored breathing, multiple episodes of collapse, cardiomegaly, and suspected congestive heart failure. Congestive heart failure was confirmed with thoracic radiographs and echocardiogram revealed dilated cardiomyopathy.

Date Problem Started: 12/30/2017

Concurrent Medical Problem: Yes

Pre Existing Conditions: B6 and

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: California Natural Grain-Free Kangaroo and Red Lentils Recipe

Product Type: Pet Food

Lot Number:

Package Type: BAG

Purchase Date: 01/02/2018

Possess Unopened Product: No

Possess Opened Product: Yes

Product Use Information:

Description: B6 had been eating this dog food since she first displaced signs of B6 as a puppy and B6 was considered as a potential contributor.

Last Exposure Date: 01/10/2018

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: 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:	Mixed (Dog)	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	25.1 Kilogram	
	Age:	6 Years	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	4	
	Number of Animals Reacted:	4	
	Owner Information:	Owner Information provided:	Yes
		Contact:	Name: B6
			Phone: B6
			Email: B6
	Address:	B6	
United States			
Healthcare Professional Information:	Practice Name:	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:	Phone		
Reported to Other Parties:	Other		
Additional Documents:	Attachment:	Medical record.pdf	
	Description:	Medical record and echo report	
	Type:	Medical Records	

Attachment:	Taurine level.pdf
Description:	Taurine level
Type:	Laboratory Report
Attachment:	Listserve on kangaroo and lentil diets.pdf
Description:	Discussion amongst veterinary cardiologists of dilated cardiomyopathy in patients eating either kangaroo and lentil or vegan diets with lentils
Type:	Other

Report Details - EON-345831

ICSR: 2040528
 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: 2018-01-22 18:04:59 EST

Reported Problem:

Problem Description: One week prior to presentation at a local emergency and specialty clinic, owners noted [B6] to be tiring more quickly when playing catch. On the day of her initial presentation to the ER clinic, she had been coughing more than usual and sank to the ground when attempting to chase a ball, but recovered quickly. At the ER clinic she was diagnosed with atrial fibrillation and early congestive heart failure. Treatment was initiated there January 20, 2017. She was transferred to our clinic on January 23, 2017 for further evaluation and care. Her arrhythmia converted back to a normal sinus rhythm on January 20th prior to transfer and her congestive heart failure resolved with treatment. She had a second collapse episode prior to referral. Echocardiogram showed evidence of dilated cardiomyopathy with concurrent chronic degenerative valve disease.

Date Problem Started: 01/20/2017

Concurrent Medical Problem: Yes

Pre Existing Conditions: [B6]
 owner occasionally uses an herbal supplement for calming when this occurs, unknown

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: California Natural Grain-Free Kangaroo and Red Lentils Recipe

Product Type: Pet Food

Lot Number:

Package Type: BAG

Purchase Date: 08/14/2017

Possess Unopened Product: No

Possess Opened Product: No

Product Use Information:

Description: [B6] had eaten this diet for years alongside her housemate who was being fed it for a [B6]

Last Exposure Date: 09/01/2017

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

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: 32.1 Kilogram
	Age: 8 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 4
	Number of Animals Reacted: 4
	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: Phone	
Reported to Other Parties: Other	
Additional Documents:	Attachment: cardio0009.pdf
	Description: Taurine level
	Type: Laboratory Report
	Attachment: cardio0008.pdf

Description: Echo reports from initial presentation, 5/2017, and 12/2017

Type: Medical Records

Report Details - EON-345835		
ICSR:	2040532	
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:	2018-01-22 18:42:17 EST	
Reported Problem:	Problem Description: B6 had been presented to his regular veterinarian for a week long history of cough on August 22, 2017. Radiographs were taken and B6 was initially placed on antibiotics for presumed pneumonia. B6 Radiographs were reviewed by a radiologist who revised the diagnosis to congestive heart failure and B6 were added. I evaluated B6 on September 5, 2017 and diagnosed him with dilated cardiomyopathy with congestive heart failure.	
	Date Problem Started: 08/15/2017	
	Concurrent Medical Problem: No	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: Zignature Kangaroo Limited Ingredient Formula Dry Dog Food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Product Use Information:	Description: B6 had been fed this diet since he was one year of age because it was recommended by B6. He was also given grain free treats, carrots and apples.
		Time Interval between Product Use and Adverse Event: 3 Years
		Product Use Stopped After the Onset of the Adverse Event: Yes
		Product Use Started Again: 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: Spaniel - Cocker American	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 15.5 Kilogram	
	Age: 4 Years	
Assessment of Prior Health: Excellent		

	Number of Animals Given the Product:	4
	Number of Animals Reacted:	4
	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:	Phone
	Reported to Other Parties:	Other
Additional Documents:	Attachment:	cardio0011.pdf
	Description:	Initial visit with echo report and most recent recheck medical record
	Type:	Medical Records
	Attachment:	cardio0012.pdf
	Description:	Taurine level
	Type:	Laboratory Report

Report Details - EON-365078

ICSR:	2054883
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2018-09-12 15:03:03 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:	09/12/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

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:	09/12/2018	
	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:	<div style="border: 1px dashed black; padding: 5px; display: inline-block;"> <p style="font-size: 2em; margin: 0;">B6</p> </div>	

			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:	
		Address:	B6 United States	
Healthcare Professional Information:	Practice Name:	B6		
	Contact:	Name:	B6	
		Phone:	B6	
		Email:		
	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:		
	Permission To Contact Sender:	Yes		
	Preferred Method Of Contact:	Email		
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-363846			
ICSR:	2054472		
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 11:53:01 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	The dog started experiencing symptoms of exertional dyspnea and panting from around 6mo of age. The dog has been fed an exclusively grain free diet from Acana. The dog was seen by the vet, referred to the cardiologist, and has been diagnose with Dilated Cardiomyopathy (DCM) on ultrasound.	
	Date Problem Started:	01/01/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Worse/Declining/Deteriorating	
Product Information:	Product Name:	Acana Large Breed Puppy Grain Free	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	Description:	As recommended
		First Exposure Date:	06/24/2017
		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:		No	
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:	37 Kilogram	

	Age:	15 Weeks
	Assessment of Prior Health:	Excellent
	Number of Animals Reacted:	1
	Owner Information:	
Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6
		Phone: B6
	Address:	Canada
	Type of Veterinarian:	Referred veterinarian
	Date First Seen:	08/29/2018
	Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6
	Address:	B6
		Canada
	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:	Manufacturer	
Additional Documents:	Attachment:	B6 VetReport.pdf
	Description:	B6 Vet Report Dilated Cardiomyopathy
	Type:	Investigation Report

Report Details - EON-366509

ICSR: 2055227
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: 2018-09-22 15:14:54 EDT

Reported Problem:
Problem Description: Owner volunarily requested a blood taurine level after seeing alerts about food related taurine deficiency in dogs. Patient's blood taurine level returned critically low.
Date Problem Started: 09/22/2018

Product Information:
Product Name: Zignature Duck formula
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

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

Report Details - EON-366570

ICSR:	2055234		
Type Of Submission:	Initial		
Report Version:	FPSR.FDA.PETF.V.V1		
Type Of Report:	Both		
Reporting Type:	Voluntary		
Report Submission Date:	2018-09-23 22:36:20 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Whole blood test for taurine level was low; B6 no clinical symptoms echocardiogram showed normal heart	
	Date Problem Started:	09/10/2018	
	Date of Recovery:	09/17/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Recovered Completely	
Product Information:	Product Name:	Merrick Duck and Sweet Potato	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	no longer have	
	Package Type:	BAG	
	Package Size:	15 Pound	
	Purchase Date:	01/25/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	in original bag placed in plastic tub	
	Product Use Information:	Description:	one cup in the morning, one cup in the evening
		First Exposure Date:	01/26/2018
		Last Exposure Date:	06/15/2018
		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:		Possibly related	
Other Foods or Products Given to the Animal During This Time Period:		Yes	
Manufacturer /Distributor Information:			
Purchase Location Information:	Name:	various	

	Product Name:	Taste of the Wild Canine Recipe Wetlands, Pacific Stream, High Prairie		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	no longer have		
	Package Type:	BAG		
	Package Size:	15 Pound		
	Purchase Date:	05/05/2010		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	stored in original bag inside plastic tub		
	Product Use Information:	Description:	one cup in the morning and one cup in the evening	
		First Exposure Date:	05/07/2010	
		Last Exposure Date:	01/30/2018	
		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	
		Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	various	
		Address:	United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	72 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:				
Other Phone:				
Email:				
Address:	B6			

			B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	09/17/2018
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		
	Address:	B6	
		United States	
	Contact:	Phone:	
		Other Phone:	B6
		Email:	
	Reporter Wants to Remain Anonymous:	No	
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Reported to Other Parties:	Unknown		
Additional Documents:	Attachment:	B6	chocardiogram 001.jpg
	Description:		chocardiogram
	Type:		Echocardiogram

Report Details - EON-361543

ICSR:	2053366
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 08:48:34 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	It was thought that [B6] was having allergies to his food, he was losing weight, lethargic, and vomiting. We changed to a grain free food. I am not sure of all the details but have medical documentation over the next several years of everything that happened. He ended up w/CDM, congestive heart failure also. We managed it all with medications, vet support, and love from us. When I heard about this new case, I knew I needed to say something. My boy was healthy and 190 lbs, his siblings were healthy, & his parents. If I could go back, I could of saved him but instead we had to put him to sleep. [B6] I am willing to submit a copy of all his vet records and testing to help. Thanks [B6]
	Date Problem Started:	10/07/2014
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Diamond Naturals Grain Free		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	41 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In sealed dogfood container		
	Product Use Information:	Description:	Fed twice a day	
		First Exposure Date:	09/12/2013	
		Last Exposure Date:	[B6]	
		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:	Name:	B6	
		Address:	B6	
		United States		
Animal Information:		Name:	B6	
	Type Of Species:	Dog		
	Type Of Breed:	Great Dane		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	140 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:	B6	
		Address:	B6	
		United States		
	Type of Veterinarian:	Primary/regular veterinarian		
	Date First Seen:	09/12/2013		
	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:	02/27/2015		
	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:	None

Additional Documents:

Report Details - EON-362570

ICSR:	2053856
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:	2018-08-17 02:32:42 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Dog had cough. Vet originally diagnosed kennel cough. Dog didn't get worse, but also didn't improve. After 1-2 weeks went by the dog started panting heavily. Took her to emergency vet who diagnosed with dilated cardio myopathy. Cardiac specialist narrowed cause to possible genetic, but taurine level taken showed very low level. Immediately placed dog on taurine supplement, cleared fluid around heart, and put dog on various heart medications. Dog showed very good improvement, but about a month later passed away at home while resting. Food samples were sent off and a necropsy was performed at UC Davis. Since she was a service dog all tests were ordered by [B6] and therefore all the results are unknown to me, but should be available from [B6]
	Date Problem Started:	08/04/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Naturally
	Date of Death:	[B6]

Product Information:	Product Name:	Nature's Domain Organic Chicken and Pea Formula		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	unkown		
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	07/01/2015		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in plastic sealed dog food container at room temperature.		
	Product Use Information:	Description:	1 and 1/4 cup twice a day. Numerous bags were purchased over approximate 49 month time period. (July 2015- August 2017)	
		First Exposure Date:	07/01/2015	
	Last Exposure Date:	08/18/2017		
	Time Interval between Product Use and Adverse Event:	49 Months		
	Product Use Stopped After the Onset of the Adverse Event:	Yes		
	Adverse Event Abate After Product Stop:	Unknown		
	Product Use	No		

		Started Again:	
		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 (unspecified)	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	60 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:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	
		Address:	B6 United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	08/19/2017
		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	
	Reported to Other Parties:	None	

Additional Documents:

Report Details - EON-361616

ICSR:	2053407
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-08-07 18:53:00 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was eating 4Health grain free chicken and vegetable kibble from Tractor Suppy. When his taurine level was tested on 7/28/17 at UC Davis, the results were PLASMA B6 WHOLE BLOOD B6 Extremely low. He is now taking taurine supplements.
	Date Problem Started:	11/07/2015
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	4Health Grain-free chicken and vegetables formula adult		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	I dont have it		
	Package Type:	BAG		
	Package Size:	16 Pound		
	Purchase Date:	06/15/2017		
	Number Purchased:	2		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In the bag		
	Product Use Information:	Description:	1 cup twice per day, moistened	
		Last Exposure Date:	08/15/2017	
		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:		Definitely related		
Other Foods or Products Given to the Animal During This Time Period:		Yes		
Manufacturer /Distributor Information:				

	Purchase Location Information:	Name: Tractor Supply Address:	United States <div style="border: 1px dashed black; padding: 5px; text-align: center; font-size: 2em; font-weight: bold;">B6</div>
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 70 Pound 8 Years Good 1 1 	Healthcare Professional Information: Practice Name: Contact: Name: Phone: Other Phone: Email: Address: United States Type of Veterinarian: Date First Seen: Permission to Release Records to FDA:
Sender Information:	Name: Address: Contact: Permission To Contact Sender: Preferred Method Of Contact: Reported to Other Parties:	<div style="border: 1px dashed black; padding: 5px; text-align: center; font-size: 3em; font-weight: bold;">B6</div> United States Phone: Other Phone: Email:	<div style="border: 1px dashed black; padding: 5px; text-align: center; font-size: 3em; font-weight: bold;">B6</div> Yes Email Other
Additional Documents:	Attachment: Description:	AF639C64-E0F0-4538-953A-277927AD6034.jpeg Lab test results	

Report Details - EON-363976

ICSR:	2054542
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:	2018-08-31 16:05:29 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I have had my three dogs on the Nutro brand dog food both kibble and canned for 7-12 months. When I took my dogs in for their annual exam it was recommend for two of them to go to a cardiologist because one had an arrhythmia and the second a hear murmur. The dog with an arrhythmia was diagnosed by the cardiologist with dilated cardiomyopathy (DCM), ventricular premature complexes occurring regularly, and a taurine deficiency. The second dog was diagnosed with a heart murmur, a taurine deficiency, and is trending towards DCM. It is thought by the cardiologist that the DCM and taurine deficiency in the first dog and the trending towards DCM and taurine deficiency in the second dog is caused by their diet. And was recommend that my third dog's taurine level be test which is still pending.	
	Date Problem Started:	07/21/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	

Product Information:	Product Name:	Nutro Hearty Stews Grandma's Farm Stew with Lamb & Rice Chunks in Gravy Senior		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	CAN		
	Product Use Information:	Perceived Relatedness to Adverse Event:	Probably related	
	Manufacturer /Distributor Information:			
	Purchase Location Information:	Name:	Petclub and Target	
	Product Name:	Nutro Kitchen Classic Premium Loaf Grass Fed Lamb & Brown Rice Dinner Adult		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	CAN		
	Product Use Information:	Perceived Relatedness to Adverse Event:	Probably related	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
	Product Name:	Nutro Hearty Stews Meaty Lamb & Rice Stew Chunks in Gravy Adult		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	CAN		
	Storage Conditions:	Before opening stored in a cabinet in the house. After opening covered with a can food lid and stored in the fridge.		
	Product Use Information:	Description:	Fed 2 tablespoons to 1/2 cup twice a day	
		Perceived	Probably related	

		Relatedness to Adverse Event:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Petclub and Target
	Product Name:	Nutro Limited Ingredient Diet Grain Free Lamb & Potato Recipe Premium Loaf Adult	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	CAN	
	Storage Conditions:	Before opening stored in a cabinet inside. After opening covered with a canned food lid and stored in the fridge.	
	Product Use Information:	Description:	2 tablespoons to 1/2 cup twice a day
		Perceived Relatedness to Adverse Event:	Probably related
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Petclub and Target
	Product Name:	Nutro Wholesome Essentials Complete Daily Nutrition Small Bites Adult 1+ Years Pasture-Fed Lamb & Rice Recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Storage Conditions:	The kibble was stored in a sealed dog food container outside.	
	Product Use Information:	Description:	Approximately three cups of kibble two times a day.
		Perceived Relatedness to Adverse Event:	Probably related
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Petclub and Target
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Terrier - Bull - American Pit	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	53 Pound	
	Age:	3 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:	
		Type of	Primary/regular veterinarian

	Veterinarian:	
	Practice Name:	B6
	Contact:	Name: B6 Phone:
	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

Additional Documents:	Attachment:	IMG_6448.JPG
	Description:	Canned food that was fed
	Type:	Product Label
	Attachment:	IMG_6454.JPG
	Description:	Canned food that was fed
	Type:	Product Label
	Attachment:	IMG_6451.JPG
	Description:	Canned food that was fed
	Type:	Product Label
	Attachment:	IMG_6445.JPG
	Description:	Canned food that was fed
	Type:	Product Label
	Attachment:	IMG_6440.JPG
	Description:	Kibble that was fed
	Type:	Product Label

Report Details - EON-364365

ICSR: 2054661
 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 18:06:51 EDT

Reported Problem:

Problem Description: Two dogs in the family, both unrelated American Staffordshire Terriers presented with taurine deficiency and DCM like phenotype on echo. [REDACTED] initially presented due to [REDACTED] B6's noted on physical exam, echo was consistent with a DCM like phenotype- this prompted

Date Problem Started: 08/11/2018

Concurrent Medical Problem: No

Outcome to Date: Stable

Product Information:

Product Name: Nutro Hearty Stews Meaty Lamb and Rice Stew (canned)

Product Type: Pet Food

Lot Number:

Package Type: CAN

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Product Use Information:

Description: 2 tablespoons - 1/2 cup twice daily

First Exposure Date: 09/01/2017

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:

Product Name: Nutro Limited Ingredients grain free lamb and potato loaf (canned)

Product Type: Pet Food

Lot Number:

Package Type: CAN

Possess Unopened Product: Unknown

Possess Opened Product: Unknown

Product Use Information:

Description: 2 tablespoons to 1/2 cup twice daily

First Exposure Date: 09/01/2017

Product Use Stopped After the Yes

		Onset of the Adverse Event:		
		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:			
	Product Name:	Nutro Small Bites Pasture- Fed Lamb and Rice Recipe Dry Kibble		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Possess Unopened Product:	Unknown		
	Possess Opened Product:	Unknown		
	Product Use Information:	Description:	Approx 3 cups twice daily	
		First Exposure Date:	09/01/2017	
		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:			
	Product Name:	Nutro Kitchen Classics Loaf Lamb and Brown Rice Canned		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	CAN		
	Possess Unopened Product:	Unknown		
	Possess Opened Product:	Unknown		
	Product Use Information:	Description:	2 tablespoons- 1/2 cup twice daily	
		First Exposure Date:	09/01/2017	
		Time Interval between Product Use and Adverse Event:	1 Years	
		Product Use Stopped After the	Yes	

		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:		
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Terrier - Bull - Staffordshire	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Age:	3 Years	
	Assessment of Prior Health:	Excellent	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	2	
	Owner Information:	Owner Information provided:	Yes
		Contact: Name:	B6
		Phone:	
		Address:	B6
			United States
	Healthcare Professional Information:	Practice Name:	B6
		Contact: Name:	B6
		Phone:	
		Email:	
		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:	Email	

Additional Documents:

Report Details - EON-364371

ICSR: 2054662
 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 18:15:52 EDT

Reported Problem:
Problem Description: B6 presented after her sister was diagnosed with a ventricular arrhythmia and DCM like phenotype suspected to be due to a taurine deficiency (confirmed via whole blood taurine); B6 was being fed the same diet, screening was not prompted by clinical signs.
Date Problem Started: 08/17/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Nutro Hearty Stews Meaty Lamb and Rice Stew
Product Type: Pet Food
Lot Number:
Package Type: CAN
Possess Unopened Product: Unknown
Possess Opened Product: Unknown
Product Use Information:
Description: 2 tablespoons to 1/2 cup twice daily
First Exposure Date: 09/01/2017
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:
Product Name: Nutro Limited Ingredient Grain Free Lamb and Potato Loaf
Product Type: Pet Food
Lot Number:
Package Type: CAN
Possess Unopened Product: Unknown
Possess Opened Product: Unknown
Product Use Information:
Description: 2 tablespoons to 1/2 cup twice daily
First Exposure Date: 09/01/2017
Product Use Stopped After the Yes

		Onset of the Adverse Event:	
		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:		
	Product Name:	Nutro Small Bites Pasture Fed Lamb and Rice Recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Possess Unopened Product:	Unknown	
	Possess Opened Product:	Unknown	
	Product Use Information:	Description:	3 cups twice daily
		First Exposure Date:	09/01/2017
		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:		
	Product Name:	Nutro Kitchen Classics loaf Lamb and Brown Rice	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	CAN	
	Possess Unopened Product:	Unknown	
	Possess Opened Product:	Unknown	
	Product Use Information:	Description:	2 tablespoons to 1/2 cup twice daily
		First Exposure Date:	09/01/2017
		Product Use Stopped After the Onset of the Adverse Event:	Yes
		Adverse Event Abate After	Unknown

		Product Stop:	
		Product Use Started Again:	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 - Bull - Staffordshire	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Assessment of Prior Health:	Good	
	Number of Animals Given the Product:	2	
	Number of Animals Reacted:	2	
	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
Sender Information:	Name:		
	Address:	B6	
			United States
	Contact: Phone:	B6	
	Email:		
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			

Report Details - EON-364929		
ICSR:	2054833	
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:	2018-09-11 13:19:06 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: In trying to find out why the breathing pattern of my Golden Retriever had become more rapid, my research led me to the Taurine Deficiency in Golden Retriever study by Dr. Joshua Stern from UC-Davis. Upon his recommendation, I had my vet draw whole blood sample to test the taurine. His level came back very low at B6 . I then scheduled an echocardiogram with CVCA located in B6 . They detected an innocent heart murmur and noted that my dog's heart is either at the early stages of DCM or a very athletic heart. I have changed foods and have begun supplementing with taurine. Will recheck levels in 3-4 months to confirm food suspicion.	
	Date Problem Started: 06/01/2018	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: Increasingly experienced heavy panting and breathing that prompted trip to the vet. Further research has pointed to taurine deficiency in the dry dog food kibble I have been feeding to my pup. He has been fed Acana dry dog food since he was born. He was initially rotated between the various Single formulas with a fish formula at every other bag however the last three bags have been the Appalachian Ranch formula because I thought the high protein level would be more advantageous to my dog.	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: Acana Appalachian Ranch Regionals Formula	
	Product Type: Pet Food	
	Lot Number:	
	UPC: 6499252325	
	Package Type: BAG	
	Package Size: 25 Pound	
	Purchase Date: 08/01/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Food was transferred to a large plastic food bin, BPA free.	
	Product Use Information:	Description: Product was given one cup twice a day
		Last Exposure Date: 09/01/2018
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 No		

		Products Given to the Animal During This Time Period:		
Manufacturer /Distributor Information:	Name:	Champion Pet Foods		
	Type(s):	Manufacturer		
	Address:	12871 Bowling Green Road Auburn Kentucky 42206 United States		
	Contact:	Phone:	1-877-939-0006	
		Web Address:	https://www.championpetfoods.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:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	69 Pound		
	Age:	2.5 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:				
Email:				
Address:		B6		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		08/20/2018		
Permission to Release Records to FDA:		Yes		
Practice Name:		B6		
Contact:		Name:	B6	
	Phone:			

			Email:	B6
		Address:	B6	
			United States	
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	09/05/2018	
		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:	Store/Place of Purchase Other			
Additional Documents:	Attachment:	B6	UC Davis Taurine Results.jpg	
	Description:	Taurine levels tested at UC Davis by Dr. Joshua Stern		
	Type:	Laboratory Report		

Report Details - EON-364933		
ICSR:	2054835	
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:	2018-09-11 13:26:43 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: We fed B6 (Golden Retriever) the following foods and duration of feeding: Orijen Puppy ~12 months Orijen Puppy Large ~6 months Acana Grasslands ~3 months We decided to have his Taurine levels checked and submitted his blood to Amino Acid Laboratory at UC Davis, School of Veterinary Medicine Results of the Whole Blood Taurine Test: B6 . He now has to get an echocardiogram, food change and taurine supplements.	
	Date Problem Started: 09/10/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Unknown	
Product Information:	Product Name: Orijen Puppy Orijen Puppy Large Acana Regionals Grasslands Formula Grain Free Dry Dog Food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 25 Pound	
	Purchase Date: 02/01/2017	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Put original packaging with the food in a sealed plastic container	
	Product Use Information:	Description: 1 1/2 Cups in the Morning 1 1/2 Cups in the Evening Fed
		First Exposure Date: 02/01/2017
		Last Exposure Date: 09/09/2018
		Time Interval between Product Use and Adverse Event: 18 Months
Product Use Stopped After the Onset of the Adverse Event: Yes		
Adverse Event Abate After Product Stop: Unknown		
Product Use Started Again: No		
Perceived Relatedness to Adverse Event: Definitely related		
Other Foods or Products Given to the Animal 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: Retriever - Golden

Gender: Male

Reproductive Status: Neutered

Weight: 80 Pound

Age: 21 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:

Other Phone:

Email:

B6

Permission To Contact
Sender: Yes

Preferred Method Of
Contact: Email

Reported to Other
Parties: Other
Store/Place of Purchase

Additional Documents:

Report Details - EON-365145		
ICSR:	2054895	
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:	2018-09-13 09:57:20 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Was diagnosed with was Dilated Cardiomyopathy and subsequently died	
	Date Problem Started: 08/17/2018	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6	
	Outcome to Date: Died Naturally	
	Date of Death: B6	
Product Information:	Product Name: Horizon Pulsar Pulses & Chicken Formula Grain Free	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 25 Pound	
	Purchase Date: 07/01/2018	
	Number Purchased: 2	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Stored in cool, dry location inside house	
	Product Use Information:	Description: Fed as meals
		First Exposure Date: 07/01/2018
		Last Exposure Date: 08/17/2018
		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: 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 data-bbox="667 114 889 153">Name:</td> <td data-bbox="889 114 1539 153">Chewy online</td> </tr> <tr> <td data-bbox="667 153 889 202">Address:</td> <td data-bbox="889 153 1539 202">United States</td> </tr> </table>	Name:	Chewy online	Address:	United States
Name:	Chewy online					
Address:	United States					
Animal Information:	Name:	B6				
	Type Of Species:	Dog				
	Type Of Breed:	Mastiff				
	Gender:	Male				
	Reproductive Status:	Neutered				
	Weight:	200 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:	Practice Name:	B6				
	Contact:	<table border="1"> <tr> <td data-bbox="667 761 889 799">Name:</td> <td data-bbox="889 761 1539 799">B6</td> </tr> <tr> <td data-bbox="667 799 889 840">Phone:</td> <td data-bbox="889 799 1539 840"></td> </tr> </table>	Name:	B6	Phone:	
Name:	B6					
Phone:						
	Type of Veterinarian:	Primary/regular veterinarian				
	Date First Seen:	08/17/2018				
	Permission to Release Records to FDA:	Yes				
	Practice Name:	B6				
	Contact:	<table border="1"> <tr> <td data-bbox="667 1116 889 1155">Name:</td> <td data-bbox="889 1116 1539 1155">B6</td> </tr> <tr> <td data-bbox="667 1155 889 1196">Phone:</td> <td data-bbox="889 1155 1539 1196"></td> </tr> </table>	Name:	B6	Phone:	
Name:	B6					
Phone:						
	Type of Veterinarian:	Referred veterinarian				
	Date First Seen:	B6				
	Permission to Release Records to FDA:	Yes				
Sender Information:	Name:					
	Address:	B6				
		United States				
	Contact:	<table border="1"> <tr> <td data-bbox="667 1591 889 1629">Phone:</td> <td data-bbox="889 1591 1539 1629">B6</td> </tr> <tr> <td data-bbox="667 1629 889 1670">Email:</td> <td data-bbox="889 1629 1539 1670"></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:	None				
Additional Documents:						

Report Details - EON-365526

ICSR:	2054945
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 13:28:42 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	In short: otherwise pretty healthy-for-age, 13-year-old goldendoodle develops moderate-severe DCM with outrageously low taurine levels 5 months after switching to Zignature Kangaroo. UCD results: [B6] Long version: In March 2018, [B6] began eating Zignature Kangaroo to have a novel protein that would manage his [B6]. At last checkup in March his heart sounded good, his regular blood work was good, declared basically healthy for age. The ultrasound that dr. [B6] didn't include a formal echo, but they gave his heart a listen as long as they had the wand out, and didn't see/hear anything out of the ordinary. In August 2018, [B6] developed an occasional hacking cough, so on August 29, I took him to the vet, who heard a heart murmur. Same day X-ray found slightly enlarged heart, so we scheduled a cardiac study (echo/EKG) for Sept 6. After Aug 29 appointment, a friend pointed me to info about grain free diets, and I saw a list of foods and associated taurine levels. Zig Kangaroo had almost entirely low taurine levels, so I called my vet on Aug 30 and requested blood draw to send to UC Davis. After reviewing info from Dr. Stern's lab, my vet agreed that it would be worth following up, so on Sept 4 we drew blood and sent to UCD. On Sept 6, the echo/EKG study diagnosed moderate-severe DCM with "impending congestive heart failure." The doctor suspected taurine-deficient DCM because of kangaroo diet and prescribed several supportive meds. Following recommendations from UC Davis, we also began taurine and l-carn supplements, and I began transitioning to Nutro Ultra food. On Sept 10, we received the UCD taurine blood results, which were extremely low. Whole blood taurine: [B6] normal = 200 - 350); plasma [B6] (normal = 60-120). I am filing this report Sept 14. The dates in this report are a little artificial due to the built-in restrictions on this form. For example, we started the food in March 2018, and his symptoms began early August 2018, but the most recent bag purchased was in mid-August 2018, so symptoms began before the most recent bag was purchased, but the problem is tied to many bags purchased since early March. I've done my best to complete this with dates the form will accept, but I hope this description will help account for discrepancies, and I'm happy to communicate with someone from FDA to clarify anything.
	Date Problem Started:	08/01/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Stable

Product Information:	Product Name:	Zignature Kangaroo Formula "limited ingredient formula"		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	8C27P 1908 3	
		Expiration Date:	09/25/2019	
	UPC:	88641131327		
	Package Type:	BAG		
	Package Size:	27 Pound		
	Purchase Date:	07/29/2018		
	Number Purchased:	1		
	Possess Unopened	No		

	Product:	
	Possess Opened Product:	Yes
	Storage Conditions:	bag was vacuum sealed before opening, stored at room temperature after.
	Product Use Information:	<p>Description: Fed recommended serving size of 3 cups per day, split in two meals. PLEASE NOTE: The dates I entered in this form are not accurate because the form won't let me use dates that reflect the ongoing use of the product. "Please check your date. This date cannot be after today, the date the problem started, and the date last fed to the animal. Also, the date must be after the last purchase date." ACTUAL DATES Date problem (minor symptoms) started: 8/1/2018 Date of diagnostics: 8/29 - 9/10 Date last fed to animal: 9/10/18 (transitioning to new food) Last purchase date: 8/15/18 Date product was first given to the animal is 3/1/18, because we've used the same type of food for months.</p> <p>First Exposure Date: 07/29/2018</p> <p>Last Exposure Date: 09/10/2018</p> <p>Time Interval between Product Use and Adverse Event: 5 Months</p> <p>Product Use Stopped After the Onset of the Adverse Event: Unknown</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>
	Manufacturer /Distributor Information:	<p>Name: Pets Global</p> <p>Type(s): Unknown</p> <p>Address: 28334 Industry Drive Valencia California 91355 United States</p> <p>Contact: Phone: (888) 897-7207</p> <p>Possess One or More Labels from This Product: Yes</p>
	Purchase Location Information:	<p>Name:</p> <p>Address: B6 United States</p>
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	86 Pound

	Age: 13 Years
	Assessment of Prior Health: Good
	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: 08/29/2018
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: Store/Place of Purchase Other	
Additional Documents:	Attachment: B6 taurine results.pdf
	Description: B6 taurine levels from UCDavis lab
	Type: Laboratory Report
	Attachment: B6 Cardiac.pdf
	Description: Results of B6 cardiac study 9/6/2018
	Type: Echocardiogram

Report Details - EON-362940		
ICSR:	2054012	
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:	2018-08-21 12:11:37 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Exercise intolerance; diagnosed with DCM by echocardiogram; given 6-8 months survival time due to severity of disease; with medication and diet change B6 has shown significant improvement in his overall condition 10 months post-diagnosis; a second echocardiogram will be scheduled within the next 2 months	
	Date Problem Started: 10/26/2017	
	Concurrent Medical Problem: No	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: Zignature Kangaroo Formula	
	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 - German	
	Reproductive Status: Intact	
	Pregnancy Status: Not Applicable	
	Lactation Status: Not Applicable	
	Assessment of Prior Health: Excellent	
	Number of Animals Reacted: 1	
	Owner Information:	
	Healthcare Professional Information:	Contact:
		Name: B6
		Phone:
Type of Veterinarian: Referred veterinarian		
Date First Seen: 10/31/2017		
Permission to Release Records to FDA: Yes		
Sender Information:	Name:	
	Contact:	
	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
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Additional Documents:

Report Details - EON-365904

ICSR:	2055088
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-09-18 23:36:10 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I previously reported about my other dog [B6] that had been on Honest Kitchen that developed heart disease Because my current dog was still on the same food and because of all the publications relating to grain free food with peas, potatoes, etc. I had her taurine levels and just got her results back as low [B6] with normal being 60-120. In addition to being feed Honest Kitchen as a primary food she also was eating Acada and Orijen as kibble treats. In the last 6 or so months it has been Acada with Beef etc. — Date Problem started below is the date I found out she had an issue
	Date Problem Started:	09/17/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Unknown

Product Information:	Product Name:	Honest Kitchen Preference	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	Various	
	Package Type:	BOX	
	Package Size:	7 Pound	
	Purchase Date:	07/02/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In box This dog has been on this product for 4 years approx	
	Product Use Information:	Description:	Honest Kitchen Preference prepared as directed with added chicken thighs as protein Acana Regional used as kibble for treats (less than 1/4 cup a day)
		Last Exposure Date:	09/18/2018
		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:		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:

Various - have purchased this product over 8 years - 4 years for this dog

Address:

Various

Various

B6

United States

Animal Information:

Name:

B6

Type Of Species: Dog

Type Of Breed: Sheepdog - Shetland

Gender: Female

Reproductive Status: Neutered

Weight: 25 Pound

Age: 8 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:

Phone:

Other Phone:

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

Sender Information:

Name:

Address:

B6

United States

Contact:

Phone:

Other Phone:

Email:

B6

Reporter Wants to Remain Anonymous: No

Permission To Contact: Yes

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

Additional Documents:

Report Details - EON-364376

ICSR:	2054663
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 19:11:21 EDT
Reporter is the Animal Owner:	Yes

Reported Problem: **Problem Description:** 3 years ago 2015 I switched both my miniature schnauzers to Whole Earth Farms grain free dog food Chicken and Turkey recipe. last year in 2017 at B6 annual check up the doctor told me that she heard a heart murmur. The Vet wanted to keep an eye on it and see where we were a year later. On August 10th, 2018 B6 had her yearly exam, there was no noted difference in her murmur. On B6 B6 after giving B6 a bath at 5pm she started acting funny. She normally runs around like a mad dog after a bath and this time she just stood there. When she walked away she was walking like she was unsure of herself. I thought maybe she had hurt her back because she does have spinal stenosis of her spinal cord between her shoulder blades. I thought maybe during the bath I may have moved her wrong. So I gave her B6 15lb does that the vet had given me to use when her back acts up. Between 5 and 5:30pm I fed the dogs as always but B6 would not eat, this is not unusual for her, she only eats if she wants to so this didn't set off any alarms. After the other dogs ate, she went outside with them like normal and was eating some grass, again not unusual she and the other dog do this from time to time. After being outside she came in and laid on the sofa till 10 when it was bed time. I called her to come to bed and when she stood up she puked. At this time I was concerned but not worried to the point I need to rush her to the emergency vet. Around 1130p or so I woke up with her vomiting and starting to cough. She vomited again around 1230am and started having some funny breathing but I thought she was trying to clear her throat because of her vomiting. I laid down and went back to sleep and round 3:30am I woke up with her coughing uncontrollably and gasping for air. I immediately took her to B6 B6 and we checked in at 4:44am. They immediately took her back checked her sats and put her in an O2 tank and hooked her up to an EKG. She was sinus tack with a heart rate of 174. Labs and films were obtained and I was told she had CHF with pulmonary adema. She had right sided heart enlargement and blood was backing up into her lungs. Staff started her on B6 and heart meds and put in ICU. By 1130am or B6 was much worse then she was when I brought her in. She was now coughing up red frothy sputum and lots of it. After spending time with her and talking with the Vet Doctor and the techs Euthanasia was opted for. With B6 grim prognosis and zero improvement I thought this was the best option. B6 was euthanized at 1153am. I was unaware of the grain free dog foods maybe being related to CHF until after this happened. As of B6 I have switched my other schnauzer over to Hills Science Diet as well as my puppy of 11weeks (Chihuahua). I am hoping to meet with my Vet to have my other schnauzer looked at and have a possible cardiac work up. I hope that switching the food at this time will help reverse any affects he may have suffered. B6 was adopted 5/6 years ago at the age of 5 and she had a clean bill of health until her murmur diagnosed in 2017.

Date Problem Started:	B6
Concurrent Medical Problem:	Yes
Pre Existing Conditions:	B6
Outcome to Date:	Died Euthanized
Date of Death:	B6

Product Information:	Product Name:	Whole Earth Farms Chicken and Turkey Recipe Grain Free
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	15 Pound
	Purchase Date:	01/01/2015

	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	It was brought home in the product bag and then stored in a large plastic container lid.
	Product Use Information:	Description: B6 was fed dry dog food at 5am and 5pm 1/2 cup each feeding
		First Exposure Date: 01/01/2015
		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: 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:
		Address: B6 United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Schnauzer - Miniature
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	15 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:	
			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:	
			Email:	
	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
		Email:		
Permission To Contact Sender:		Yes		
Preferred Method Of Contact:		Email		
Reported to Other Parties:		None		
Additional Documents:	Attachment:		B6	death.pdf
	Description:		This is the medical record for	B6
	Type:		Medical Records	

Report Details - EON-364227	
ICSR:	2054592
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:	2018-09-04 13:15:23 EDT
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: B6 has been on a grain-free diet for about three years. He eats Earthborn Holistic Meadow Feast food. In the last few months, he has developed heart disease and is now in heart failure. After his diagnosis, we did some research online and came across the FDA's announcement in July about grain-free dog food and DCM. We are reporting this to hopefully help the FDA's investigation on this topic.
	Date Problem Started: 07/15/2018
	Concurrent Medical Problem: Yes
	Pre Existing Conditions: B6
	Outcome to Date: Stable
Product Information:	Product Name: Earthborn Holistic Meadow Feast
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Package Size: 28 Pound
	Purchase Date: 06/01/2018
	Number Purchased: 1
	Possess Unopened Product: Yes
	Possess Opened Product: Yes
	Storage Conditions: In a plastic tub with a lid.
Product Use Information:	Description: Fed twice a day for several years. Note that I've been purchasing this about monthly for the last three years. The date of last purchase is actually August 30, just days before we had to switch B6 to a different diet. His symptoms started in July of this year, but he had an acute attack on September 1.
	First Exposure Date: 07/01/2018
	Last Exposure Date: 09/02/2018
	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: Possibly related

		Relatedness to Adverse Event:	
		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:	Great Dane	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	135 Pound	
	Age:	6 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	
	Contact:	Email:	B6
	Reporter Wants to Remain Anonymous:	No	
	Permission To Contact Sender:	Yes	
	Preferred Method Of Contact:	Email	
Additional Documents:			

Report Details - EON-363998

ICSR:	2054547
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:	2018-08-31 19:11:47 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	She went into cardiac arrest and was later diagnosed with severe DCM. The vet tested her for taurine levels due to an enlarged left ventricle and it came back critically low at a level of [B6]. She had been on Acana Duck and pear for just under a year. But has been on "grain free" diets since she was given to us at 6 weeks.
	Date Problem Started:	07/31/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Acna Duck and Pear	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	13 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	On self and sealed	
	Product Use Information:	Description:	I dont feel like there is something wrong with this specific bag of food. I just believe grain free foods with lentils, peas and legumes is either inhibiting taurine production or causing some sort of deficiency. And although ACANA seems to have the most effected amounts, its a very popular food choice in [B6] it takes up most of the shelves in store so its highly likely to be chosen. So it may just be the ingredients in all grain free foods.
		Time Interval between Product Use and Adverse Event:	9 Months
		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]	
	Address:	[B6]	

			B6 Canada	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Mastiff		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	125 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	
Email:			B6	
Address:		B6		
		Canada		
Type of Veterinarian:		Referred veterinarian		
Date First Seen:	08/13/2018			
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6		
	Address:	B6		
		Canada		
	Contact:	Phone:	B6	
		Email:	B6	
	Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email			
Reported to Other Parties:	Other			
Additional Documents:	Attachment:	B6 21-Aug-2018 (09_14_55 AM) Care Instructions.pdf		
	Description:	The diagnosis of B6 DCM		
	Type:	Letter		

Report Details - EON-364898

ICSR: 2054821
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: 2018-09-11 10:22:19 EDT

Reported Problem:
Problem Description: Presented for historic Grade II/VI heart murmur and two litter mates with early DCM/Atrial fibrillation and an ASD; he was diagnosed with mitral insufficiency and suspect valvular dysplasia which progressed to emerging cardiomyopathy in September 2018 when he was started on Taurine supplementation. He was also diagnosed with **B6** in June 2018.
Date Problem Started: 12/06/2017
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Fromm Heartland Grain Free Large Breed
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information:
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: Great Dane
Gender: Male
Reproductive Status: Neutered
Weight: 74.9 Kilogram
Age: 8 Years
Assessment of Prior Health: Good
Number of Animals Given the Product: 4
Number of Animals Reacted: 3
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: Phone: Email:
	Address:	B6 United States
Sender Information:	Name:	B6
	Address:	B6 United States
	Contact:	Phone: Email:
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	None
Additional Documents:		

Report Details - EON-365625

ICSR:	2054969
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:	2018-09-16 15:44:46 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	After being on Wild Calling food for 11 months, B6 was experiencing difficulty breathing. Our primary vet could hear a murmur, see her heart was enlarged and had fluid around it. she immediately got us an appt with a cardiologist. It was discovered that B6 had DCM and was in CHF. The cardiologist vet tested her Taurine Levels and they came back extremely low, B6 and we looked at the ingredients on the bag to find that Taurine was not in the list of ingredients. B6 started Taurine supplement and was switched to a different food. At her 3 month check up, B6 had improved significantly and is no longer in CHF but looks to have possible irreversible damage to the left side of her heart. B6 was then switched to a low sodium grain free food and is supplemented with taurine and at her next 6 month follow up (in Sept 2018), her heart size has slightly increased and this is when the cardiologist asked us if we had heard about the reports about a possible link to grain free foods and DCM. And recommended maybe to stop feeding a grain free food.
	Date Problem Started:	12/15/2017
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Wild calling, xotic essentials, rabbit meal recipe		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	21 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in a sealed plastic container		
	Product Use Information:	Description:	Pet was fed 3/4 cup twice a day. Started feeding this food in January of 2017 and stopped feeding this food in December of 2017 when the pet was diagnosed with DCM. We found out her Taurine level was extremely low, B6 and that this food had no added taurine in it.	
		Time Interval between Product Use and Adverse Event:	11 Months	
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		Yes		
Perceived Relatedness to		Probably related		

		Adverse Event:	
		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:	Samoyed	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	50 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:	B6
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	12/15/2017
		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-363409		
ICSR:	2054228	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-08-25 18:21:28 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Sudden development of heart murmur--echo-cardiogram revealed severe degenerative mitral and tricuspid valve disease.	
	Date Problem Started: 07/31/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: Acana Meadowlands Poultry and Freshwater Fish Grain Free Dog Food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 25 Pound	
	Purchase Date: 05/15/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Stored in original packaging, tightly closed within a plastic garbage can (with lid) in my basement.	
	Product Use Information:	Description: Fed the dog 2 cups of kibble, moistened with water, twice a day since Feb 2017
		First Exposure Date: 05/15/2018
		Last Exposure Date: 06/29/2018
		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: Probably related
Other Foods or Products Given to the Animal During This Time Period: Yes		
Manufacturer /Distributor Information:		
Purchase Location Information:	Name: Jet.com	
	Address: United States	

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Doberman Pinscher		
	Gender:	Male		
	Reproductive Status:	Intact		
	Weight:	85 Pound		
	Age:	9 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:		Referred veterinarian		
Date First Seen:		07/31/2018		
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:	Attachment:	B6	Taurine UC Davis 7 10 18.pdf	
	Description:	Taurine Test Result (U.C. @ Davis Amino Acid Lab)		
	Type:	Laboratory Report		
	Attachment:	B6	Cardio Diagnosis 7-31-18.pdf	
	Description:	Diagnosis Report from	B6 DVM Cardiologist	
	Type:	Medical Records		

Report Details - EON-370936

ICSR: 2058785
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: 2018-11-13 12:00:07 EST

Reported Problem:
Problem Description: Presented to the Emergency Service on **B6** for coughing and respiratory distress. The cough was first observed approximately 5 to 7 days prior. The cough became more consistent in the 3 days leading up to presentation. Was taken to the rDVM on 10/1/18. Chest x-rays were performed and antibiotics were prescribed for suspected pneumonia. The following day, the radiographs were interpreted by a radiologist and were considered more consistent with heart failure. The owners scheduled a cardiology consultation. However, **B6** developed a decreased appetite and respiratory distress, so he was brought to the **B6** emergency Service. During hospitalization at **B6** congestive heart failure was confirmed on chest x-rays. Echocardiogram showed severe dilated cardiomyopathy (DCM). Taurine levels were normal to increased (**B6** inMol/mL). The patient was hospitalized until **B6** at which time he was discharged.
Date Problem Started: **B6**
Date of Recovery:
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: V-dog
Product Type: Pet Food
Lot Number:
Package Type: BAG
Product Use Information: **Description:** Fed V-dog kibble for several years
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: **B6**
Type Of Species: Dog
Type Of Breed: American Pit Bull Terrier
Gender: Male
Reproductive Status: Neutered
Weight: 32 Kilogram
Age: 7 Years
Assessment of Prior Health: Excellent
Number of Animals Given the Product: 1
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** Yes
Contact: **Name:** **B6**
Phone:
Email:
Address: **B6**

			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:	B6	Discharge Instructions.pdf	
	Description:	Discharge instructions		
	Type:	Medical Records		
	Attachment:	B6	Taurine Level.pdf	
	Description:	Taurine level		
	Type:	Laboratory Report		
	Attachment:	B6	10-11-18.docx	
	Description:	Holter monitor report		
	Type:	Medical Records		
	Attachment:	B6	Echo Report .pdf	
	Description:	Echo report		
	Type:	Medical Records		

Report Details - EON-372463

ICSR:	2059498
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:	2018-11-30 19:40:08 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	When we returned from vacation on Nov. 17, our dog sitter informed my wife that [B6] may have an ear infection because he was scratching his ear. We scheduled an appt. with his vet the next day they were open (Mon. Nov. 19). Leading up to that appt. we noticed [B6] wasn't looking well and wasn't acting like himself. At the appt. the vet confirmed he had an ear infection but also noted his heart rate was elevated. Vet thought potentially a case of pneumonia. We left to visit my wife's family for Thanksgiving for Thur - Sat (with the dogs coming with us) [B6] was lethargic and not eating during the trip and generally looked sick most of the time. Brought him to a vet near my wife's family if [B6] where they took x-rays and blood work. Blood work was fine but xrays showed an enlarged heart and fluid around the abdominal area. Since we were leaving to go home the vet if [B6] recommended that we bring him in to a vet around our area for further evaluation. On [B6] was losing his balance while trying to stand so I rushed him to the nearest emergency vet hospital. He was diagnosed with congestive heart failure. The hospital ran a number of tests on him including check for lyme disease - all negative. Their conclusion is that it was probably his grain free diet - more specifically a lack of the taurine amino acid which based on studies they said there has found to be a lack of in the grain free diets. [B6] was released the following day by the cardiologist but will be on heavy heart medications for the foreseeable future. Below we're using 11/17 as a start date but realistically we think this may be something that has been happening for a while as some of our family members commented over the past few months that [B6] looked skinnier than normal. We had our 2nd dog [B6] tested when we picked [B6] up at the hospital and she was fine. Both have been on the same grain free diets.
	Date Problem Started:	11/17/2018
	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:	28 Pound
	Purchase Date:	10/14/2018
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	Yes
	Storage Conditions:	Before opening product was shipped to house from Chewey.com in a cardboard box. The kibble was in a sealed dog food bag. After opening, the product is stored in a closed plastic bin.
Product Use Information:	Description:	Product was used daily to feed our 2 dogs. They each would eat twice a day - about 1.5-2 cups each/day.
	First Exposure Date:	10/16/2018
	Last Exposure	11/26/2018

		Date:	
		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:	Chewy.com
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Bulldog - French	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	28 Pound	
	Age:	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:	B6
		Phone:	
		Address:	B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	11/26/2018
		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:	Other
Additional Documents:		

Report Details - EON-361703

ICSR:	2053486		
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 20:03:05 EDT		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Low Taurine results - whole blood: B6 Noted decreased energy levels over past few months. Scheduled for cardiology consultation/echo to diagnose or rule out Taurine Deficient Dilated Cardiomyopathy	
	Date Problem Started:	08/07/2018	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Not Applicable	
Product Information:	Product Name:	Zignature turkey	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Product Use Information:	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:	Definitely related	
	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:	65 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:	
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact:	B6
	Phone:	B6
	Email:	B6
	Permission To Contact Sender:	Yes
Preferred Method Of Contact:	Email	
Reported to Other Parties:	None	
Additional Documents:	Attachment:	{0DD0EE39-1877-4D58-8BF1-23F58DC42DCD} B6 Taurine level.pdf
	Description:	Taurine results from UC Davis Amino Acid lab
	Type:	Laboratory Report

Report Details - EON-361640												
ICSR:	2053429											
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 09:11:35 EDT											
Reporter is the Animal Owner:	Yes											
Reported Problem:	Problem Description: We started feeding Zignature Kangaroo formula to help [B6] it worked great. In June we noticed a little cough, the cough became more frequent. we went to the vet after about a week, our vet suspected collapsing trachea, common in yorkies, we began a course of medication. That medication [B6] did not help. we went back to the vet 7/14/18 for chest x rays to rule out bronchitis. Dr. [B6] didn't like the way the x rays looked, sent it to a radiologist, and then called back letting us know her heart was enlarged & she had fluid in her lungs due to the heart enlargement. Dr. [B6] put us in touch with a veterinary cardiologist about the early stages of congestive heart failure. We saw the specialist, Dr. [B6] 7/23/18 who did a cardiac work up, including a Taurine test, we are waiting for the results of this. She was diagnosed with DCM - suspect taurine-deficiency dilated cardiomyopathy. Isabelle is being treated with medication & we are also in the process of changing her food from the Zignature food to a hydrolyzed protein diet by Royal Canin.											
	Date Problem Started: 06/15/2018											
	Concurrent Medical Problem: Yes											
	Pre Existing Conditions: [B6]											
	Outcome to Date: Better/Improved/Recovering											
Product Information:	Product Name: Canned Dog Food											
	Product Type: Pet Food											
	Lot Number:											
	Package Type: CAN											
	Package Size: 13 Ounce											
	Number Purchased: 10											
	Possess Unopened Product: Yes											
	Possess Opened Product: Yes											
	Storage Conditions: unopened cans, in pantry. Opened cans are stored in the fridge with a plastic can top. We use it for several days, before tossing it out & opening a new can. We only use this to disguise her medication.											
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>we use the canned food to hide her medication. We are still using this at this time during the food transition.</td> </tr> <tr> <td>First Exposure Date:</td> <td>01/02/2018</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>Probably related</td> </tr> <tr> <td>Other Foods or</td> <td>Yes</td> </tr> </table>	Description:	we use the canned food to hide her medication. We are still using this at this time during the food transition.	First Exposure Date:	01/02/2018	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:	Probably related	Other Foods or
Description:	we use the canned food to hide her medication. We are still using this at this time during the food transition.											
First Exposure Date:	01/02/2018											
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:	Probably 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
	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	
	Number Purchased:	3	
	Possess Unopened Product:	Yes	
	Possess Opened Product:	Yes	
	Storage Conditions:	Unopened bags are stored in original packaging in a pantry closet. After opening we store in an airtight dog food storage container	
	Product Use Information:	Description:	she is fed twice daily 1/2 cup each feeding.
		First Exposure Date:	01/02/2018
		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:	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:	Terrier - Yorkshire	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	11 Pound	
	Age:	8 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
		Other 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
	Practice Name:	B6
	Contact:	Name: B6
		Phone: B6
		Other Phone: B6
	Address:	B6
	United States	
Type of Veterinarian:	Referred veterinarian	
Date First Seen:	07/23/2018	
Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	
	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:	Manufacturer Store/Place of Purchase	
Additional Documents:		

Report Details - EON-367631

ICSR: 2055695
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Both
Reporting Type: Voluntary
Report Submission Date: 2018-10-04 16:00:27 EDT

Reported Problem: **Problem Description:** Taste of the Wild High Prairie diet, developed dilated cardiomyopathy.
Date Problem Started: 09/28/2018
Outcome to Date: Not Applicable

Product Information: **Product Name:** Taste of the Wild High Prairie
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 - Australian
Gender: Male
Reproductive Status: Neutered
Number of Animals Given the Product: 2
Number of Animals Reacted: 1
Owner Information: **Owner Information provided:** No

Healthcare Professional Information: **Practice Name:** B6
Contact: **Name:** B6
Phone: B6
Email:
Address: B6
United States

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

Additional Documents:

Report Details - EON-365883		
ICSR:	2055082	
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:	2018-09-18 16:47:59 EDT	
Reported Problem:	Problem Description: Diet Associated Dilated Cardiomyopathy	
	Date Problem Started: 08/31/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: Blue Buffalo Basics Limited Ingredient Diet	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Product Use Information:	Time Interval between Product Use and Adverse Event: 8 Months
		Product Use Stopped After the Onset of the Adverse Event: Yes
		Adverse Event Abate After Product Stop: Unknown
		Product Use Started Again: No
		Perceived Relatedness to Adverse Event: Definitely related
		Other Foods or Products Given to the Animal During This Time Period: No
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Sheepdog - Shetland	
	Gender: Male	
	Reproductive Status: Neutered	
	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
		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	
Additional Documents:		

Report Details - EON-366028

ICSR:	2055103
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 10:42:37 EDT

Reported Problem:	Problem Description:	B6 got dilated cardiomyopathy. She was diagnosed by cough and exercise intolerance, cardiomegaly and ultrasonographically proven DCM, but was not in full congestive heart failure. She had eaten a monotonous and very limited ingredient diet with novel proteins http://www.californianaturalpet.com/products/1121 (venison, red/green lentils, peas, and flaxseed oil for two and half years before diagnosis. For 8-12 weeks before diagnosis she ate a different novel diet for dogs http://www.forza10usa.com/legend-all-life-small/ I suspect her diet contributed to her disease either through a deficiency, through altered availability of a key nutrient, or due to a toxic effect in combination with her phenotype. I suspect the longer-fed California Natural, but of course both or neither may have contributed. California Natural is no longer available. The owner no longer has samples of the Forza. The taurine level I obtained was right after diagnosis in July, and so reflects the level after eating the Forza for a month or so exclusively. It does not reflect the levels for the prior two and a half years, of course - and, of course, taurine may not be the issue.
	Date Problem Started:	07/13/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Dear FDA CVM doctors, B6 is a three year old spayed Boston Terrier with dilated cardiomyopathy. She had a cough and exercise intolerance of a week's duration on July 13. Chest radiographs that day revealed cardiomegaly. She was diagnosed with DCM via echocardiogram July 13. She did not have effusion, edema, or tachypnea, but did have mild pulmonary hypertension according to the report from B6 . Additionally the liver had cysts and was hyperechoic, and the abdominal lymph nodes appeared large. Blood tests and history do not suggest hepatopathy so the significance or persistence of this is unknown yet. B6 has a possibly contributory novel diet history. She was on a limited ingredient diet for 2.5 years: California Natural Venison & Green Lentils Recipe in 13 lb. bags. (only five ingredients) http://www.californianaturalpet.com/products/1121 Then for three months before diagnosis, a different limited ingredient diet was mixed in and fed after California Natural left the market. That was LEGEND Maintenance Evolution ALL LIFE STAGES SMALL BREEDS Grain Free Formula Dog Food, ingredients: anchovy meal, peas, fava beans, sunflower oil (preserved with mixed tocopherols), fish oil http://www.forza10usa.com/legend-all-life-small/ Her pre-treatment plasma taurine level on July 17 was at UC Davis was B6 , where up to 120 is considered normal and no risk is thought likely for levels over 40. Whole blood was not favored, according to their site, so only plasma was sought. I understand both levels can be of interest. Her initial cbc and profile in July, and recent September checkup cbc/profile/ua/t4 were all unremarkable. Her treatment was: Recommended diet change: 1 egg daily and advice to feed a conventional diet with meat as the first ingredient if possible, to include grains. taurine supplementation (at 500 -1000 mg per day - owner obtained supplement) medication for DCM without CHF: B6 B6 (0.18 mg/kg q 12 hours) Her cough resolved and she seems fine to the owner so no adjustments to the medications have been made. Her reported current diet is: Blue Buffalo Life Protection with a small handful of Fromms Gold. B6 seems to LOVE the stinky cheese smelling Fromms. The eggs, if given, were discontinued. B6 inquired about infectious causes but I think Lyme, or even more remotely, Chagas' disease, is unlikely in this case. No testing or treatment was given. She has seasonal allergy and received B6 in the past but not since diagnosis. She is scheduled to see a B6 (cardiology) and (internal medicine) in a few weeks to re-evaluate her heart and see if the liver /lymphadenopathy is persistent or pertinent.
Outcome to Date:	Stable	
Product Information:	Product Name: http://www.californianaturalpet.com/products/1121 California Natural Venison &	

	Green Lentils Recipe in 13 lb. bags																			
	Product Type:	Pet Food																		
	Lot Number:																			
	UPC:	n/a																		
	Package Type:	BAG																		
	Package Size:	13 Pound																		
	Purchase Date:	01/01/2016																		
	Possess Unopened Product:	No																		
	Possess Opened Product:	No																		
	Storage Conditions:	routinely in a suburban home.																		
	Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>It was fed exclusively for two and half years prior to diagnosis. Your data entry fields required me to pretend last date of purchase was 1/1/2016 in order to reflect the duration. In fact the last bag was probably purchased in May 2018.</td> </tr> <tr> <td>First Exposure Date:</td> <td>01/01/2016</td> </tr> <tr> <td>Last Exposure Date:</td> <td>06/01/2018</td> </tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>3 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>No</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>No</td> </tr> </table>	Description:	It was fed exclusively for two and half years prior to diagnosis. Your data entry fields required me to pretend last date of purchase was 1/1/2016 in order to reflect the duration. In fact the last bag was probably purchased in May 2018.	First Exposure Date:	01/01/2016	Last Exposure Date:	06/01/2018	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:	No
Description:	It was fed exclusively for two and half years prior to diagnosis. Your data entry fields required me to pretend last date of purchase was 1/1/2016 in order to reflect the duration. In fact the last bag was probably purchased in May 2018.																			
First Exposure Date:	01/01/2016																			
Last Exposure Date:	06/01/2018																			
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:	No																			
	Manufacturer /Distributor Information:																			
	Purchase Location Information:																			
Animal Information:	Name:	B6																		
	Type Of Species:	Dog																		
	Type Of Breed:	Terrier - Boston																		
	Gender:	Female																		
	Reproductive Status:	Neutered																		
	Weight:	15 Pound																		
	Age:	3 Years																		
	Assessment of Prior Health:	Good																		
	Number of Animals Given the Product:	1																		
		1																		

	Number of Animals Reacted:								
	Owner Information:	Owner Information provided:	Yes						
		Contact:	<table border="1"> <tr> <td data-bbox="878 239 1040 282">Name:</td> <td data-bbox="1040 239 1554 282">B6</td> </tr> <tr> <td data-bbox="878 282 1040 325">Phone:</td> <td data-bbox="1040 282 1554 325"></td> </tr> <tr> <td data-bbox="878 325 1040 360">Email:</td> <td data-bbox="1040 325 1554 360"></td> </tr> </table>	Name:	B6	Phone:		Email:	
Name:	B6								
Phone:									
Email:									
		Address:	<table border="1"> <tr> <td data-bbox="878 360 1166 480">B6</td> <td data-bbox="1166 360 1554 480"></td> </tr> <tr> <td colspan="2" data-bbox="878 480 1554 519">United States</td> </tr> </table>	B6		United States			
B6									
United States									
	Healthcare Professional Information:	Practice Name:	B6						
		Contact:	<table border="1"> <tr> <td data-bbox="878 562 1040 605">Name:</td> <td data-bbox="1040 562 1554 605">B6</td> </tr> <tr> <td data-bbox="878 605 1040 648">Phone:</td> <td data-bbox="1040 605 1554 648"></td> </tr> <tr> <td data-bbox="878 648 1040 696">Email:</td> <td data-bbox="1040 648 1554 696"></td> </tr> </table>	Name:	B6	Phone:		Email:	
Name:	B6								
Phone:									
Email:									
		Address:	<table border="1"> <tr> <td data-bbox="878 696 1208 817">B6</td> <td data-bbox="1208 696 1554 817"></td> </tr> <tr> <td colspan="2" data-bbox="878 817 1554 858">United States</td> </tr> </table>	B6		United States			
B6									
United States									
Sender Information:	Name:	B6							
	Address:	<table border="1"> <tr> <td data-bbox="667 901 1040 1021">B6</td> <td data-bbox="1040 901 1554 1021"></td> </tr> <tr> <td colspan="2" data-bbox="667 1021 1554 1065">United States</td> </tr> </table>		B6		United States			
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-378016

ICSR:	2061896
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 19:38:20 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	For the past 6-9 months my dog has been losing weight. Over this period of time he has vomited his food and had loose bowel movements. Starting in October of 2018, he developed diarrhea off and on. By November the diarrhea was constant. On [B6] we had to rush our dog to the emergency hospital because he became listless, vomiting and continued diarrhea. Once at the hospital the doctor told us our dog had heart disease. We had no idea of this condition. As a matter of fact, during his comprehensive exam in October his heart was fine. Our local emergency hospital could not treat our dog and referred us to the [B6] [B6]. The doctors at [B6] [B6] told us about DCM which may be linked to grain free foods. We have been feeding our Dog Zignature Grain Free food for over a year now. Prior to feeding him Zignature we fed him Nutro which is another grain free food. Besides having DCM, our dog has [B6]. Over the past week and a half, he has been in the hospital twice totally 7 days and he probably won't come home for another 2-4 days. Our expected medical expenses will be close to \$10,000.
	Date Problem Started:	10/01/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Zignature brand dog food (pork, beef, turkey, salmon and lamb) kibble and canned 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	
	Storage Conditions:	The kibble was kept in sealed containers and the canned food was stored in the refrigerator.	
	Product Use Information:	Description:	We free feed our dogs. I gave our dog 7-10 cups a day of kibble and a little bit of canned food to administer his medicine to him.
	First Exposure Date:	07/01/2017	
	Last Exposure Date:	01/19/2019	
	Product Use Stopped After the Onset of the Adverse Event:	Yes	
	Adverse Event Abate After Product Stop:	No	
	Product Use	No	

		Started Again:	
		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
		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:	2	
	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:	10/31/2018
		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	

Additional Documents:

Report Details - EON-378035

ICSR:	2061910
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 06:37:31 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	We moved homes in July of 2017. At that time, we switched all 4 of our dogs to Costco Kirkland Super Premium Adult Chicken and Rice formula and one of our dogs on the Kirkland Natures Domain Turkey and Sweet Potato. All dogs were healthy prior to starting the food. On [B6] was rushed to the ER due to not being able to breath. After extensive testing at [B6] Veterinary School in [B6] it was determined she was diagnosed with DCM (dilated cardiomyopathy, left sided congestive heart failure, and ventricular arrhythmia. Keep in mind she had her physical in March of that year and was a perfectly healthy girl. [B6] prescribed her [B6] [B6] and Taurine supplement. Even with all the medicines and medical treatment, she passed away a few short months later on [B6]. I truly believe after doing my research part of the problem was diet related and I wish I had changed her food right away after she was diagnosed but I did not know. Since that time, I have switched all my other dogs totally of Kirkland brand food as well as grain free food.
	Date Problem Started:	[B6]
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Kirkland Signature Adult Dog chicken, rice, and vegetable formula
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Purchase Date:	08/01/2018
	Number Purchased:	2
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	in closed,sealed container
	Product Use Information:	Description: [B6] was def 1.5 cups in AM and PM
	Last Exposure Date: 09/16/2018	
	Time Interval between Product Use and Adverse Event: 13 Months	
	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:

Name: Costco

Address: B6
United States

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Mastiff - Neapolitan

Gender: Female

Reproductive Status: Neutered

Weight: 85 Pound

Age: 5 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:

Address: B6

Type of
Veterinarian: Primary/regular veterinarian

Permission to
Release Records
to FDA: No

Practice Name: B6

Contact: Name: B6
Phone:

Address: B6

United States

Type of
Veterinarian: Referred veterinarian

Date First Seen: 07/01/2018

Permission to
Release Records
to FDA: No

Sender Information:

Name: B6

Address: B6
United States

Contact: Phone: B6
Email:

Reporter Wants to No

	Remain Anonymous:	
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email
	Reported to Other Parties:	Other

Additional Documents:

Report Details - EON-378720

ICSR:	2062166
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:	2019-02-05 12:31:14 EST
Reporter is the Animal Owner:	Yes

Reported Problem:

Problem Description: Our dog was fed Acana Grain free food for her lifetime. We did a lot of research and thought we were feeding her a good brand. She began to have a coughing spell like she was choking or gagging. After a few days we took her to the veterinarian to find out that her heart was extremely enlarged and she was in congestive heart failure. We immediately took her to a cardiac specialist that day and were told that the outcome was not overly optimistic. We were told this was highly unlikely for a dog her age and her breed as she was diagnosed with Dilated Cardiomyopathy. This was in August 2017. At the time we were told she would probably have about 6-8 months to live and we began giving her many different heart medications. At the time we were still feeding her Acana grain free food. Her repeat visits showed no improvement and actually her heart continued to enlarge. In March 2018 we received a call from our heart specialist regarding some studies they had found with DCM and grain free food and we were told to immediately take her off this food. She continued on her medication regime which includes 4 heart medications as well as taurine and L-carnitine supplements and a drug was added for high blood pressure in her lungs. At her next visit several months after being removed from grain free food, her heart actually showed some improvement and at her visit in January 2019 we received additional great news that her heart has continued to get smaller and her blood pressure issues have resolved in her lungs. In addition, for the first time her heart function has improved! We were told that there is no way that her condition would have improved like this from just medication and there is definitely some correlation from removing her from grain free food. I have thought about this for a long time and have decided that this must be reported. I am confident that the food is a contributing factor to my Dog's heart condition.

Date Problem Started:	08/18/2017
Concurrent Medical Problem:	No
Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Acana - grain free formulas. We fed both chicken and beef formulas.		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	I don't have		
	Package Type:	BAG		
	Purchase Date:	05/01/2016		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	We stored in the bag closed and placed into a plastic container.		
	Product Use Information:	Description:	We used it for daily nutrition for dog	
		First Exposure Date:	05/10/2016	
		Last Exposure Date:	03/01/2018	
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:	Definitely related
Other Foods or Products Given to the Animal During This Time Period:	Yes

Manufacturer /Distributor Information:	
Purchase Location Information:	Name:
	Address:
	United States

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Labrador
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	70 Pound
	Age:	1.5 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1

Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	B6
	Address:	B6	
		United States	
	Type of Veterinarian:	Primary/regular veterinarian	
	Date First Seen:	08/18/2017	
	Permission to Release Records to FDA:	Yes	
	Practice Name:	B6	
		Contact:	Name:
Phone:			B6
Address:		B6	
	United States		
Type of	Referred veterinarian		

Veterinarian:	
Date First Seen:	08/18/2017
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:	Email
Reported to Other Parties:	Other

Additional Documents:

[Empty area for additional documents]

Report Details - EON-378845	
ICSR:	2062222
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 12:58:22 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: B6 went into Congestive Heart Failure that required emergency interventions over the weekend. 7 days prior to emergency admission he had a sedated tooth extraction which he tolerated well. He had a persistent cough after the surgery (to which I was told was related to the intubation). His cough increased and respiratory distress increased, and so I took him to emergency. There they discovered an enlarged heart/severe tachycardia/fluid on his lungs. He was kept in emergency for 24 hours to stabilize him and then brought home on B6 . B6 He followed up with a veterinary cardiologist 2 days later to confirm diagnosis and move forward. His ECHO confirmed DCM. He has been started on 5 medications, and 2 supplements (taurine and carnitine). Taurine level tests were sent off and expected back in 2 weeks. B6 has exclusively eaten a diet of Zigniture Grain Free Kangaroo Food since he was a puppy. This is the concern I am reporting. It is my understanding that there is concern that grain free/exotic protein dog foods have been linked to DCM in dogs without a genetic predisposition for it. Thank you for following up with me about this report, and the research you are doing in regards to this public health concern.
	Date Problem Started: 02/01/2019
	Concurrent Medical Problem: No
	Outcome to Date: Stable
Product Information:	Product Name: Zigniture Kangaroo Limited Ingredient Grain Free Dry Dog Food
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Package Size: 27 Pound
	Purchase Date: 01/25/2019
	Number Purchased: 1
	Possess Unopened Product: No
	Possess Opened Product: No
	Storage Conditions: Inside/ In dark basement/ in bag before opening. After opening: In dark basement in airtight container.
Product Use Information:	Description: Fed this food dry to dog twice daily/ morning and evening. Sometimes three times.
	First Exposure Date: 01/25/2019
	Last Exposure Date: 02/01/2019
	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: Unknown

		Product Stop:	
		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:	Pointing Dog - German Short-haired	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	55 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:	
		Email:	
		Address:	B6
			United States
		Type of Veterinarian:	Referred veterinarian
		Date First Seen:	02/05/2019
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:		
	Address:	B6	
	Contact: Phone:	B6	
	Email:		

Reporter Wants to Remain Anonymous:	No
Permission To Contact Sender:	Yes
Preferred Method Of Contact:	Email
Reported to Other Parties:	Manufacturer Store/Place of Purchase Other Distributor

Additional Documents:

Report Details - EON-379473	
ICSR:	2062542
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:	2019-02-12 12:47:23 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: My Golden Retriever was placed on a prescription diet years ago due to allergies. She was prescribed ' Royal Canine Hydrolyzed Protein Adult PS' and has been eating this food exclusively. She tested low for her Taurine level at B6 mol/ml , whole blood sample, on 2/4/19 at Dr Stern's lab at UC Davis, CA. According to Dr Stern, this is a low result and an Echo is indicated with this result followed by a diet change. If I feed my dog a prescription dog food, I am assuming that this food should have all the nutrition a dog needs. This does not seem to be the case for this food. Please investigate. Thank you.
	Date Problem Started: 02/04/2019
Product Information:	Product Name: Royal Canine Hydrolyzed Protein Adult PS
	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:	Name: Chewy.com
	Address: United States
Animal Information:	Name:
	Owner Information:
	Healthcare Professional Information:
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:
Attachment: img003.jpg	
Description: Lab results for Taurine from Dr Stern, UC Davis.	
Type: Laboratory Report	

Report Details - EON-379484

ICSR:	2062544
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-02-12 13:37:12 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I am contacting you because I noticed that the FDA was looking into grain free dog food being a link to DCM. On [B6] My wife and I had to put our Rottweiler down. The reason he was put down per the veterinarian was he had DCM / enlarged heart. This is something that came out of nowhere. The day before he was running in the back yard and showed no signs of DCM. The vet stated DCM is hard to find until its too late and there was not much we could do. [B6] (our Rottweiler) was 7 years old and we took him to the vet every year and he never showed any signs. After [B6] died I contacted the breeder where we got him and notified them of what the vet stated. The breeder stated no other dogs from [B6] litter had any problems with DCM and the parents of [B6] were still alive and doing well. I thought this was odd as DCM can be genetic but out of the 5 Rottweiler from [B6] litter and his parents still being alive and showing no signs this brought questions to me. Its been over year now that [B6] has been gone and this morning I saw a news article that the FDA was looking into grain free dog food being a link to DCM and I wanted to make contact with you guys and pass on my story and maybe it could help. Information about [B6] and what food we provided him is below. Thanks for looking into this and also if you could keep me informed about the FDA findings that would be great. Also if I can be anymore help please contact me. [B6] Rottweiler American / German mix. Have papers from breeder. Dog Food- BLUE Wilderness@SalmonFor Adult Dogs. Started feeding him this in 2015.
	Date Problem Started:	[B6]
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	BLUE Wilderness Salmon For Adult Dogs	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	n/a	
	Package Type:	BAG	
	Package Size:	24 Pound	
	Purchase Date:	02/01/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	The product was open and place into a bin that you can buy for dog food.	
	Product Use Information:	Description:	This product was my dog's food. first given 2015
		Last Exposure Date:	[B6]
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:	Name:	Chewy.com
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Rottweiler	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	98 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:	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-379520

ICSR:	2062549
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-02-12 14:47:11 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was on a grain free diet from the time we weened her off of her puppy food. Yesterday at 1 year and 10 months old B6 was diagnosed with DCM by a cardiologist at B6 through an echocardiogram. There was no previous forms of heart disease in B6 bloodline. The only cause the cardiologist could assume was grain based diet. The Taurine test is being completed and B6 is now on 4 different medicines to try and reverse the damage. In her hearts current condition, with no medication or changes in her diet, the cardiologist said she would have under a year to live. We thought we were doing our dogs good by putting them on a grain free diet from a reputable, fairly expensive product (4health Untamed Lamb and Lentil). We took her to our vet on Friday 2/8/19. They did a chest x-ray and noticed the bigger heart and liquid in her abdomen. From there we took her to an Emergency vet and they did a liquid test. Monday 2/11/19 we took her to B6 to be looked at by a cardiologist who performed an echocardiogram.
	Date Problem Started:	02/02/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	4health Untamed Open Highland Recipe Lamb and Lentil Recipe	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	06/20/2017	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	Kibble was stored in an airtight container. Canned food was stored covered in the refrigerator.	
Product Use Information:	Description:	Our dogs were fed a cup and a half at breakfast and dinner along with a tablespoon of Untamed Lamb and Lentil 14.1 oz. can.	
	First Exposure Date:	06/20/2017	
	Last Exposure Date:	02/11/2019	
	Time Interval between Product Use and Adverse Event:	18 Months	
	Product Use Stopped After the Onset of the Adverse Event:	Yes	
	Adverse Event Abate After Product Stop:	Unknown	

		Product Use Started Again:	No
		Perceived Relatedness to Adverse Event:	Definitely related
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	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:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	25.7 Kilogram	
	Age:	2 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:	
		Other Phone:	
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	02/08/2019
		Permission to Release Records to FDA:	Yes
Sender Information:	Name:	B6	
	Address:	B6	
		United States	
	Contact: Phone:	B6	
	Other Phone:		

Email:

B6

**Reporter Wants to
Remain Anonymous:** No

**Permission To Contact
Sender:** Yes

**Preferred Method Of
Contact:** Phone

**Reported to Other
Parties:** Store/Place of Purchase

Additional Documents:

Report Details - EON-379608

ICSR: 2062601
 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: 2019-02-13 11:16:47 EST

Reported Problem:
Problem Description: 4 year old neutered male Maltese on examination showed a 1-2/6 left holosystolic murmur which was not noted previously 6 months prior. Owner has recently (last 2 months) switched to Stella and Chewy's Super beef grain free food (<https://www.stellaandchewys.com/dog-food/frozen-raw-dinners/patties/stella-super-beef>). Unsure if murmur is secondary to potential dilated cardiomyopathy from taurine deficiency secondary to grain free or age related changes.
Date Problem Started: 02/13/2019

Product Information:
Product Name: Stella's Super Beef Frozen Patties
Product Type: Pet Food
Lot Number:
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name:
Owner Information: Owner Information provided: No
Healthcare Professional Information:

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: None

Additional Documents:

Report Details - EON-379851

ICSR: 2062732
 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 11:38:11 EST

Reported Problem:

Problem Description: B6 a 2 Yrs. 6 Mos., Neutered Male, Great Dane, owned by B6 was presented on B6 for cardiac evaluation following presentation to our ER service for evaluation of peritoneal effusion. He was seen by his pDVM today for abdominal distension. A rapid, irregular rhythm was noted on physical exam and an ECG was run showing rapid atrial fibrillation. Owners noted the abdominal distension and a decline in appetite x 2 days. He is fed 4 health large breed grain free diet. ECG: Rapid atrial fibrillation and widened QRS complexes consistent with LV enlargement, average heart rate of 240-260 bpm. There is severe global cardiac dilation and severe left ventricular myocardial failure consistent with dilated cardiomyopathy. There is mild low velocity mitral regurgitation and mild tricuspid regurgitation with mildly elevated velocities. There is severe peritoneal effusion and moderate pleural effusion. Performed abdominocentesis and thoracocentesis after patient was given B6 7.3 liters of straw colored abdominal fluid was removed, 1.3 liters of pleural fluid was removed. Diagnosis: Atrial fibrillation, Dilated cardiomyopathy, Congestive heart failure (pleural and peritoneal effusion), Mild pulmonary hypertension

Date Problem Started: B6

Concurrent Medical Problem: Unknown

Outcome to Date: Better/Improved/Recovering

Product Information:

Product Name: 4 Health Large Breed Grain Free (unknown protein source in food)

Product Type: Pet Food

Lot Number:

Product Use Information: Perceived Relatedness to Adverse Event: Probably related

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: 62 Kilogram

Age: 2 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: Primary/regular veterinarian

		Veterinarian:	
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-380576

ICSR: 2063073
 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: 2019-02-22 14:46:48 EST

Reported Problem:
Problem Description: Presented for sudden onset of lethargy, exercise intolerance, not eating well. Performed bloodwork, x-rays, ultrasound, ECG and report from Cardiologist. Was diagnosed with Dilated Cardiomyopathy by Cardiologist. Has been fed a grain free dog food her entire life and with new research developing about these diets being linked to DCM it was recommended to stop the food and run a Taurine blood level. Heart medications were started. Did not respond well to treatment and was humanely euthanized 2 weeks later.
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 & Lentil Formula
Product Type: Pet Food
Lot Number:
Package Type: BAG
Possess Unopened Product: Unknown
Possess Opened Product: Unknown
Product Use Information:
Description: Fed orally to the dog at meal time
Perceived Relatedness to Adverse Event: Possibly related
Manufacturer /Distributor Information:
Purchase Location Information:

Animal Information:
Name: B6
Type Of Species: Dog
Type Of Breed: Shepherd Dog - German
Gender: Female
Reproductive Status: Neutered
Weight: 66 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: Yes
Contact:
Name: B6
Phone:
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	
			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-380618

ICSR: 2063101
 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: 2019-02-22 22:51:26 EST
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: On [B6] collapsed, rushed him to the vet, it was determined that he had DCM, was immediately put on [B6] On Feb. 11th, we saw a cardiologist at [B6] vet school, they did an echo and repeated x-rays and labs. All his labs were perfect. they increased the doses. He died on [B6] while napping in my bedroom.
Date Problem Started: [B6]
Concurrent Medical Problem: Yes
Pre Existing Conditions: [B6]
Outcome to Date: Died Naturally
Date of Death: [B6]

Product Information:
Product Name: Acana Singles Mackerel
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 13 Pound
Purchase Date: 01/14/2019
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No

Storage Conditions: Stored in air-tight containers
Product Use Information:
Description: Dry kibble was mixed with canned pumpkin
First Exposure Date: 01/15/2019
Last Exposure Date: [B6]
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: 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: Terrier - Tibetan

Gender: Male

Reproductive Status: Neutered

Weight: 31.7 Pound

Age: 9 Years

Assessment of Prior
Health: Excellent

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

Date First Seen:

B6

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:

02/11/2019

Permission to
Release Records
to FDA:

Yes

Sender Information:

Name:

Address:

B6

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: Store/Place of Purchase
Manufacturer

Additional Documents:

Report Details - EON-380700		
ICSR:	2063112	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)	
Reporting Type:	Voluntary	
Report Submission Date:	2019-02-24 14:38:26 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: B6 has skin allergies that never went away (pimples in his belly area). I switched to grain free food for his last 4 years. He developed a cough. After 3 days I took him to the ER. They discovered he had DCM and went into cardiac arrest at the hospital. I am now learning about the connection with grain free food and DCM. My other Doberman also does spontaneously at 8 from the same thing. They lived like happy young pups with no symptoms. They both had the same diet.	
	Date Problem Started: B6	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Other	
	Date of Death: B6	
Product Information:	Product Name: Taste of the wild grain free	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 30 Pound	
	Purchase Date: 10/12/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Tight seal storage container for dogs	
	Product Use Information:	Description: 3 cups daily in stainless steel bowl with drops of water
		First Exposure Date: 10/15/2018
		Last Exposure Date: 10/17/2018
Time Interval between Product Use and Adverse Event: 4 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: No		
Manufacturer /Distributor Information:		
Purchase Location Name: Chewy		

	Information:	Address: Online purchase <div style="border: 1px dashed black; padding: 5px; display: inline-block;">B6</div> United States
Animal Information:	Name:	<div style="border: 1px dashed black; padding: 2px;">B6</div>
	Type Of Species:	Dog
	Type Of Breed:	Doberman Pinscher
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	70 Pound
	Age:	9 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	2
	Number of Animals Reacted:	2
	Owner Information:	
Healthcare Professional Information:		
Sender Information:	Name:	
	Address:	<div style="border: 1px dashed black; padding: 2px;">B6</div> United States
	Contact:	
	Reporter Wants to Remain Anonymous:	Yes
	Reported to Other Parties:	None
Additional Documents:		

Report Details - EON-380735

ICSR:	2063127	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2019-02-24 23:26:07 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description:	B6 had started to gag more frequently, I thought she just drank her water too quickly but she continued to gag and pant more heavily. She is an Old English Sheepdog and they typically pant as they have long coats. I had her shaved to a puppy cut so it would be much cooler for her and put a fan by her. Then she started breathing with difficulty and we rushed her to the emergency Veterinary hospital. B6 there she was diagnosed with CHF (congested heart failure) she was put on B6 a day and B6 we lowered her activity level through the winter but sadly she lost her fight when she passed at home B6
	Date Problem Started:	06/01/2017
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Died Naturally
	Date of Death:	B6
	Product Information:	Product Name: Zignature Kangaroo Formula
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	27 Pound
	Number Purchased:	1
	Possess Unopened Product:	No
	Possess Opened Product:	Yes
	Storage Conditions:	in bag that i stored in a container
	Product Use Information:	Description: fed three times a day total 3 cups
		Last Exposure Date: B6
		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: chewy.com B6
		Address: B6 United States
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Sheepdog - Old English	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 87 Pound	
	Age: 8 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: Referred veterinarian		
Date First Seen: 09/04/2017		
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: Phone	
Additional Documents:	Reported to Other Parties: None Distributor Store/Place of Purchase Manufacturer	

Report Details - EON-380774

ICSR: 2063146
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 11:01:44 EST

Reported Problem:

Problem Description: HISTORY: B6 a 3 Yrs. 11 Mos., Neutered Male, Great Dane, was presented on 1/23/2019 for cardiac evaluation. B6 was noted to have labored breathing and coughing about 3 weeks ago. He was seen at the rDVM and had radiographs completed at that time. The owner also has noted a rapid heart rate at home. He was started on B6. The owner states that he was evaluated in October for heart disease and had an echo at the rDVM which was normal. The rDVM records indicate an ECG was done at that time that was normal. They have restricted B6 exercise since he was diagnosed, however he is still interested in play. She is aware of the concerns of grain free diets, however is feeding Prey Grain Free due to GI issues. He has been on a grain free diet his entire life. B6 is eating/drinking normally. No vomiting or diarrhea is noted. He is current on vaccines. Current Medications: B6

B6

1/16/19 - VHS 14.0; pulmonary venous dilation; generalized cardiomegaly (severe); evidence of pulmonary edema. B6

B6

jugular venous distention or abnormal jugular pulses, grade III/VI left apical systolic murmur, rapid regular rhythm; lungs clear, pulses moderate. Nervous system normal. Skin normal. Musculoskeletal system normal. Normal peripheral lymph nodes Diagnostics Doppler Blood Pressure: 118 mm Hg; # 5 cuff LR ECG: Sinus tachycardia with tall QRS complexes and widened p waves consistent with LV and LA enlargement. average heart rate of 160 bpm. Echocardiogram:

B6

B6 Left ventricle: - Chamber size: severely increased end-diastolic and end-systolic dimensions - Free wall thickness: slightly decreased - IVS thickness: slightly decreased - Shortening fraction: moderately decreased - Ejection fraction: decreased - Global wall movement: hypokinetic - E point to septal separation: severely increased Left atrial size: severely dilated Right ventricle: - Chamber size: severely dilated - Global wall movement: hypokinetic Right atrial size: moderately to severely dilated Mitral valve leaflets: normal 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 low velocities - Mitral inflows: summated - Mitral annulus motion (TDI): summated - Tricuspid regurgitation: mild with mildly increased velocities - LVOT: normal flow pattern and velocities. - Aortic insufficiency: none - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none Diagnosis: Dilated cardiomyopathy leading to recent onset congestive heart failure Treatment/Medications - We would like to recheck B6 in 3 months to recheck his echocardiogram. - Recheck blood work (kidney values /electrolytes) with primary veterinarian in 1-2 weeks. - Recommended transitioning B6 off his current grain free diet to a Royal Canin, Science Diet or Purina diet.

Medications: B6

B6

Date Problem Started: 01/23/2019

Concurrent Medical Problem: Unknown

Outcome to Date: Unknown

Product Information:

Product Name: Taste of The Wild PREY (unknown formula)

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:	61.7 Kilogram
	Age:	3 Years
	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:	B6
		United States
	Contact: Phone:	B6
		Ema: B6
	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-380783

ICSR:	2063151
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 11:49:16 EST

Reported Problem:	Problem Description:	<p>HISTORY: [B6] a 7 Yrs. 0 Mos., Neutered Male, Retriever, Labrador, was presented on 1/27/2019 for cardiac evaluation after transferring from out [B6] [B6] location for further work up of a ventricular arrhythmia. He presented to our ER service there last night for shaking, lethargy, labored breathing and an episodes of disorientation yesterday evening. O reports he was normal when they left at 2:45p today and appeared abnormal when they returned home [B6] was short of breath and collapsed and appeared disoriented after walking outside. He has no known toxin exposure and has otherwise been healthy. He has been fed Taste of the Wild (Salmon) and grain-free treats for life. Diagnostics: Thoracic radiographs- mild to moderate generalized cardiomegaly; no overt pulmonary edema tFAST- minimal cardiac contractility noted with arrhythmia ECG-</p> <p style="text-align: center; font-size: 48pt; font-weight: bold;">B6</p> <p style="text-align: center; font-size: 48pt; font-weight: bold;">B6</p> <p>ventricle: - Chamber size: severely increased end-diastolic and end-systolic dimensions - Free wall thickness: normal - IVS thickness: normal - Shortening fraction: severely diminished - Ejection fraction: decreased - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: mildly dilated Right ventricle: - Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: normal 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 low velocities - Mitral inflows: increased velocity wave profiles - Mitral annulus motion (TDI): normal - Tricuspid regurgitation: mild with normal velocities - LVOT: normal flow pattern and velocities. - Aortic insufficiency: none - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none Diagnosis: Dilated cardiomyopathy- r/o diet-related vs. idiopathic Ventricular arrhythmia-improved with [B6] therapy Treatment/Medications Recommended that owner transition off grain-free diet over the next couple weeks to Royal Canin, Science diet or Purina. Medications/supplements [B6] mg tablets: continue 1/2 [B6] current manufacturer's backorder). Taurine - start 1 gram by mouth every 12 hours (see handout for brand recommendations) L-carnitine - start 1,750 grams by mouth every 8 hours with food (see handout for brand recommendations) Discussed sending out whole blood/plasma Taurine levels to UC Davis- owner declined. A Holter monitor is recommended in 2-3 weeks. Recheck echocardiogram in 3 months to reassess response to therapy.</p>
	Date Problem Started:	01/27/2019
	Concurrent Medical Problem:	Unknown
	Outcome to Date:	Unknown
Product Information:		

	Product Name:	Taste of The Wild - Salmon grain free		
	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 - Labrador		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	32.9 Kilogram		
	Age:	7 Years		
	Assessment of Prior Health:	Unknown		
	Number of Animals Reacted:	1		
	Owner Information:	Owner Information provided:	No	
	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:	Phone		
	Reported to Other Parties:	None		
Additional Documents:				

Report Details - EON-380855

ICSR: 2063193
 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: 2019-02-25 21:23:55 EST

Reported Problem:
Problem Description: Low Taurine level, Tested on 2/19/19, results received 2/25/19
Date Problem Started: 02/25/2019

Product Information:
Product Name: Merrick Classic Real Beef + Green Peas Recipe with Ancient Grains Adult Dry Dog Food
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 12 Pound
Purchase Date: 02/22/2019
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: Yes
Product Use Information:
Manufacturer /Distributor Information:
Name: Chewy.com
Type(s): Distributor
Address: United States
Contact:
Phone: 1-800-672-4399
Web Address: www.chewy.com
Possess One or More Labels from This Product: Yes
Purchase Location Information:
Name:
Address: **B6**
 United States

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

Additional Documents:	Attachment:	UC Davis Taurine result.pdf	
	Description:	Taurine level results	
	Type:	Record	
	Attachment:	UCD Diet and DCM Handout.pdf	
	Description:	Sent with Taurine level results from UC Davis	
	Type:	Article	
	Attachment:	Stern Lab Taurine Recommendations.pdf	
	Description:	Sent with Taurine level results from UC Davis	
	Type:	Analysis	

Report Details - EON-381121

ICSR: 2063345
 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: 2019-02-28 12:05:53 EST

Reported Problem:

Problem Description: HISTORY: **B6** a 4 Yrs. 5 Mos., Neutered Male, Retriever, Labrador, owned by **B6** was presented on 2/13/2019 for cardiac evaluation. **B6** was initially seen at the rDVM for a change in his bark and increased panting. He has been less interested in playing with her other dog. He had radiographs taken at the rDVM showing cardiomegaly and an echocardiogram was recommended. He was previously fed Nutro Max large breed chicken formula (no corn, wheat, soy) since puppyhood which owner has abruptly changed to Hill's sensitive skin and stomach. Current Medications: **B6**
 Diagnostics: rDVM Radiographs 2/9/2019: mild cardiomegaly, normal pulmonary vasculature; normal pulmonary parenchyma **B6**

B6

B6 Left ventricle: - Chamber size: normal end-diastolic dimensions; mildly increased end-systolic dimensions - Free wall thickness: normal - IVS thickness: normal - Shortening fraction: mildly decreased - Global wall movement: mildly hypokinetic - E point to septal separation: normal Left atrial size: mildly dilated Right ventricle: - Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: normal 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: trace - Mitral inflows: inverted - 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-sided cardiomegaly- rule out early dilated cardiomyopathy - potentially diet-related vs idiopathic Treatment/Medications Continue: **B6** as previously prescribed (owner requests compounding d/t cost). Start Taurine 1 gm PO BID and L-carnitine 2 gm PO TID with food. Recheck echocardiogram in 3-6 months.

Date Problem Started: 02/13/2019
Outcome to Date: Unknown

Product Information:

Product Name: Nutro Max Limited Ingredient Diet Adult Large Breed Dry Dog Food (unknown protein source 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: Neutered
	Weight: 39.9 Kilogram
	Age: 4 Years
	Number of Animals Reacted: 1
	Owner Information: Owner Information provided: No
Healthcare Professional Information:	Practice Name: B6
	Contact: Name: multiple doctors multiple doctors Phone: B6
	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
	Reported to Other Parties: None
Additional Documents:	

Report Details - EON-381133

ICSR:	2063352		
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:	2019-02-28 13:44:02 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	food related Diagnosed with DCM after being fed Zignature Kangaroo for 2 years. Had xray. Treating with cardi. Have seen 2 times. Next apt in 2 weeks.	
	Date Problem Started:	12/04/2018	
	Date of Recovery:	01/01/2019	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Zignature Kangaroo	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	do not have	
	Package Type:	BAG	
	Package Size:	35 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In a sealed container	
	Product Use Information:	Description:	2 x per day for 2 years
		First Exposure Date:	12/12/2016
		Last Exposure Date:	12/01/2018
		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:	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: Address:	<div style="border: 1px dashed black; padding: 5px; text-align: center; font-size: 2em; font-weight: bold;">B6</div>	
		United States		
Animal Information:	Name:	B6		
		Type Of Species:	Dog	
		Type Of Breed:	American Pit Bull Terrier	
		Gender:	Male	
		Reproductive Status:	Neutered	
		Weight:	56 Pound	
		Age:	2.5 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
		Address:		B6
		United States		
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	12/05/2018	
		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-381145

ICSR: 2063360
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: 2019-02-28 15:07:34 EST

Reported Problem:
Problem Description: HISTORY: **B6** a 6 Yrs. 1 Mos. Spayed Female, Retriever, Golden, was presented on 2/14/2019 for cardiac evaluation. **B6** started coughing last summer and the dog trainer noted that she acted like an old dog. She stopped playing with the housemate and appetite was decreased. She was seen at the rDVM in January and radiographs showed cardiomegaly. **B6** will usually cough/gag after eating. The owner does note a change in breathing sounds. **B6** was fed Kangaroo diet for past 2-3 years and was on Zignature duck or lamb prior to that for life. In December the owner switched her to Fromm Veggie & Duck formula. She has been supplementing with Taurine and L-Carnitine since December. **B6** is eating/drinking normally. No vomiting or diarrhea is noted. She is current on vaccines and heartworm prevention. **B6** has a some muscle atrophy in her hips and skin issues. Current Medications: Taurine Powder: 3 scoops PO SID; L-Carnitine PO SID. Previous Diagnostics: rDVM Radiographs - 1/8/2019: severe left-sided/generalized cardiomegaly; normal pulmonary parenchyma; normal pulmonary vasculature. 1/8/2019: CBC - NSF.

B6

Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, no murmur, muffled heart sounds, no arrhythmias, lungs clear, pulses good. Skin normal. Musculoskeletal system normal. Normal peripheral lymph nodes. Diagnostics: Doppler Blood Pressure: 122 mm Hg. # 5 cuff.

B6

B6 Left ventricle: - Chamber size: severely increased - Free wall thickness: normal - IVS thickness: normal - Shortening fraction: severely decreased - Ejection fraction: decreased - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: severely dilated Right ventricle: - Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: normal 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: severe low velocity flow - Mitral inflows: increased velocity wave profiles - Mitral annulus motion (TDI): normal - Tricuspid regurgitation: mild with mildly increased velocities - LVOT: normal flow pattern and velocities. - Aortic insufficiency: trace - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none
Diagnosis: Dilated cardiomyopathy - rule out diet-related vs. idiopathic Treatment/ Medications Start the following medications/supplements: **B6**

B6

Taurine 1 gram PO BID - L-Carnitine 1,500 mg PO TID with food We would like to recheck **B6** in 3 months to repeat her echocardiogram. Please follow up with your primary veterinarian to have **B6** blood work (kidney values /electrolytes) rechecked in 1-2 weeks. I would recommend transitioning **B6** off Fromm to Royal Canin, Science diet, Purina or Iams.

Date Problem Started: 02/14/2019

Outcome to Date: Unknown

Product Information:
Product Name: Zignature Kangaroo Limited Ingredient Formula Grain-Free Dry Dog Food
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:	30.6 Kilogram
	Age:	6 Years
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: No
	Healthcare Professional Information:	Practice Name:
Contact: Name:		unknown vet multiple vets in clinic
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-381160

ICSR: 2063365
 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: 2019-02-28 16:56:37 EST

Reported Problem:
Problem Description: HISTORY: B6 a 8 Yrs. 1 Mos., Spayed Female, Great Dane, was presented on 6/29/2018 for cardiac evaluation. Cardiomegaly was noted on recent CXR with our ER service and a cardiac consultation was recommended. A rare cough has been noted. She has been panting more frequently. Her appetite has waned. No unusual sneezing, vomiting or diarrhea. No polyuria/polydypsia. Current Medications: none Physical Exam Weight: 136 lb HR- 180; RR- pant Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, no murmur, no arrhythmias, rapid regular rhythm, lungs clear, pulses fair. No overt abdominal distension. Diagnostics ECG: Sinus tachycardia with left bundle branch block morphology. QRS complexes:

B6

B6 Comments: There is severe generalized cardiomegaly and severe left ventricular hypokinesis consistent with dilated cardiomyopathy. There is mild mitral and tricuspid regurgitation. All cardiac valves appear normal. Pulmonary arterial pressure appear mildly increased consistent with mild pulmoanary hypertension. 2D/M-MODE Left ventricle: - Chamber size: severely increased - Free wall thickness: normal - IVS thickness: normal - Shortening fraction: severely decreased - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: severely dilated Right ventricle: - Chamber size: moderately to severely dilated - Global wall movement: hypokinetic Right atrial size: moderately to severely dilated Mitral valve leaflets: normal 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. A mild to moderate volume of peritoneal effusion was noted. CFD/PWD/CWD: - Mitral regurgitation: mild with low velocities - Mitral inflows: summated - Mitral annulus motion (TDI): summated - Tricuspid regurgitation: mild with mildly increased velocities - LVOT: normal flow pattern and velocities. - Aortic insufficiency: none - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none Diagnosis: Dilated cardiomyopathy, Peritoneal effusion - suspect congestive heart failure Mild pulmonary hypertension Treatment/Medicatins Medications: Start the following medications:

B6

B6 Recheck a focused echocardiograms, bloodwork (renal /electrolytes) and ECG in 2 weeks. Recheck earlier with any concerns.

Date Problem Started: 06/29/2018

Outcome to Date: Unknown

Product Information:
Product Name: Taste of The Wild (unknown protein source 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: Great Dane
	Gender: Female
	Reproductive Status: Neutered
	Weight: 61.8 Kilogram
	Age: 8 Years
	Number of Animals Reacted: 1
	Owner Information: Owner Information provided: No
	Healthcare Professional Information:
Sender Information:	Name:
	Address:
	United States
	Contact: Phone:
	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-381162

ICSR: 2063371
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: 2019-02-28 17:32:10 EST

Reported Problem:

Problem Description: HISTORY: B6 a 4 Yrs. 9 Mos., Male, Great Dane was presented on 9/26 /2017 for cardiac evaluation. He presented to B6 for progressive coughing, labored breathing and inappetance for 2 weeks. He would intermittently groan when laying down. A tachyarrhythmia was noted on exam. Chest radiographs were consistent with cardiomegaly and pulmonary edema. Blood work was unremarkable. B6 was started on B6 pending cardiac consultation. His owners report that his clinical signs have improved to nearly resolved. Current Medications B6

B6 Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, grade II/VI left apical systolic murmur, irregular rhythm, lungs clear, pulses variable. Skin normal. Musculoskeletal system normal. Normal peripheral lymph nodes
Diagnostics ECG: Atrial fibrillation with average heart rate of 180 bpm. B6

B6

B6 Chamber size: moderately increased end-diastolic dimensions; severely increased end-systolic dimensions - Free wall thickness: normal - IVS thickness: mildly increased - Shortening fraction: severely depressed - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: moderately dilated Right ventricle: - Chamber size: mild to moderately dilated - Global wall movement: hypokinetic Right atrial size: moderately dilated Mitral valve leaflets: normal 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 decreased velocities - Mitral inflows: increased E wave velocity profiles - Tricuspid regurgitation: none - LVOT: variable flow pattern and velocities secondary to patient arrhythmia. - Aortic insufficiency: none - RVOT: variable flow pattern and velocities secondary to patient arrhythmia. - Pulmonic insufficiency: none Diagnosis: Atrial fibrillation Dilated cardiomyopathy - r/o idiopathic vs. tachycardia-induced Congestive heart failure (pulmonary edema) - clinically improved/resolved Treatment/Medications - B6

B6

B6 - recheck in 2 weeks to assess HR/rhythm, renal panel/lytes +/- thoracic radiographs - repeat echocardiogram and ECG in 3 to 6 months or earlier if necessary.

Date Problem Started: 09/26/2017
Outcome to Date: Worse/Declining/Deteriorating

Product Information:

Product Name: Blue Buffalo Grain Free (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: Great Dane

	Gender: Male
	Reproductive Status: Intact
	Weight: 67 Kilogram
	Age: 4 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
	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-381167

ICSR: 2063373
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: 2019-02-28 17:57:29 EST

Reported Problem: **Problem Description:** HISTORY: **B6** a 8 Yrs. 0 Mos., Male, Pinscher, Doberman, was presented on 11/26/2018 for cardiac evaluation. The owner notes that looking back **B6** had a nuisance cough prior to October of this year. In October, he was seen at the rDVM for coughing and changes in respirations. He was diagnosed with CHF and started on **B6** at the rDVM. Initially he was taking **B6** tab - 3 tabs PO BID, they have decreased and increased with his **B6** based on coughing. **B6** is current on vaccines and heartworm prevention. No unusual sneezing, vomiting or diarrhea. Appetite and activity level normal. He is fed Wellness Core food. The owner notes that he has had GI issues on chicken diets. The owner notes no prior health issues. Current Medications: **B6** previous

Diagnostics: rDVM Radiographs: generalized cardiomegaly; pulmonary edema; pulmonary venous distension **B6**

B6 Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, grade III/VI left apical systolic murmur, no arrhythmias, lungs clear, pulses good. Skin normal. Musculoskeletal system normal. Normal peripheral lymph nodes. Intact. Diagnostics Doppler Blood

B6

B6 Left ventricle: **B6** - Chamber size: severely increased end-diastolic and end-systolic dimension - Free wall thickness: mildly decreased - IVS thickness: mildly decreased - Shortening fraction: severely decreased - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: moderately dilated Right ventricle: - Chamber size: moderately dilated - Global wall movement: hypokinetic Right atrial size: moderately dilated Mitral valve leaflets: normal with annular dilation 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 decreased velocities - Mitral inflows: normal - Mitral annulus motion (TDI): normal - Tricuspid regurgitation: scant with normal velocities - LVOT: normal flow pattern and velocities. - Aortic insufficiency: none - RVOT: normal flow pattern and velocities. - Pulmonic insufficiency: none Diagnosis: Dilated cardiomyopathy History of congestive heart failure Treatment/Medications 1)

B6

B6 5) Taurine give 1 gram by mouth every 12 hours 6) L-carnitine give 2 grams by mouth every 8 hours with food Recommended 24 hour Holter monitor- owner declined at this time. Discussed unlikely potential for a taurine deficiency secondary to grain-free diet and taurine testing (whole blood/plasma)- owner declined at this time. Recommended rechecking renal values/lytes with pDVM in 1-2 weeks. A repeat echocardiogram is recommended in 3-6 months.

Date Problem Started: 11/26/2018
Outcome to Date: Died Naturally
Date of Death: **B6**

Product Information: **Product Name:** Blue Wilderness (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: Intact
	Weight: 42.27 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: 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-382676		
ICSR:	2064216	
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:	2019-03-18 15:38:33 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: She developed Congestive heart failure / enlarged heart and I received a letter from vet saying grain free food causes this of which she had been on for several years.	
	Date Problem Started: 05/06/2017	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Naturally	
	Date of Death: B6	
Product Information:	Product Name: Wellness Core Ocean Formula and Natural Balance Sweet Potato and fish formula	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 28 Pound	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: stored in a sealed airtight bin	
	Product Use Information:	Description: alternated between both brands. Fed twice daily
		First Exposure Date: 01/01/2010
		Last Exposure Date: B6
		Time Interval between Product Use and Adverse Event: 7 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: chewy.com, Petco B6	
	Address: United States	
Animal Information:	Name: B6	

	Type Of Species:	Dog
	Type Of Breed:	Retriever - Labrador
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	95 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:	Practice Name: B6
		Contact: Name: B6
		Phone:
		Type of Veterinarian: Primary/regular veterinarian
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:	Store/Place of Purchase

Additional Documents:

Report Details - EON-383661

ICSR:	2064892
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:	2019-03-28 23:40:46 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 female - 5 month old puppy- Stopped eating abruptly- after some misdiagnosis (heart disease is not appropriate in puppies) -her heart was found to be enlarged. She started grain free food on Jan 18th- became sick March 12th. On March 12 she refused to eat anything- I took her to see vet in B6 because we were out of town. The next way she was no better so we went to our regular vet. Is presently being treated by our vet but may need specialist if it does not clear up. Chest xray looks terrible. The puppy has been switched to IAMs at this time. The grain free food they were on is American Journey, made by Chewy. American Journey Chicken & Sweet Potato Recipe Grain-Free Large Breed Puppy Dry Dog Food, 24-lb bag / American Journey Chicken & Brown Rice Protein First Recipe Puppy Dry Dog Food, 28-lb bag She was given various treats but varied widely- only consistent food is the grain free and pieces of grain free kibble were often given as treats.
	Date Problem Started:	03/12/2019
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	American Journey Chicken & Sweet Potato Recipe Grain-Free Large Breed Puppy Dry Dog Food, 24-lb bag / American Journey Chicken & Brown Rice Protein First Recipe Puppy Dry Dog Food, 28-lb bag		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	24 Pound		
	Purchase Date:	01/16/2019		
	Number Purchased:	2		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	dry in container		
	Product Use Information:	Description:	Fed daily to puppy	
		First Exposure Date:	01/16/2019	
		Last Exposure Date:	03/12/2019	
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		No		

		Started Again:	
		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
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Mixed (Dog)	
	Gender:	Female	
	Reproductive Status:	Intact	
	Pregnancy Status:	Not Pregnant	
	Lactation Status:	Not lactating	
	Weight:	35 Pound	
	Age:	5 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:	United States
		Date First Seen:	03/13/2019
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:	Distributor Store/Place of Purchase Manufacturer	
Additional Documents:			

Report Details - EON-359094

ICSR:	2051951
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-07-13 11:05:18 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Due to my dog having allergies, I have been trying to find a suitable grain free food that he can tolerate without itching or redness of his ears. We started feeding Zignature grain free venison formula approximately a year ago and before that fed Pure Vita grain free. In March, my dog started coughing, had lack of energy and lack of appetite. I brought him to the vet thinking he had kennel cough and after an x ray, he was diagnosed with dilated cardiomyopathy and given two months to live. I read an article about taurine deficiency causing DCM and asked her to draw a taurine level but she said only cats have taurine deficiency so she didn't do this. I have since read more articles about dogs being diagnosed with DCM after being on a legume heavy diet and wish I would have insisted on a taurine level. I have since started supplementing taurine and L carnitine to my dog's diet along with the three heart medications he needs to take twice daily and he has survived four months so far. I contacted Zignature and implored them to add taurine to their food and a representative wrote me back and said they are going to start adding this. While it is probably too late to save my dog, it is my hope that many other dogs and owners will not have to go down this terrible road by simply having dog food companies make sure they change up their foods by adding taurine and not adding so many legumes. I am also cooking fresh ground venison to add to my dog's diet and only giving half the amount of kibble. The heart meds are really expensive as well. The B6 alone is about \$3 a pill and he has to take 1 1/2 pills daily. I am asking you to please step in and save future dogs from an untimely death due to pet food. I did so much research trying to find the absolute best food to help my allergic dog and I rue the day I started feeding him Zignature. He is a rescue and we do not know his breed but the vet thinks he is Am Staff/hound and the shelter he came from listed him as a boxer/hound mix, so he might be a combination of all four. Thank you for your time.
	Date Problem Started:	03/15/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Zignature Venison Formula	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Purchase Date:	06/08/2018	
	Number Purchased:	1	
	Possess Opened Product:	Yes	
	Storage Conditions:	Product stored in heated garage before opening and afterwards the bag was placed in a freezer to keep product fresh as there is no ziplock closing on Zignature bag to keep it fresh	
	Product Use Information:	Description:	Served two cups twice daily for dog's meal
		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:	No
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Chewys
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Unknown	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	70 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:		
Sender Information:	Name:		
	Address:	B6 United States	
	Contact:		
	Reporter Wants to Remain Anonymous:	Yes	
	Reported to Other Parties:	Manufacturer	
Additional Documents:			

Report Details - EON-359102

ICSR:	2051957
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 11:35:01 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	He gradually had more coughing and heavy breathing. At first vet could find no reason but finally found arrhythmia. Took him to specialist and they diagnosed dilates cardiomyopathy. He was fed food from Costco that was grain free and contained sweet potato.
	Date Problem Started:	08/17/2016
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Kirkland Natures Domain Turkey and Sweet Potato food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	35 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	The food was stored in the bag in a climate controlled house. The top was closed between feedings.		
	Product Use Information:	Description:	The food was his sole diet.	
		First Exposure Date:	08/01/2012	
		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:	Probably related	
		Other Foods or Products Given to the Animal During This Time Period:	Yes	
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	Costco		
	Address:	B6 United States		

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Greyhound		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	75 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:	
Email:				
Address:		B6		
		United States		
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		10/01/2016		
Permission to Release Records to FDA:		Yes		
Healthcare Professional Information:		Practice Name:	B6	
		Contact:	Name:	Unknown cardiac service Unknown cardiac service
			Phone:	B6
			Email:	
		Address:	B6	
	United States			
	Date First Seen:	B6		
	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:	Phone			

Additional Documents:

Report Details - EON-359143		
ICSR:	2051983	
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 16:21:46 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: My dog died of heart failure as a result of dilated Cardiomyopathy in October, 2015. She had been diagnosed 6 months earlier. We had fed her Nature's Recipe Easy to Digest Fish and Potato formula for years. I just read a report that diets containing potatoes may lead to dilated cardiomyopathy. She was an Australian Shepherd, a breed that doesn't usually have this disease.	
	Date Problem Started: 04/01/2015	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Euthanized	
	Date of Death: B6	
Product Information:	Product Name: Nature's Recipe Easy to Digest Fish meal and Potato recipe dry dog food.	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 32 Pound	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Stored in air tight plastic container.	
	Product Use Information:	Description: Fed 1 cup to dog twice a day.
		First Exposure Date: 04/01/2015
		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: Probably 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: Shepherd Dog - Australian
	Gender: Female
	Reproductive Status: Neutered
	Weight: 40 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:
	Address: B6 United States
	Permission to Release Records to FDA: Yes
Sender Information:	Name:
	Address: B6
	Contact: Phone: B6 Email:
	Reporter Wants to Remain Anonymous: No
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
	Reported to Other Parties: Manufacturer
Additional Documents:	

Report Details - EON-359149	
ICSR:	2051989
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 17:10:50 EDT
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: In mid-December of 2017, my dog started exhibiting signs of breathing difficulty. My family told me it was nothing, and they didn't notice any difference. For the next few months, I was paranoid of his breathing and constantly monitoring him. In early February 2018, my worry reached a peak when he was visibly losing weight and his ribs were beginning to show through significantly. I set up an appointment with my regular vet, and an x-ray was conducted that revealed possible fluid build up in the abdomen. I was referred to a specialist in [REDACTED] B6. Many tests were conducted there, and the vets initially thought he had a hernia. He went into surgery and was fully opened only to discover that he did not have a hernia. After further tests and additional vet involvement (a cardiologist was added to the team), it was discovered that [REDACTED] B6 has chyle build up in his chest cavity due to his heart working improperly. This lead to a diagnosis of Dilated Cardiomyopathy. We had no idea the cause of the disease given his young age, prior good health, and breed type (mixed) until reports of a possibly connection of Grain Free dog food & DCM. Echo had been eating grain free dog food (Rachel Ray Nutrish Zero Grain Beef, Potato, & Bison and Rachel Ray Nutrish Zero Grain Salmon & Sweet Potato) since approximately April 2017. We are currently making regular visits to the vet specialist in [REDACTED] B6 for check ups on his condition. I believe that this dog food has a strong connection with the development of this disease in my dog.
	Date Problem Started: 02/07/2018
	Concurrent Medical Problem: No
	Outcome to Date: Unknown
Product Information:	Product Name: Rachael Ray Nutrish Zero Grain Natural Salmon & Sweet Potato Recipe Grain-Free Dry Dog Food
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Package Size: 23 Pound
	Purchase Date: 01/04/2018
	Number Purchased: 1
	Possess Unopened Product: No
	Possess Opened Product: No
	Storage Conditions: Air-tight dog food container
Product Use Information:	Description: Fed to dog 2x daily at 1.5 cups per feeding
	First Exposure Date: 01/04/2018
	Last Exposure Date: 02/06/2018
	Time Interval between Product Use and Adverse Event: 1 Years
	Product Use Stopped After the Onset of the No

	Adverse Event:	
	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:	Mixed (Dog)
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	35 Pound
	Age:	3.5 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
		Other Phone: B6
	Address:	B6
		United States
	Type of Veterinarian:	Referred veterinarian
	Date First Seen:	02/09/2018
	Permission to Release Records to FDA:	Yes
	Practice Name:	B6
	Contact:	Name: B6
		Phone: B6
		Other Phone: B6
	Address:	B6
		United States
	Type of Veterinarian:	Referred veterinarian
	Date First Seen:	02/07/2018
	Permission to	Yes

Release Records to FDA:

Practice Name:

B6

Contact:

Name:

B6

Phone:

Other Phone:

Address:

B6

United States

Type of Veterinarian:

Primary/regular veterinarian

Date First Seen:

02/08/2018

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 Parties:

None

Additional Documents:

Report Details - EON-359172

ICSR:	2052001
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 21:09:36 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	One day she started coughing/sneezing I let it go thinking it was just a cold but it started getting worse so day 3 I took her to the emergency vet clinic and they did x-rays and found her lungs almost completely filled with fluid and her heart enlarged. So they took her for 2 days and kept her in an oxygen cage to help her breathe. She was diagnosed with dilated cardiomyopathy and was given 5 months from the time of diagnosis to live. She was put on 5 medications to help with the fluid retention and arrhythmia. Since then she has lived well past the prognosis.
	Date Problem Started:	10/26/2016
	Concurrent Medical Problem:	No
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	Purina one lamb and rice formula
	Product Type:	Pet Food
	Lot Number:	
	Storage Conditions:	In an air tight container
	Product Use Information:	Description: To feed my dog
	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:	43 Pound	
	Age:	8 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:
Address:		B6	
		United States	
	Date First Seen:	10/26/2016	

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
Reported to Other Parties:	None

Additional Documents:

Report Details - EON-359174

ICSR:	2052002
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 22:15:00 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	<p>B6 had terrible allergies, including a plastic allergy and food allergies. Over the course of her life she was on several different grain-free diets with different types of proteins to try and get the allergies to subside. The last several years she was fed California Natural Grain Free Kangaroo & Red Lentils Recipe. Towards the end of April, 2017 we went for our normal 3 mile walk one day and 3 days later, 4/27/2017, we headed out to do the same and while we were still within site of the house, B6 fell over funny. It wasn't until I talked to the vet the next day that I understood likely she fainted. Prior to this she had started coughing funny but with her allergy issues I dismissed it. And when we went to the vet I realized she had gone from almost 15 lbs to 12 lbs. The vet informed me from an xray that her heart was severely enlarged and she would likely only make it a few more months. I was shocked! Prior to this her only health issue was allergies. Despite the multiple heart medicines she was prescribed she went down hill quite quickly, including a very extended belly. She fainted often, panted constantly, and soon was losing her bladder when she fainted. I made the decision on B6 to euthanize her and end her suffering. That was 3 weeks after we had done our last walk! I read an article online today about a link to a heart disease DCM and grain free diets that encouraged us to turn it in if we might have been affected. I have no idea if B6 official diagnosis was DCM, but I know she had congestive heart failure that took her quite quickly and she was on a grain free diet for approximately her last 7.5 years. B6 was a 9 year old pure bred Bichon Frise.</p>	
	Date Problem Started:	04/27/2017	
	Concurrent Medical Problem:	Yes	
	Pre Existing Conditions:	B6	
	Outcome to Date:	Died Euthanized	
	Date of Death:	B6	

Product Information:	Product Name:	California Natural Grain Free Kangaroo & Red Lentils Recipe		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In an airtight metal container		
	Product Use Information:	Description:	Feed twice daily	
		Last Exposure Date:	B6	
		Perceived Relatedness to Adverse Event:	Probably related	
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	B6		
	Address:	B6		
		United States		

Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Bichon Frise		
	Gender:	Female		
	Reproductive Status:	Neutered		
	Weight:	12 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:	
		Address:	B6	
United States				
Type of Veterinarian:		Primary/regular veterinarian		
Date First Seen:		04/28/2017		
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-359183

ICSR:	2052006
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 00:46:05 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	DCM - suffered from congestive heart failure - treated by B6 specialists. Would not eat . Continued to retain fluid in spite of treatment by a cardiologist. Was euthanized in Early 2017 as he was unable to eat or function with any quality of life.
	Date Problem Started:	11/01/2016
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Natures Domain Organic Chicken and Pea		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	96619 03317		
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	06/21/2018		
	Number Purchased:	2		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	No		
	Storage Conditions:	In house or garage		
	Product Use Information:	Description:	I have fed this product to my dogs for several years - the dogs diagnosed with DCM were fed other foods once diagnosed	
		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:		Possibly related		
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	Costco	B6	
	Address:	B6		

			B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Chinese Crested Dog Hairless		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	20 Pound		
	Age:	7 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	6		
	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:		11/01/2016		
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:	Phone			
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-359187									
ICSR:	2052007								
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 07:03:56 EDT								
Reporter is the Animal Owner:	Yes								
Reported Problem:	Problem Description: Read recent news article and report that was linking DCM in dogs to grain free diet. My dog has recently developed an enlarged heart and is now in heart failure. He has been fed a grain free diet most of his adult life of brand Fromm. Have given him multiple flavors of the food but mostly the game bird flavor of the grain free. Just within the past year he has developed his enlarged heart. It may or may not have anything to do with the food but was told to report in article.								
	Date Problem Started: 12/27/2017								
	Concurrent Medical Problem: Yes								
	Pre Existing Conditions: Has had seizures since a puppy and on medication B6 which he has since stopped taking a little over a year ago								
	Outcome to Date: Stable								
Product Information:	Product Name: Grain Free Fromm Dog Food- Game Bird								
	Product Type: Pet Food								
	Lot Number:								
	Package Type: BAG								
	Possess Unopened Product: No								
	Possess Opened Product: Yes								
	Storage Conditions: Stored in bag it came in in a cool dry place on shelf								
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>Given to dog as daily meal morning and night</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>Possibly related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	Given to dog as daily meal morning and night	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
	Description:	Given to dog as daily meal morning and night							
	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: Crossbred Canine/dog								
	Gender: Male								
	Reproductive Status: Intact								
	Weight: 24 Pound								
	Age: 12 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:	
	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-359189

ICSR: 2052009
 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 07:33:18 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Our dog received a diagnosis of Cardiomyopathy one year ago. According to your report, avocados can cause this condition. She has been eating Avoderm dog food for at least 7 years of her life.
Date Problem Started: 09/27/2017
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:
Product Name: Avoderm Natural Dog Food for Adults
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 30 Pound
Purchase Date: 01/01/2018
Possess Unopened Product: No
Storage Conditions: In plastic bim
Product Use Information:
Description: 1 cup, twice a day
Perceived Relatedness to Adverse Event: Probably related
Manufacturer /Distributor Information:
Purchase Location Information:
Name: Amazon
Address: United States

Animal Information:
Name:
Type Of Species: Dog
Type Of Breed: Retriever - Golden
Gender: Female
Reproductive Status: Neutered
Weight: 83 Pound
Age: 9 Years
Assessment of Prior Health: Poor
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

B6

United States

Type of Veterinarian: Primary/regular veterinarian

Date First Seen: 11/01/2017

Sender Information:

Name:

Address:

B6

United States

Contact:

Reporter Wants to Remain Anonymous: Yes

Reported to Other Parties: None

Additional Documents:

Report Details - EON-359192

ICSR:	2052011
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 08:53:35 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	[B6] had been on vet prescribed diet for many years due to a urinary crystals episode early in life. I had been reading about the potential negative effects of long term use of these prescription diets which it turned out have very little actual nutrition - hair loss, skin issues etc. He was also starting to have some elevated levels in blood work indicative of Cushing a. I kept coming back to the prescription diet. So did a little digging and started giving him a supplement to keep the crystals issue under control and switched him to Merrick dog food in May of 2016 - all recognizable ingredients including sweet potatoes and potatoes within top 5 ingredients. In Nov of 2016, he was diagnosed with coronary heart failure. The vet was shocked and said usually there is a heart murmur that would have been detected prior to this condition but in his case it seems to have come out of nowhere/quickly. He was prescribed 4 drugs he would have to be on for the remainder of his life - it was indicated most dogs diagnosed have a life expectancy of 12-24 months after diagnosis. [B6] had been on a low sodium diet since the diagnosis and as Merrock was not listed as low sodium we switched him. This morning I read an FDA report indicating a possible connection between diet and heart disease in dogs. Specifically it listed potatoes as a main ingredient. And indicated the time of use could be as short as a few months. It is possible it is a coincidence that he was on a diet with potatoes and peas for several months before a sudden onset of heart disease but, in case there is any link at all, Im filing this report to help save other well meaning pet owners and their pups from this horrible disease.
	Date Problem Started:	11/18/2016
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	Had periodic urinary infections and early signs of fishings
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Merrick Grain-free Real Chicken and Sweet Potatoes	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	25 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In sealed bag	
	Product Use Information:	Description:	2 x/ day as main diet for our dog
		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:		No	
		No	

		Product Use Started Again:	
		Perceived Relatedness to Adverse Event:	Probably related
	Manufacturer /Distributor Information:		
	Purchase Location Information:		
Animal Information:	Name:		
	Type Of Species:	Dog	
	Type Of Breed:	Mixed (Dog)	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	23 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:	Contact:	Name: B6
			Phone:
		Type of Veterinarian:	Referred veterinarian
		Permission to Release Records to FDA:	No
Sender Information:	Name:		
	Address:	B6 United States	
	Contact:		
	Reporter Wants to Remain Anonymous:	Yes	
	Reported to Other Parties:	None	
Additional Documents:			

Report Details - EON-359227		
ICSR:	2052014	
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 17:13:53 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Was feeding Triumph brand grain free kibble Turkey/Pea/Sweet potato and Salmon/Pea/Sweet Potato variety dog foods for three plus years and suddenly lost dog to enlarged heart out of the blue. This had been a perfectly healthy, high activity working Border Collie prior to this suddenly happening. Saw the report linking possible DCM to dog food with peas, lentils, other legumes and sweet potatoes and thought this very well could be related.	
	Date Problem Started: 01/27/2017	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Naturally	
	Date of Death: B6	
Product Information:	Product Name: Triumph Grain Free Salmon & Sweet Potato Recipe Dog Food and Triumph Grain Free Turkey, Pea & Sweet Potato Recipe Dog Food	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 28 Pound	
	Purchase Date: 01/07/2018	
	Number Purchased: 12	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Cool dry place in house before opening and in air tight food bin after opening. Used within 2 weeks as I have multiple dogs.	
	Product Use Information:	Description: Fed one cup twice daily.
		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		
Manufacturer /Distributor Information:		
Purchase Location Information:	Name: Chewy.com online purchase	
	Address: United States	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Collie - Border	
	Gender: Male	

	Reproductive Status:	Intact
	Weight:	50 Pound
	Age:	8 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	10
	Number of Animals Reacted:	1
	Owner Information:	
Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6 Phone:
	Address:	B6
	Type of Veterinarian:	Primary/regular veterinarian
	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-359285		
ICSR:	2052082	
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 19:49:33 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: DCM, medication, coughing, enlarged heart, unable to pick him up anymore without inducing coughs, lethargy	
	Date Problem Started: 01/01/2017	
	Concurrent Medical Problem: No	
	Outcome to Date: Stable	
Product Information:	Product Name: Rachel Ray Nutrish Possibly also IAMS prior to 2013	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 20 Pound	
	Purchase Date: 12/22/2017	
	Number Purchased: 2	
	Possess Unopened Product: Unknown	
	Possess Opened Product: Unknown	
	Storage Conditions: Kitchen cabinet	
	Product Use Information:	Description: Daily food for pet for years
		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 to the Animal During This Time Period: Yes		
Manufacturer /Distributor Information:		
Purchase Location Information:	Name: Walmart	
	Address: B6 United States	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Shih Tzu	
	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:	Practice Name:	B6
	Contact:	Name: B6
		Phone: B6
	Address:	B6
		United States
	Type of Veterinarian:	Primary/regular veterinarian
	Date First Seen:	01/01/2017
	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	
Additional Documents:		

Report Details - EON-359304		
ICSR:	2052098	
Type Of Submission:	Initial	
Report Version:	FPSR.FDA.PETF.V.V1	
Type Of Report:	Both	
Reporting Type:	Voluntary	
Report Submission Date:	2018-07-16 00:05:58 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: B6 was diagnosed in August 2012 with Dilated Cardiomyopathy and congestive heart failure. I believe, although I can't confirm the exact timing, that I had switched him to a grain-free diet to help with his allergies roughly around that time (not close enough to connect the incidents at the time though). At that time he was eating Halo Salmon dry food. After he was diagnosed I tried several different foods until I found one that satisfied both his low sodium requirements and also didn't exacerbate his allergies; he has eaten Pinnacle Trout and Sweet Potato dry food since then. His Taurine levels were never checked but he was put immediately on a Taurine supplement. He is well controlled on a long list of medications but I work in the veterinary industry and so I have seen the articles suggesting a connection between DCM and grain-free diets and I wanted to provide the information in case it would help. I have also contacted my cardiologist to discuss a possible change in diet. I would be happy to provide more information if it would be helpful!	
	Date Problem Started: 08/14/2012	
	Concurrent Medical Problem: Yes	
	Pre Existing Conditions: B6	
	Outcome to Date: Stable	
Product Information:	Product Name: Pinnacle Trout and Sweet Potato Dry dog food	
	Product Type: Pet Food	
	Lot Number:	
	Product Use Information:	
	Manufacturer /Distributor Information:	
	Purchase Location Information:	
	Product Name: Halo Salmon Dry Food	
	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: Male		
Reproductive Status: Neutered		
Weight: 55 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
	Contact: Phone:	B6
	Type of Veterinarian:	Referred veterinarian
	Date First Seen:	08/14/2012
	Permission to Release Records to FDA:	Yes
	Contact: Name:	B6
	Contact: Phone:	B6
	Type of Veterinarian:	Primary/regular veterinarian
	Date First Seen:	08/14/2012
Permission to Release Records to FDA:	Yes	
Sender Information:	Name:	B6
	Address:	B6
		United States
	Contact: Phone:	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-359330

ICSR:	2052108
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 10:29:57 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	She began with a cough that we thought might be a lung issue so we took her to the vet and got antibiotics. She got better for a bit but then started coughing again. We ended up at the emergency vet where the diagnosis was DCM in August of 20115. We then went to the heart specialist who put her on the combo of [B6]. In the mean time the [B6] flared back up and we put her back on the low dose of steroids. We ended up adding Taurine supplements to her diet after I did some research and spoke to the heart specialist. Her heart enlargement started to shrink, which at the time we thought was from her exercise regimen. Unfortunately, just before we started step her off the meds, she developed [B6] and died in [B6].
	Date Problem Started:	08/15/2015
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Kirkland Signature Nature's Domain		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	35 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In an Air Tight Containers		
	Product Use Information:	Description:	Daily Feeding	
		First Exposure Date:	05/26/2007	
		Last Exposure Date:	01/18/2016	
		Time Interval between Product Use and Adverse Event:	9 Years	
		Product Use Stopped After the Onset of the Adverse Event:	No	
Perceived Relatedness to Adverse Event:		Possibly related		
Other Foods or Products Given		No		

to the Animal
During This Time
Period:

Manufacturer
/Distributor Information:

Purchase Location Information: Name: Costco

Animal Information:

Name: B6

Type Of Species: Dog

Type Of Breed: Sheepdog - Shetland

Gender: Female

Reproductive Status: Neutered

Weight: 35 Pound

Age: 16 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

Type of Veterinarian: Primary/regular veterinarian

Date First Seen: 08/23/2015

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:

Report Details - EON-359498

ICSR:	2052237
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 11:22:05 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Our 11 y.o. Spinone Italiano suffered from allergies most of his life. At the suggestion of our local pet food store about 2 years ago, I started giving him Candidae Under the Sun Grain Free with Lamb to see if that might help his symptoms. At some point during this time frame, we noticed out Spinone having an occasion cough, as if he had something in his throat he was trying to get out. The cough was very sporadic, so didn't concern us too much, and when we asked vet, she didn't express great concern. We had him in at the vet 5 months ago as he had developed arthritis and was having difficulty getting up and down, and his pace had slowed. We began giving him medication for that. 3 months ago, the coughing became persistent. An examination showed his chest was full of fluid and there was likely little we could do for him. We were advised to keep an eye on his breathing and see vet for euthanization when we felt it was time. Within a couple days, his behavior showed us it was time to say good-bye. We have no way of knowing for sure if the grain-free dog food he was eating led to his condition, but after seeing this FDA report, I felt it was important to report our experience.
	Date Problem Started:	07/01/2016
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	Candiae Under The Sun Grain FreeDog Food with Lamb.		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Poured immediately after purchase from bag into large, plastic storage container. Website isn't letting me input correct dates for purchase/use of food. But first purchased approximately 2 years ago and feed daily until the week of our dog's dog when he would no longer eat.		
	Product Use Information:	Description:	2 cups/day	
		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		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:	Pointing Dog - Italian
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	90 Pound
	Age:	11 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: 05/08/2018
		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:	Distributor Manufacturer Store/Place of Purchase
Additional Documents:		

Report Details - EON-359532

ICSR:	2052251
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-07-17 14:08:30 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Last week, B6 started developing a small cough but still was eating. By B6 morning, she had a deep cough, heavy breathing and stopped eating. I took her to B6 (Pet emergency) and there she had to stay the entire weekend. The Xrays showed an enlarged heart but had a hard time clearing her lungs of fluid which made breathing difficult. She was declining most of the weekend. On B6 morning, we moved her to my primary vet, B6	
	Date Problem Started:	B6	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Unknown	

Product Information:	Product Name:	GO! SENSITIVITY + SHINE Salmon Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	06/30/2018		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	I pour the bag into her dog food container after I get it and throw the bag away. So do not have the bag and I am due to buy her more within the next week or so but most likely wont now that this has happened.		
	Product Use Information:	Description:	I feed her 1.5 cups in the mornings and 1.5 cups in the evening.	
		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:		No		
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	B6		
	Address:	B6		

			B6
			United States
Animal Information:	Name:		B6
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Labrador	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	64 Pound	
	Age:	9.5 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:	Primary/regular veterinarian
		Date First Seen:	07/16/2018
		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-359673

ICSR:	2052320
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:	2018-07-18 14:08:54 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dog B6 died unexpectedly overnight. She had slightly labored breathing early in the evening and was coughing slightly like she had a tickle in her throat. The cough calmed down and when I woke up my darling B6 had passed. No other health issues prior to that night. I had her on Blue Wilderness grain free chicken. She was the only one of my three dogs that suffered from a possible grain allergy so I went with the "best" grain free I could find. No I find out that food with potatoes lentils and/or peas has the potential for causing canine heart disease, this food has several of those ingredients. Date of death below is approximate but am able to supply exact date if necessary
	Date Problem Started:	B6
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Naturally
	Date of Death:	B6

Product Information:	Product Name:	Healthy Holistic BLUE Wilderness 100% Grain Free Wilderness High Protein - Grain Free Nature's Evolutionary Diet with Chicken and LifeSource bits ADULT		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	not available		
	Package Type:	BAG		
	Package Size:	17 Pound		
	Purchase Date:	08/01/2016		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	in a sealed plastic dog food container		
	Product Use Information:	Description:	Served daily as the major ingredient of the major meal.	
		First Exposure Date:	08/01/2016	
		Last Exposure Date:	B6	
		Time Interval between Product Use and Adverse Event:	2 Hours	
Product Use Stopped After the Onset of the Adverse Event:		Yes		
Adverse Event Abate After Product Stop:		No		
Product Use Started Again:		No		
Perceived	Probably related			

		Relatedness to Adverse Event:	
		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:	Retriever - Golden	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	75 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:		
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-359699															
ICSR:	2052338														
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:	2018-07-18 17:10:42 EDT														
Reporter is the Animal Owner:	Yes														
Reported Problem:	Problem Description: B6 has allergies to grains and potatoes, and was switched a a limited ingredient diet to avoid her allergies. She has been eating Instinct by Nature's Variety Limited Ingredient Diet Grain-Free Recipe with Real Lamb Dry Dog Food for the past four years, with the first ingrediendent being lamb meal and the second being peas. Just over a year ago, she was taken to the vet because she had begun coughing when she got excited. The vet discovered an enlarged heart was pressing on her windpipe in these instances. I have been reading online about the link between dog foods containing lentils like peas and enlarged hearts, and felt that I should report this case.														
	Date Problem Started: 05/01/2017														
	Concurrent Medical Problem: No														
	Outcome to Date: Stable														
Product Information:	Product Name: Instinct by Nature's Variety Limited Ingredient Diet Grain-Free Recipe with Real Lamb Dry Dog Food														
	Product Type: Pet Food														
	Lot Number:														
	Package Type: BAG														
	Storage Conditions: In a plastic tub with snap on lid, inside the kitchen														
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>Fed to dog twice (1 cup at a time) daily</td> </tr> <tr> <td>First Exposure Date:</td> <td>01/01/2014</td> </tr> <tr> <td>Last Exposure Date:</td> <td>07/18/2018</td> </tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>36 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>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 to dog twice (1 cup at a time) daily	First Exposure Date:	01/01/2014	Last Exposure Date:	07/18/2018	Time Interval between Product Use and Adverse Event:	36 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
	Description:	Fed to dog twice (1 cup at a time) daily													
	First Exposure Date:	01/01/2014													
	Last Exposure Date:	07/18/2018													
	Time Interval between Product Use and Adverse Event:	36 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:															
Name: B6															
Type Of Species: Dog															
Type Of Breed: Retriever - Golden															

	Gender: Female
	Reproductive Status: Neutered
	Weight: 57 Pound
	Age: 11 Years
	Assessment of Prior Health: Good
	Number of Animals Given the Product: 1
	Number of Animals Reacted: 1
	Owner Information: Owner Information provided: No
Healthcare Professional Information:	Practice Name: B6
	Contact: Name: unknown_Unknown
	Phone: B6
	Address: B6 United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 04/01/2017
Sender Information:	Name:
	Address: B6 United States
	Contact:
	Reporter Wants to Remain Anonymous: Yes
	Reported to Other Parties: None
Additional Documents:	

Report Details - EON-359722					
ICSR:	2052357				
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:	2018-07-18 21:48:02 EDT				
Reporter is the Animal Owner:	Yes				
Reported Problem:	Problem Description: B6 was on a grain free diet for many years and developed cardiomyopathy that was eventually controlled with a mix of B6 eventually died of an unrelated cause, but I wanted to add to the body of evidence that indicate an association between grain free diets and dilated cardiomyopathy.				
	Date Problem Started: 11/15/2013				
	Concurrent Medical Problem: No				
	Outcome to Date: Died Euthanized				
	Date of Death: B6				
Product Information:	Product Name: Innova EVO Canidae Grain Free Orijen				
	Product Type: Pet Food				
	Lot Number:				
	Product Use Information: <table border="1"> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>No</td> </tr> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Possibly related</td> </tr> </table>	Product Use Stopped After the Onset of the Adverse Event:	No	Perceived Relatedness to Adverse Event:	Possibly related
	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: Boxer (German Boxer)				
	Gender: Female				
	Reproductive Status: Neutered				
	Weight: 50 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:					
Sender Information:	Name:				
	Address: B6 United States				
	Contact:				
Reporter Wants to	Yes				

	Remain Anonymous:	
	Reported to Other Parties:	None
Additional Documents:		

Report Details - EON-359964	
ICSR:	2052523
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:	2018-07-21 13:31:15 EDT
Reported Problem:	Problem Description: 10yo FS Chesapeake Bay Retriever. Pet dealt with a chronic cough for appx 2 years, owners had previously declined all workup. Pet presented to me early in 2018 for an annual exam, but reported that as of that morning she was having trouble breathing and was wheezing a lot. On exam the pet's signs were consistent with potential laryngeal paralysis, and we discussed possible causes with owner. Due to her history of chronic cough we suspected pathology in the thoracic cavity affecting the recurrent laryngeal nerve and took thoracic radiographs. Her heart was notably enlarged in all chambers, and she had signs of widespread alveolar patterns and edema. Suspected dilated cardiomyopathy vs possible metastatic neoplasia, O declined workup. Was started on a trial of B6 and pet improved drastically, and was then started on long term B6 and B6 . Pet's disease progressed over the next few months and she was euthanized. When I heard about this possible correlation to grain free boutique diets and DCM in atypical breeds I immediately thought of her and pulled up her chart, noting she was on a grain free diet from Blue Buffalo.
	Date Problem Started: 01/23/2017
	Concurrent Medical Problem: No
	Outcome to Date: Died Euthanized
	Date of Death: B6
Product Information:	Product Name: Blue Buffalo and Blue Wilderness, multiple types and flavors throughout her lifetime
	Product Type: Pet Food
	Lot Number:
	Product Use Information: Description: Fed as pet's regular diet
	Manufacturer /Distributor Information:
	Purchase Location Information:
Animal Information:	Name: B6
	Type Of Species: Dog
	Type Of Breed: Retriever - Chesapeake Bay
	Gender: Female
	Reproductive Status: Neutered
	Age: 10 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:
	Address:

B6

United States

Contact:

**Reporter Wants to
Remain Anonymous:** Yes

**Reported to Other
Parties:** None

Additional Documents:

Report Details - EON-359967		
ICSR:	2052528	
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:	2018-07-21 14:41:48 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: I am self reporting that our dog, a labradoodle, passed away prematurely for his breed from cardiomyopathy in B6 . He had been eating grain free food for a good portion of his life. I read the report from US Food & Drug Administration and thought I should report what happened to our dog. https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm	
	Date Problem Started: 01/01/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Euthanized	
	Date of Death: B6	
Product Information:	Product Name: Blue Buffalo -- I switched him to this brand in December 2017. I purchased several varieties -- all were grain free. I don't have the products in the house anymore	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Number Purchased: 2	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: We kept the bag stored in a tall plastic container -- similar to a garbage can. We never emptied the food into the bin -- we dropped the bag into the container.	
	Product Use Information:	Description: B6 was given 1-2 cups in the morning and again in the evening.
		First Exposure Date: 12/04/2017
		Last Exposure Date: B6
		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: Retriever - Labrador	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 84 Pound	
Age: 9.5 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 rowspan="4">B6</td> </tr> <tr> <td>Phone:</td> </tr> <tr> <td>Other Phone:</td> </tr> <tr> <td>Email:</td> </tr> </table> </td> </tr> <tr> <td>Address:</td> <td> <table border="1"> <tr> <td>B6</td> </tr> </table> United States </td> </tr> <tr> <td>Type of Veterinarian:</td> <td>Primary/regular veterinarian</td> </tr> <tr> <td>Date First Seen:</td> <td>02/19/2018</td> </tr> <tr> <td>Permission to Release Records to FDA:</td> <td>Yes</td> </tr> </table>	Practice Name:	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:	Email:	Address:	<table border="1"> <tr> <td>B6</td> </tr> </table> United States	B6	Type of Veterinarian:	Primary/regular veterinarian	Date First Seen:	02/19/2018	Permission to Release Records to FDA:	Yes
Practice Name:	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:	Email:														
Name:	B6																			
Phone:																				
Other Phone:																				
Email:																				
Address:	<table border="1"> <tr> <td>B6</td> </tr> </table> United States	B6																		
B6																				
Type of Veterinarian:	Primary/regular veterinarian																			
Date First Seen:	02/19/2018																			
Permission to Release Records to FDA:	Yes																			
Sender Information:	Name:																			
	Address:	<table border="1"> <tr> <td>B6</td> </tr> </table> United States	B6																	
B6																				
	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-360637

ICSR:	2052844
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:	2018-07-27 14:00:28 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Last B6 at approximately 8:45 PM, our dog B6 tragically dropped to the ground, howled twice and died. My wife and I were in the back yard with him when he died and moments before he was walking around normally. We have security and personal videos of B6 just prior to his death if you need for your investigation. A few days after his death we saw in the news that the FDA has started an investigation into "No Grain" diets and Canine Dilated Cardiomyopathy. Our vet said that the way B6 had died pointed to heart failure. We've been feeding B6 a no grain dog food called "Taste of the Wild", specifically the "High Prairie Canine Formula with Roasted Bison & Roasted Venison" for all his adult life.
	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:	"Call of the Wild, High Prairie Canine Formula with Roasted Bison & Roasted Venison, A Grain-Free Diet"		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	7419860964		
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	05/20/2018		
	Number Purchased:	1		
	Possess Unopened Product:	Yes		
	Possess Opened Product:	Yes		
	Storage Conditions:	Unopened bags were stored in our pantry, open bags were dumped into a dog food bin that had an airtight seal.		
	Product Use Information:	Description:	2 cups in the morning, 2 cups in the evening.	
		First Exposure Date:	06/01/2018	
	Last Exposure Date:	B6		
	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:	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:	Name:	Chewy.com
		Address:	600 New Commerce Blvd. Suite R Hanover Pennsylvania 18706 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Mixed (Dog)	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	129.4 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:	
		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
		Email:	B6
	Permission To Contact	Yes	

	Sender:	
	Preferred Method Of Contact:	Email
Additional Documents:	Attachment:	B6 5 mins before death.gif
	Description:	This animated gif is grabbed from our backyard security camera about 5 mins before B6 death. You can see us sitting next to the big pine tree as B6 walks towards us.
	Type:	Photograph
	Attachment:	B6 202808_1.gif
	Description:	This is an animated gif of B6 15 prior to his death. As it was his custom, he would rather drink from the kiddie pool after we filled it than his water dish.
	Type:	Photograph

Report Details - EON-361124

ICSR:	2053106
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-08-02 00:26:57 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 was a goldendoodle. His mother was a golden retriever. He was on a grain free diet, as so many dogs are these day. Shortly before his 11th birthday, he dropped dead suddenly. He had shown no signs of illness before this happened. He was happy, and spunky. The only thing I remember was that he coughed a few times the night before when we were going to bed. The next afternoon we found him dead in our family room. I had seen him minutes earlier and he was fine and happy. We brought the body to our vet, who said it looked like he had suffered from some form of heart incident. We didn't do a necropsy, but the vet guessed that there might have been a genetic or congenital component. That was in November 2016. After reading the FDA's report on grain free diets and the increased incidence of DCM, particularly among goldens, I feel that this information is important to pass on.
	Date Problem Started:	B6
	Concurrent Medical Problem:	Unknown
	Outcome to Date:	Died Naturally
	Date of Death:	B6

Product Information:	Product Name:	Various dry and canned foods with no grain added.		
	Product Type:	Pet Food		
	Lot Number:			
	Storage Conditions:	the dry food was kept in a bin. The canned food was refrigerated if not use up.		
	Product Use Information:	Description:	We fed a combination of dry and canned foods daily	
		Perceived Relatedness to Adverse Event:	Possibly related	
	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:	60 Pound	
	Age:	11 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:	B6
	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
		Email:	
	Reporter Wants to Remain Anonymous:	No	
Permission To Contact Sender:	Yes		
Preferred Method Of Contact:	Email		
Additional Documents:			

Report Details - EON-361365

ICSR:	2053235
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:	2018-08-04 18:10:51 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	On 8/11/17 the vet noticed a heart murmur during his annual exam. We were advised that this could lead to heart disease, but shortly after that this clinic closed so we started going to a new one. On 2/16/18 the new vet saw him for an irritated eye and also noticed the heart murmur. When I took him back on 6/23/18 for a hematoma on his ear we saw another vet at that clinic who heard the murmur very loudly and concluded after talking with the other vet at this clinic that it had gotten much worse in four months. I agreed to a chest x-ray which showed a slightly enlarged heart. We started him on B6 . A few weeks later I saw the FDA report about certain types of "designer" or grain free dog food possibly causing this heart problem in dogs that normally wouldn't get it. I have been feeding him various Rachael Ray dog chows over the past 4 years, from Zero Grain to the current one which is Rachael Ray Nutrish with Turkey, Brown Rice & Venison. It lists peas near the top of the ingredient list, so I became concerned that this may have contributed to his heart condition. I have started tapering off on this one and adding in Hill's Science Diet Adult 7+ Active Longevity Chicken Meal Rice and Barley, and will continue until I am finished with the Rachael Ray and then he will just get the Hill's. He also gets a little of the Rachael Ray Nutrish wet food mixed in.
	Date Problem Started:	08/11/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Rachael Ray Nutrish Super Premium Food for Dogs - Turkey, Brown Rice & Venison Recipe.	
	Product Type:	Pet Food	
	Lot Number:	Lot Number:	DL8089606:58
		Expiration Date:	09/29/2019
	UPC:	071190008176	
	Package Type:	BAG	
	Package Size:	13 Pound	
	Purchase Date:	06/12/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	It was opened within days of receiving it, but stored closed on a shelf until that time. The opened bag is stored in a sealed plastic tub.	
	Product Use Information:	Description:	1/2 cup in morning and evening with a spoonful of Rachael Ray wet food mixed in.
Last Exposure Date:		08/04/2018	
Product Use Stopped After the Onset of the Adverse Event:		No	
Perceived Relatedness to		Possibly related	

		Adverse Event:		
		Other Foods or Products Given to the Animal During This Time Period:	Yes	
	Manufacturer /Distributor Information:	Name:	Ainsworth Pet Nutrition	
		Type(s):	Manufacturer	
		Address:	Meadville Pennsylvania 16335 United States	
		Contact:	Phone: 18003237738 Web Address: nutrish.com	
		Possess One or More Labels from This Product:	Yes	
	Purchase Location Information:	Name:	Amazon	
		Address:	United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Shepherd Dog - Australian		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	33.3 Pound		
	Age:	10.5 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:		Primary/regular veterinarian		
Date First Seen:		02/16/2018		
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:			

Report Details - EON-361568

ICSR:	2053383
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 12:46:52 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I have 4 dogs, only dog food gave them since 2008 is Rachael Ray Nutrish Chicken & Veggies or Beef & Brown Rice [B6] a 14 yr old Shiba Inu, developed heart disease in April 2017 and was on medication [B6] a 12 yr old Basenji mix who had been in excellent health, also developed heart disease in September 2017 and had to be put down that same month [B6] heart finally gave out in December 2017. I realize the dogs were seniors, but recently read how the FDA reported that dogs were getting dialated cardiomyopathy not normally seen in these breeds, suspected from ingredients such as peas. Just wanted to report this in case Nutrish unknowingly is causing heart issues in some dogs. Like, possibly, mine. (p.s. "date problem started" is an estimate, can't remember exact date).
	Date Problem Started:	04/08/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Other
	Date of Death:	[B6]

Product Information:	Product Name:	Rachael Ray Nutrish Natural Chicken & Veggies Recipie dry dog food	
	Product Type:	Pet Food	
	Lot Number:		
	UPC:	n/a	
	Package Type:	BAG	
	Package Size:	28 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Keep the opened bag in a latched Iris pet food container.	
	Product Use Information:	Description:	Been feeding this dog food to my dogs since 2008
	First Exposure Date:	02/01/2008	
	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:	Amazon
		Address:	United States

Animal Information:	Name:	[B6]
	Type Of Species:	Dog
	Type Of Breed:	Shiba Inu
	Gender:	Male

	Reproductive Status:	Neutered
	Weight:	25 Pound
	Age:	14 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	4
	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:	04/08/2017
	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:	Address
Additional Documents:		

Report Details - EON-361988

ICSR:	2053607	
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:	2018-08-13 10:36:18 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description:	Possible worsening of my dog's heart condition. Please read above. This finding was in June of 2017 when he was diagnosed with severe heart enlargement. Also, I have 5 other dogs with unknown heart disease that have been on Earthborn Grain Free. They too have now been switched. Does the FDA offer assistance with Taurine testing??
	Date Problem Started:	06/20/2017
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6 my 3 year old dog) was diagnosed with severe heart enlargement with previous right sided heart failure. B6 is a mixed breed however we did have him DNA tested. He is 40% labrador retriever, 18.75% white swiss shepherd, 18.75% chow chow, 12.5% american staffordshire terrier, and 10% mixed. B6 is a rescue. B6 had a heart murmur as a 9 week old puppy. He was fed lamb and rice puppy food. When he was a 1 1/2 years old he was switched to Grain free dry dog food. Last year in June (2017) B6 developed a cough and poor appetite. Our vet indicated that his heart murmur had worsened. She did chest xrays that confirmed B6 had an enlarged heart and had fluid (congestive heart failure). She started him on a diuretic and once finished rechecked and repeated xrays. Fluid was gone however heart size was unchanged. Our vet then started him on heart medication and diuretic that he continues to take twice daily. At the time B6 was eating Rachel Ray Grain Free Turkey and Potato. He was referred to a Cardiologist who performed an ultrasound of his heart. She diagnosed him with Severe Right Atrial and Right Ventricular Enlargement, Tricuspid Valve Dysplasia with Severe Tricuspid Valve Regurgitation, and Right Sided Heart Failure and Pleural Effusion that had resolved. I did call and speak with the Cardiologist upon hearing of the FDA's investigation. The Cardiologist said she did not think B6 heart condition was caused by the dog food but said she could not rule out the worsening of his condition and stated it could have been caused by his grain free food. She said with this investigation and not knowing much it was all new. When B6 was a year and half years old he was switched to Taste of the Wild Venison that is grain free but continued with poor appetite. He was then switched to Rachel Ray Nutrish Zero Grain Turkey and Potato. Both were grain free. Due to him having difficulty gaining weight, we switched him to Earthborn Primitive Natural Grain free dry dog food. Earthborn does have taurine added to their foods. She informed me that Earthborn was linked to 2 cases in the FDA investigation. She advised changing his dog food and offered recommendations. She also advised supplementing him with Taurine 1000mg twice a day. She discussed having a Taurine level drawn but advised it was expensive and complex. We have since change his food and began his Taurine supplementation. I pray the grain free food was not the cause of his change in condition last year that has made is diagnosis severe.
	Outcome to Date:	Unknown
Product Information:	Product Name:	Taste of the Wild - High Prairie - Grain Free
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Dog food container / tote
	Product Use	

Information:											
Manufacturer /Distributor Information:											
Purchase Location Information:	<table border="1"> <tr> <td>Name:</td> <td></td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> </table>	Name:		Address:	B6						
Name:											
Address:	B6										
Product Name:	Rachel Ray Zero Grain Turkey and Potato										
Product Type:	Pet Food										
Lot Number:											
Package Type:	BAG										
Possess Unopened Product:	No										
Possess Opened Product:	No										
Storage Conditions:	In dog food container / tote										
Product Use Information:	<table border="1"> <tr> <td>Perceived Relatedness to Adverse Event:</td> <td>Possibly related</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>No</td> </tr> </table>	Perceived Relatedness to Adverse Event:	Possibly related	Other Foods or Products Given to the Animal During This Time Period:	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:	<table border="1"> <tr> <td>Name:</td> <td>Walmart</td> </tr> <tr> <td>Address:</td> <td>B6</td> </tr> </table>	Name:	Walmart	Address:	B6						
Name:	Walmart										
Address:	B6										
Product Name:	Earthborn Holistic Primitive Natural - Grain Free										
Product Type:	Pet Food										
Lot Number:											
Package Type:	BAG										
Package Size:	28 Pound										
Purchase Date:	07/24/2018										
Number Purchased:	2										
Possess Unopened Product:	No										
Possess Opened Product:	Yes										
Storage Conditions:	In a dog food tote/container										
Product Use Information:	<table border="1"> <tr> <td>Description:</td> <td>B6 was fed 1 1/2 cups twice a day</td> </tr> <tr> <td>Last Exposure Date:</td> <td>08/03/2018</td> </tr> <tr> <td>Time Interval between Product Use and Adverse Event:</td> <td>1 Months</td> </tr> <tr> <td>Product Use Stopped After the Onset of the Adverse Event:</td> <td>No</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 fed 1 1/2 cups twice a day	Last Exposure Date:	08/03/2018	Time Interval between Product Use and Adverse Event:	1 Months	Product Use Stopped After the Onset of the Adverse Event:	No	Other Foods or Products Given to the Animal During This Time Period:	No
Description:	B6 was fed 1 1/2 cups twice a day										
Last Exposure Date:	08/03/2018										
Time Interval between Product Use and Adverse Event:	1 Months										
Product Use Stopped After the Onset of the Adverse Event:	No										
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: Type Of Species: Dog Type Of Breed: Mixed (Dog) Gender: Male Reproductive Status: Intact Weight: 55 Pound Age: 3 Years Assessment of Prior Health: Fair Number of Animals Given the Product: 6 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 Permission to Release Records to FDA: No
Sender Information:	Name: 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-364322

ICSR: 2054631
 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 11:41:16 EDT
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: B6 has been having a deep cough. The vet tried several medications over about 6 months. Then an x-ray was taken that showed an enlarged heart. I researched dietary recommendations for this condition and ran across a very recent report linking a grain free diet with lentils, peas and potatoes as primary ingredients an identified source for dilated cardiomyopathy. I have fed my dogs Fromm's Grain Free Lamb and Rice for several years now. I am planning on changing diets immediately.
Date Problem Started: 01/01/2018
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Unknown

Product Information:
Product Name: Fromm's Lamb and Lentil Recipe Dog Food
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 26 Pound
Purchase Date: 12/31/2017
Number Purchased: 1
Possess Unopened Product: Unknown
Possess Opened Product: Unknown
Storage Conditions: Airtight container stored in air conditioned room temperature.
Product Use Information:
Description: About 1/3 cup twice daily.
First Exposure Date: 01/01/2018
Last Exposure Date: 09/05/2018
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
Manufacturer /Distributor Information:
Purchase Location Information:
Name: B6
Address:

			B6 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Chihuahua	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	13 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:		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-369500

ICSR:	2058140
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:	2018-10-27 02:05:16 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	In September 2015, [B6] presented with a likely skin-related allergic reaction and an elimination diet was recommended by the vet. We switched his food to Wellness CORE Wild Game at that time. In December 2016, [B6] presented with a cough, dyspnea, edema, and anorexia. His blood panel showed low electrolytes, and he was admitted overnight for treatment. X-Rays showed an enlarged heart, and he was diagnosed with left-sided congestive heart failure. At that time, he was put on diuretics, [B6]. In fall 2017, [B6] had several episodes of collapse. In October 2017, [B6] health deteriorated such that he was euthanized.
	Date Problem Started:	12/01/2016
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6] He began a grain free diet of Nature's Recipe Grain Free Small Bites in 2008/2009 due to these issues. In 2010/2011, he was diagnosed with a heart murmur. Due to the recent FDA release, "FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease", I am submitting these details in case they can be helpful. [B6] was a small/medium Jack Russell/Parson Russell terrier who was diagnosed with an enlarged heart and congestive heart failure following a switch in diet to a new grain free food. This diagnosis is uncommon for dogs of his breed and size, and I am concerned his grain free diet had an effect on the development of this disease.
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Wellness Ninety-Five Percent Mixer or Topper Ninety-Five Percent Chicken		
	Product Type:	Pet Food		
	Lot Number:			
	Product Use Information:	Description:	This product was used to administer medications from 2017-2018.	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
	Product Name:	Small Breed Grain Free Easy to Digest Chicken, Sweet Potato, & Pumpkin Recipe		
	Product Type:	Pet Food		
	Lot Number:			
	Product Use Information:	Description:	This product was administered from about 2009	
		Perceived Relatedness to Adverse Event:	Possibly related	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
	Product Name:	Wellness Core Wild Game		
	Product Type:	Pet Food		
Lot Number:				

Product Use Information:	Description:	This product was administered from September 2016 - October 2017.		
	Time Interval between Product Use and Adverse Event:	2 Months		
	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:	Terrier - Jack Russell		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	26 Pound		
	Age:	16 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:	
		Type of Veterinarian:	Primary/regular veterinarian	
Date First Seen:		12/01/2016		
Permission to Release Records to FDA:	Yes			
Sender Information:	Name:	B6		
	Address:	B6		
		United States		
	Contact:			
	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-371023

ICSR:	2058821
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:	2018-11-14 00:53:52 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	After the [B6] medicine didnt help his hair grow back, I decided to put [B6] on a grain free diet, thinking maybe he had an allergy of some kind to grains? And to just ensure his overall health was the best it could be (or so I assumed based on advertising etc, that grain free is healthiest for dogs). My dog very (seemingly) rapidly developed heart problems within a couple years of being grain free. He was seen regularly and the vet never mentioned any signs of heart murmur. He developed a cough all of a sudden and was taken to a different vet after the cough didnt go away over time (about a month). The new vet immediately recognized a heart murmur and suggested a chest x-ray. Once the x-ray was completed it showed he had a very enlarged heart and was in congestive heart failure. He was given a very short time to live initially, but managed to pull through and make it a year almost to the day. **I read an article that the FDA was currently investigating a link between grain free dog food and DCM so that is why I figured I would submit this...just to contribute information in case there is a link. I just dont want any one else to have to lose a pet like I did if it can be avoided.**
	Date Problem Started:	10/20/2017
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	[B6]
	Outcome to Date:	Died Naturally
	Date of Death:	[B6]

Product Information:	Product Name:	Various brands of grain free dog kibble. The last year of his life after his heart failure diagnosis, he was given FreshPet refrigerated dog food because I wanted him to be happy.		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Storage Conditions:	The product was poured into a dog food dispensing container, which was closed and stored in the room the pet ate and drank in.		
	Product Use Information:	Description:	I fed him once a day. He had access to it all day and would eat a bowl throughout the course of the day.	
		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:	Possibly related			

	Manufacturer /Distributor Information:	
	Purchase Location Information:	Name: PetSmart Address: B6 United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Spitz - German Pomeranian
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	12 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:	
Sender Information:	Name:	
	Address:	B6 United States
	Contact:	
	Reporter Wants to Remain Anonymous:	Yes
	Reported to Other Parties:	None
Additional Documents:		

Report Details - EON-371089

ICSR:	2058862		
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:	2018-11-14 17:02:37 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	In June 2009, a grade 3 heart murmur was detected for the first time. B6 was diagnosed with "significant and severe heart disease." There was left mitral valve dysplasia and significant dilation of the left chamber. His taurine level was B6 (plasma at B6), critically low. He was eating Arcana Grain Free dog food for the year prior to diagnosis. We started 1,000 mg of taurine twice daily, changed to a new dog food (Royal Canin Early Cardiac) and started 10mg of B6 twice daily. In November 2019, B6 recheck echocardiogram showed that the dilation was no longer present and his taurine level was B6 (whole blood, UC Davis).	
	Date Problem Started:	06/26/2018	
	Date of Recovery:	11/02/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Better/Improved/Recovering	
Product Information:	Product Name:	Arcana Freshwater Fish Grain Free Dog food.	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	25 Pound	
	Purchase Date:	03/05/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	In a sealed plastic bin	
	Product Use Information:	Description:	Dog was fed 1.5 cups twice daily.
		First Exposure Date:	04/01/2018
		Last Exposure Date:	07/02/2018
		Time Interval between Product Use and Adverse Event:	1 Years
Product Use Stopped After the Onset of the Adverse Event:		Unknown	
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
		Address: United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	65 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:	
Sender Information:	Name:	
	Address:	B6 United States
	Contact:	
	Reporter Wants to Remain Anonymous:	Yes
	Reported to Other Parties:	None
Additional Documents:		

Report Details - EON-371677

ICSR: 2059185
 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 19:29:04 EST
 Reporter is the Animal Owner: Yes

Reported Problem:

Problem Description: [B6] died on [B6]. He was running around the backyard the previous weekend. On Tuesday 24JUL18 he became restless and breathed heavily. The following day we took him to his vet. The vet did not find an issue or do a chest X-ray. By [B6] could not sleep, and was Tachycardic, and we visited the ER vet [B6]. Xrays revealed dilated Cardiomyopathy [B6] was given a series of medications to reduce the fluid and assist with the heart failure. [B6] did not make it through the night as we had to have him put down. He could not breathe and his lungs had filled. [B6] ate grain free food from the age of 6 months.

Date Problem Started: 07/24/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: [B6]

Outcome to Date: Died Euthanized

Date of Death: [B6]

Product Information:

Product Name: Earth born holistic

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 28 Pound

Purchase Date: 07/14/2018

Number Purchased: 50

Possess Unopened Product: No

Possess Opened Product: Yes

Storage Conditions: 4 cups daily

Product Use Information:

Description: 4 cups daily

Last Exposure Date: [B6]

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 Name: [B6]

	Information:	Address: United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Shepherd Dog - German
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	78 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:	Contact:	Name: B6
		Phone:
	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:		

Report Details - EON-372318

ICSR:	2059410
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:	2018-11-29 14:20:45 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	My dog developed a heart murmur that was first detected in October 2017. He goes to the veterinarian every October and nothing was amiss in 2016. His murmur got significantly worse in one year's time and yesterday I took him to see a cardiologist in [REDACTED] B6 [REDACTED]. He was diagnosed with severe dilated cardiomyopathy (Grade V murmur). I switched him to a grain-free diet in August 2016 due to recommendations, as he began to have issues with his anal sacs and needed them expressed 3 times in the span of a month and a half. I was informed by the veterinarian that they have noticed a correlation and that the FDA is currently investigating.
	Date Problem Started:	10/20/2017
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Blue Buffalo Freedom Adult Chicken Recipe Grain-Free Dry Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	11 Pound		
	Purchase Date:	02/18/2017		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In an airtight plastic container immediately after receiving and opening.		
	Product Use Information:	Description:	Daily food, rotated with Blue Buffalo Wilderness Rocky Mountain Recipe with Red Meat Small Breed Grain-Free Dry Dog Food.	
		First Exposure Date:	02/25/2017	
		Time Interval between Product Use and Adverse Event:	8 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:		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

Product Name:

Blue Buffalo Wilderness Rocky Mountain Recipe with Red Meat Small Breed Grain-Free Dry Dog

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 10 Pound

Purchase Date: 02/18/2017

Number Purchased: 1

**Possess Unopened
Product:** No

**Possess Opened
Product:** No

Storage Conditions: In an airtight plastic container immediately after receiving and opening.

**Product Use
Information:**

Description:

Daily food, rotated with Blue Buffalo Freedom Adult Chicken Recipe Grain-Free Dry Dog Food.

**First Exposure
Date:**

02/20/2017

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

8 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:**

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

Product Name:

Blue Buffalo Freedom Adult Chicken Recipe Grain-Free Dry Dog Food

Product Type: Pet Food

Lot Number:

Package Type: BAG

Package Size: 11 Pound

Purchase Date: 11/11/2016

Number Purchased: 1

Possess Unopened Product:	No	
Possess Opened Product:	No	
Storage Conditions:	In airtight plastic container immediately after receiving and opening.	
Product Use Information:	Description:	Daily food, rotated with Blue Buffalo Wilderness Rocky Mountain Recipe with Red Meat Small Breed Grain-Free Dry Dog Food.
	First Exposure Date:	11/15/2016
	Time Interval between Product Use and Adverse Event:	11 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:	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
Product Name:	Blue Buffalo Wilderness Rocky Mountain Recipe with Red Meat Small Breed Grain-Free Dry Dog Food	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Package Size:	10 Pound	
Purchase Date:	11/11/2016	
Number Purchased:	1	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Storage Conditions:	Placed in airtight plastic container immediately after receiving and opening.	
Product Use Information:	Description:	Daily food, rotated with Blue Buffalo Freedom Adult Chicken Recipe Grain-Free Dry Dog Food.
	First Exposure Date:	11/12/2016
	Time Interval between Product Use and Adverse Event:	11 Months
	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:	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
Product Name:	Blue Buffalo Freedom Adult Chicken Recipe Grain-Free Dry Dog Food	
Product Type:	Pet Food	
Lot Number:		
Package Type:	BAG	
Package Size:	11 Pound	
Purchase Date:	05/30/2017	
Number Purchased:	1	
Possess Unopened Product:	No	
Possess Opened Product:	No	
Storage Conditions:	In an airtight plastic container immediately after receiving and opening.	
Product Use Information:	Description:	Daily food, rotated with Blue Buffalo Wilderness Rocky Mountain Recipe with Red Meat Small Breed Grain-Free Dry Dog Food.
	First Exposure Date:	06/15/2017
	Last Exposure Date:	10/26/2018
	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:	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
	Product Name:	Blue Buffalo Wilderness Rocky Mountain Recipe with Red Meat Small Breed Grain-Free Dry Dog Food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	10 Pound	
	Purchase Date:	05/30/2017	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in airtight plastic container immediately after receiving and opening.	
	Product Use Information:	Description:	Daily food, rotated with Blue Buffalo Freedom Adult Chicken Recipe Grain-Free Dry Dog Food.
		First Exposure Date:	05/31/2017
		Last Exposure Date:	09/28/2018
		Time Interval between Product Use and Adverse Event:	5 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:	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: 18 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:	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Email: B6
	Address: B6
	United States
	Type of Veterinarian: Referred 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: B6
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
Reported to Other Parties: None	
Additional Documents:	Attachment: 11-11-2016 order.jpg
	Description: 2016 Chewy order
	Type: Other
	Attachment: 5-30-2017 order.jpg
	Description: Chewy order from 2017
	Type: Other

Report Details - EON-380831		
ICSR:	2063184	
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 16:51:44 EST	
Reported Problem:	Problem Description: B6 was a standard schnauzer that was diagnosed originally with dilated cardiomyopathy and with ventricular arrhythmias, was managed with anti-arrhythmics and cardioprotective drugs and the heart function continued to worsen. The dogs passed away suddenly while running outside. She was a carrier for the gene mutation associated with DCM in this breed, but carriers should not develop disease as it is an autosomal recessive trait in this breed	
	Date Problem Started: 06/04/2014	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Other	
	Date of Death: B6	
Product Information:	Product Name: Homemade raw diet	
	Product Type: Other	
	Lot Number:	
	Package Type: Other - Not Specified	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Product Use Information:	Description: Medical notes indicate that it was a raw homemade diet consisting of 80% muscle, 10% organ meat, and 10% bone meal
	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:	Unknown
Manufacturer /Distributor Information:		
Purchase Location Information:		
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Schnauzer (unspecified)	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 16 Kilogram	
	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:		
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:	B6	Necropsy.pdf
	Description:	Necropsy/Histopathology report	
	Type:	Necropsy Report	
	Attachment:	B6	holter ecg.pdf
	Description:	initial Holter report	
	Type:	Medical Records	
	Attachment:	B6	06-21-2016.pdf
	Description:	Final echocardiographic report	
	Type:	Echocardiogram	

Report Details - EON-383581		
ICSR:	2064839	
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:	2019-03-28 11:47:06 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: developed cough which quickly became cardiomyopathy	
	Date Problem Started: 10/07/2017	
	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 Pacific Stream	
	Product Type: Pet Food	
	Lot Number:	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Stored in the original bag with a personal use clip to keep the bag closed after opening.	
	Product Use Information:	Description: Dog free fed daily
		Time Interval between Product Use and Adverse Event: 11 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: Tractor Supply	
	Address: United States	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Sheepdog - Shetland	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 23 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:	
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-381030

ICSR:	2063282
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Adverse Event (a symptom, reaction or disease associated with the product)
Reporting Type:	Voluntary
Report Submission Date:	2019-02-27 13:11:28 EST
Initial Report Date:	09/11/2018
Parent ICSR:	2054821
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	Presented for historic Grade II/VI heart murmur and two litter mates with early DCM/Atrial fibrillation and an ASD, he was diagnosed with mitral insufficiency and suspect valvular dysplasia which progressed to emerging cardiomyopathy in September 2018 when he was started on Taurine supplementation. He was also diagnosed with B6 in June 2018.	
	Date Problem Started:	12/06/2017	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Worse/Declining/Deteriorating	

Product Information:	Product Name:	Fromm Heartland Grain Free Large Breed		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	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:	Great Dane		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	74.9 Kilogram		
	Age:	8 Years		
	Assessment of Prior Health:	Good		
	Number of Animals Given the Product:	4		
	Number of Animals Reacted:	3		
	Owner Information:	Owner Information provided:	Yes	
Contact:		Name:	B6	
		Phone:		

			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:	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	01162019 SOAP.pdf	
	Description:	B6	most recent medical records and cardiac recheck	
	Type:	Medical Records		
	Attachment:	B6	01152019 SOAP.pdf	
	Description:	B6	most recent cardiac recheck	
	Type:	Medical Records		

Report Details - EON-381026		
ICSR:	2063276	
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:	2019-02-27 12:33:55 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Diagnosed with Advanced Cardiomyopathy while on Taste of the Wild dog food. After diagnosis at age 11.5 has been on a non-grain free food for a year, and has had mild to moderate improvement in all aspects of cardiac function. Cardiologist attributed progress to change of diet. Prior diet contributed to development of DCM.	
	Date Problem Started: 01/01/2017	
	Date of Recovery: 02/22/2019	
	Concurrent Medical Problem: No	
	Outcome to Date: Better/Improved/Recovering	
Product Information:	Product Name: Taste of the Wild	
	Product Type: Pet Food	
	Lot Number:	
	Purchase Date: 03/31/2018	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: In a closet in my home. Dry, room temperature.	
	Product Use Information:	Description: Fed daily.
		Last Exposure Date: 03/31/2018
		Time Interval between Product Use and Adverse Event: 3 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	
	Address: United States	
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Hound - Afghan	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 48 Pound	
Age: 11.5 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: Referred veterinarian
		Date First Seen: 03/19/2018
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	
Reported to Other Parties: None		
Additional Documents:		

Report Details - EON-364753

ICSR: 2054793
 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: 2018-09-10 11:07:05 EDT

Reported Problem:

Problem Description: Presented for exercise intolerance and was diagnosed with moderate pulmonic stenosis, a possible PDA, and possible tricuspid valve dysplasia; she was started on B6 and referred to B6 for a balloon valvuloplasty. However, prior to the procedure a repeat echocardiogram showed idiopathic dilated cardiomyopathy, and she was started on Taurine supplementation; she did not improve and required being started on B6

Date Problem Started: 03/01/2016
Date of Recovery: 02/12/2018
Concurrent Medical Problem: No
Outcome to Date: Stable

Product Information:

Product Name: Earthborn Holistic Meadow Feast
Product Type: Pet Food
Lot Number:
Package Type: BAG

Product Use Information:	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: Retriever - Labrador
Gender: Female
Reproductive Status: Neutered
Weight: 37 Kilogram
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:	Yes
	Contact:	Name: B6 Phone: Email:
	Address:	B6

			B6	
			United States	
Healthcare Professional Information:	Practice Name:		B6	
	Contact:	Name:	B6	
		Phone:	B6	
		Email:		
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:	Email			
Reported to Other Parties:	None			
Additional Documents:				

Report Details - EON-359281	
ICSR:	2052074
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 19:17:26 EDT
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: When I got [B6] as a puppy, he had sensitivities to foods. It was recommended to me that I feed him grain-free food. He was fed different brands of grain-free food for his entire life. All of the foods contained either lentils, potatoes, peas, or a combination of all of these products. He was diagnosed with dilated cardiomyopathy when he was 9 years old and passed away from heart failure complications 4 months later [B6]. I have another basset hound that is 6 years old and has no genetic connection to [B6]. He has eaten the same food as [B6] for his entire life. He has recently been diagnosed with dilated cardiomyopathy, as well. Although I have fed them multiple brands throughout their lives, the following food brands/formulas were each fed to them for at least 1-2 years, over a total span of 6-9 years: California Naturals Kangaroo and Red Lentils Formula, Zignature Kangaroo Formula (contains peas, chickpeas, red lentils, and green lentils), Pure Vita Venison and Red Lentil Entree, and Fromm Lamb and Lentil. Note the overwhelming trend of lentils. Basset hounds are not genetically prone to heart issues. What are the odds that I have 2 genetically unrelated basset hounds that both ate lentils their entire lives and both ended up dilated cardiomyopathy? I am not able to submit this report unless I name a specific product, so I am naming the brand of food they both ate last before I became aware of the potential dangers of lentils.
	Date Problem Started: 11/16/2017
	Concurrent Medical Problem: No
	Outcome to Date: Died Euthanized
	Date of Death: [B6]
Product Information:	Product Name: Fromm Lamb and Lentil
	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: Hound - Basset
	Gender: Male
	Reproductive Status: Neutered
	Weight: 65 Pound
	Age: 9 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:	11/16/2017
	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:	11/16/2017	
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:	Email	
Reported to Other Parties:	None	
Additional Documents:		

Report Details - EON-361233

ICSR: 2053148
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: 2018-08-02 21:17:03 EDT
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Low taurine B6 completed by UC Davis 04/2018 Diet prior 2 years: Honest Kitchen Preference 50% with chicken, turkey, fish, bison, bison hearts/liver/kidney Honest Kitchen Zeal 25%, Hope 12.5%, Verve 12.5%
Date Problem Started: 04/03/2018

Product Information:
Product Name: Honest Kitchen Verve
Product Type: Pet Food
Lot Number:
Package Type: BOX
Package Size: 10 Pound
Purchase Date: 04/01/2018
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

Product Name: Honest Kitchen Hope
Product Type: Pet Food
Lot Number:
Package Type: BOX
Package Size: 10 Pound
Purchase Date: 04/01/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No
Product Use Information:
Manufacturer /Distributor Information:
Purchase Location Information: Name: Address: B6

B6
United States

Product Name: Honest Kitchen zeal

Product Type: Pet Food

Lot Number:

Package Type: BOX

Package Size: 10 Pound

Purchase Date: 04/01/2018

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

Product Name: Honest Kitchen Preference

Product Type: Pet Food

Lot Number:

Package Type: BOX

Package Size: 8 Pound

Purchase Date: 07/01/2018

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: Yes

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:

B6

Email:

B6

**Reporter Wants to
Remain Anonymous:** No

**Permission To Contact
Sender:** Yes

**Preferred Method Of
Contact:** Email

**Reported to Other
Parties:** Manufacturer

Additional Documents:

Report Details - EON-362997

ICSR:	2054051
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-08-21 22:10:16 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Taurine level of B6 while cut off number for adequacy is 250 Echocardiogram 05/22/2018 Re-test of taurine and change of food after 22 weeks per recommendation of cardiologist. Repeat echo depending on taurine level result 08/07/2018. taurine level sent in w/ results 08/15/2018 CRITICAL LEVEL B6 . Repeat same day to original lab. level B6
	Date Problem Started:	04/26/2018
	Date of Recovery:	08/21/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Stable

Product Information:	Product Name:	Wellness Core Ocean		
	Product Type:	Pet Food		
	Lot Number:			
	UPC:	Not available		
	Package Type:	BAG		
	Package Size:	26 Pound		
	Purchase Date:	03/17/2018		
	Number Purchased:	2		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In original bag, in a metal container w. a tight lid		
	Product Use Information:	Description:	Fed daily	
		First Exposure Date:	04/01/2018	
		Last Exposure Date:	04/26/2018	
		Time Interval between Product Use and Adverse Event:	18 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:	<table border="1"> <tr> <td data-bbox="672 116 889 275"> <table border="1"> <tr> <td data-bbox="677 116 885 153">Purchase Location Information:</td> <td data-bbox="677 116 885 153">Name:</td> <td data-bbox="885 116 1190 275" rowspan="2" style="text-align: center; vertical-align: middle;">B6</td> </tr> <tr> <td data-bbox="677 153 885 275"></td> <td data-bbox="677 153 885 275">Address:</td> </tr> </table> </td> <td data-bbox="1190 116 1544 275"></td> </tr> <tr> <td colspan="2"></td> <td data-bbox="889 275 1549 325">United States</td> </tr> </table>	<table border="1"> <tr> <td data-bbox="677 116 885 153">Purchase Location Information:</td> <td data-bbox="677 116 885 153">Name:</td> <td data-bbox="885 116 1190 275" rowspan="2" style="text-align: center; vertical-align: middle;">B6</td> </tr> <tr> <td data-bbox="677 153 885 275"></td> <td data-bbox="677 153 885 275">Address:</td> </tr> </table>	Purchase Location Information:	Name:	B6		Address:				United States														
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Email:																										
Reporter Wants to Remain Anonymous:	No																									
Permission To Contact Sender:	Yes																									
Preferred Method Of Contact:	Email																									
Reported to Other Parties:	Manufacturer																									
Additional Documents:																										

Report Details - EON-364330

ICSR: 2054639
 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 13:07:08 EDT

Reported Problem:

Problem Description: She began coughing about 12 days ago, responded to antibiotics, no heart murmur heard but this past weekend started coughing again and didn't eat and had one syncope episode. She was hospitalized with us for the day on fluids, antibiotics, did some bloodwork and scheduled some more testing for the next day. She had more syncope that evening and went to the ER at **B6** and proceeded to go into full Congestive heart failure and decompensated quickly and owner elected euthanasia. They did a quick ultrasound but were not cardiologists but they said the heart looked dilated and was not contracting at all, showed little to no function at all. The dog never had a murmur and had no heart problems before. She had a dental cleaning just 4 months ago with no problems. This happened quickly and the dog's heart completely decompensated.

Date Problem Started: 08/21/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: **B6**

Outcome to Date: Died Euthanized

Date of Death: **B6**

Product Information:

Product Name: NRG Original Free Range Chicken Dehydrated Raw Food

Product Type: Pet Food

Lot Number:

Package Type: BOX

Package Size: 26 Pound

Possess Unopened Product: Unknown

Possess Opened Product: Yes

Storage Conditions: Don't know, however recommended I am sure

Product Use Information:

Description:	Dog was feed this food exclusively since 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:	Possibly related
Other Foods or Products Given to the Animal During This Time Period:	Unknown

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:	Name:	
	Type Of Species:	Dog
	Type Of Breed:	Mixed (Dog)
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	39.4 Pound
	Age:	8 Years
	Assessment of Prior Health:	Good
	Number of Animals Given the Product:	1
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: Yes
		Contact: Name: B6
		Phone: B6
		Address: B6 United States
Healthcare Professional Information:	Practice Name: B6	
	Contact: Name: B6	
	Phone: B6	
	Other Phone: B6	
	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: 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-370180	
ICSR:	2058374
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:	2018-11-04 08:40:06 EST
Reporter is the Animal Owner:	Yes
Reported Problem:	Problem Description: We started feeding 4health Untamed Wild River Recipie early 2018. This past week our dog was lethargic, not eating, breathing heavy and coughing. I took him to the vet and he was diagnosed with dilated cardiomyopathy and congestive heart failure. He was stated on: B6 We are also supplementing with Taurine: B6 has been very healthy and active prior to this.
	Date Problem Started: 10/28/2018
	Concurrent Medical Problem: No
	Outcome to Date: Unknown
Product Information:	Product Name: 4health Untamed Wild River Recipie
	Product Type: Pet Food
	Lot Number:
	UPC: 74939416534
	Package Type: BAG
	Package Size: 25 Pound
	Purchase Date: 02/01/2018
	Number Purchased: 8
	Possess Unopened Product: No
	Possess Opened Product: Yes
Storage Conditions: The food was transfered to a plastic container during use with the partial bag sealed with a metal clamp in our basement.	
Product Use Information:	Description: Our dog was fed 2 cups twice a day.
	First Exposure Date: 02/01/2018
	Last Exposure Date: 10/02/2018
	Time Interval between Product Use and Adverse Event: 8 Months
	Product Use Stopped After the Onset of the Adverse Event: Yes
	Adverse Event Abate After Product Stop: Unknown
	Product Use Started Again: No
	Perceived Relatedness to Adverse Event: Definitely related
Other Foods or Products Given to the Animal Yes	

		During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name: Tractor Supply	
		Address: B6	
			United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Weimaraner	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	95 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:	Practice Name: B6	
		Contact: Name: B6	
		Phone: B6	
		Other Phone:	
		Address: B6	
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	10/30/2018
		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	Manufacturer	

Parties: Store/Place of Purchase

Additional Documents:

Report Details - EON-372382

ICSR:	2059449
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:	2018-11-30 06:36:07 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	B6 developed DCM and she had been on a diet of 4Health grain free dog food, ever since tractor supply has carried it. She had beef and potato flavored dog food. Despite being treated for DCM she passed away of heart disease after a 3 year battle.
	Date Problem Started:	10/15/2013
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	B6

Product Information:	Product Name:	4Health Grain free dog food, beef and potato		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In an airtight dog food container		
	Product Use Information:	Description:	Free feeding, she ate when she wanted to	
		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:	Tractor Supply		

Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Shih Tzu
	Gender:	Female
	Reproductive Status:	Neutered
	Weight:	13 Pound
	Age:	12 Years
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	5
	Number of Animals Reacted:	1
Owner Information:		

	Healthcare Professional Information:	
Sender Information:	Name:	
	Address:	B6 United States
	Contact:	
	Reporter Wants to Remain Anonymous:	Yes
	Reported to Other Parties:	Unknown
Additional Documents:		

Report Details - EON-372344

ICSR:	2059433
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:	2018-11-29 17:52:37 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Since [B6] had allergies to certain foods, we had him on a grain-free diet that did not cause any allergic reactions. He had been on Earthborn Primitive Natural for several years. [B6] did pass away from heart failure following a few months of illness related to right chamber heart failure. This has been almost 2 years ago but due to the recent study regarding the connection of the high level of legume and potatoes connecting with heart failure, I wanted to just provide information. In [B6] situation he was given a better life by not having allergic reactions so it justified using the grain-free. It would be great if more was known so diets can be adjusted to hopefully prevent allergies without causing heart failure.
	Date Problem Started:	11/16/2016
	Concurrent Medical Problem:	Yes
	Pre Existing Condition:	[B6]
	Outcome to Date:	Died Other
	Date of Death:	[B6]

Product Information:	Product Name:	Earthborn Holistic Primitive Natural Grain-Free Natural Dry Dog Food.		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	28 Pound		
	Purchase Date:	11/15/2016		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Self sealing bag		
	Product Use Information:	Description:	Fed as directed on packaging.	
		Last Exposure Date:	11/30/2016	
		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:		Probably related		
Other Foods or Products Given to the Animal During This Time Period:		Unknown		

	Manufacturer /Distributor Information: Purchase Location Information:	Name: Address: <div style="border: 1px dashed black; padding: 5px; display: inline-block; 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 Reacted: Owner Information:	<div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 1.5em; font-weight: bold;">B6</div> Dog Bulldog Male Intact 75 Pound 10 Years Excellent 1 Healthcare Professional Information:
Sender Information:	Name: Address: Contact: Reporter Wants to Remain Anonymous: Permission To Contact Sender: Preferred Method Of Contact: Reported to Other Parties:	<div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 3em; font-weight: bold;">B6</div> United States Phone: Email: <div style="border: 1px dashed black; padding: 5px; display: inline-block; font-size: 2em; font-weight: bold;">B6</div> No Yes Phone Other
Additional Documents:		

Report Details - EON-372455		
ICSR:	2059497	
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:	2018-11-30 18:10:32 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Dog developed DCM with both chest and abdominal fluid buildup.	
	Date Problem Started: 09/28/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Worse/Declining/Deteriorating	
Product Information:	Product Name: Iams ProActive Health Sensitive Skin & Stomach Grain Free Recipe	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 10 Pound	
	Purchase Date: 08/01/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: Product was stored in plastic bucket with sealed lid.	
	Product Use Information:	Description: According to pkg directions
		First Exposure Date: 08/01/2018
		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: Target	
	Address: B6 United States	
Animal Information:	Name:	
	Type Of Species: Dog	
	Type Of Breed: Retriever - Labrador	
	Gender: Female	
	Reproductive Status: Neutered	

	Weight: 65 Pound
	Age: 12 Years
	Assessment of Prior Health: Excellent
	Number of Animals Reacted: 1
	Owner Information:
	Healthcare Professional Information:
Sender Information:	Name:
	Address: B6 United States
	Contact:
	Reporter Wants to Remain Anonymous: Yes
	Reported to Other Parties: None
Additional Documents:	

Report Details - EON-372581

ICSR: 2059522
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: 2018-12-02 22:08:33 EST
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: Died of Dilated Cardiomyopathy
Date Problem Started: 09/10/2015
Concurrent Medical Problem: No
Outcome to Date: Died Other
Date of Death: **B6**

Product Information:
Product Name: Nature's Domain Organic Chicken and Pea
Product Type: Pet Food
Lot Number: Lot Number: not available
UPC: not available
Package Type: BAG
Package Size: 30 Pound
Purchase Date: 01/29/2015
Number Purchased: 2
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: airtight container
Product Use Information:
Description: Fed daily
First Exposure Date: 01/29/2015
Last Exposure Date: 11/27/2015
Time Interval between Product Use and Adverse Event: 11 Months
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
Address: **B6**
United States

Animal Information: Name: **B6**

	Type Of Species: Dog
	Type Of Breed: Poodle - Miniature
	Gender: Female
	Reproductive Status: Intact
	Pregnancy Status: Not pregnant
	Lactation Status: Not lactating
	Weight: 12 Pound
	Age: 9 Years
	Assessment of Prior Health: Excellent
	Number of Animals Given the Product: 7
	Number of Animals Reacted: 5
	Owner Information:
Healthcare Professional Information:	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	Email:
	Address: B6
	United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 09/20/2015
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: Other	
Additional Documents:	

Report Details - EON-372546		
ICSR:	2059517	
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:	2018-12-02 11:02:38 EST	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: B6 has had allergies since he was a puppy. When he was about 8 months old a vet suggested putting him on kangaroo meat because he was reacting to other proteins. I started him on zignature kangaroo meat- a grain free exotic diet. In August 2018 we went in for a routine vet visit. The vet asked me if anyone had ever said he had a heart murmur. It was the first I had heard of it. (He has been going to the vet regularly since he was a puppy) I said no. she suggested we follow up with a dog cardiologist. In October of 2018 we went to see a dog cardiologist. She did an echocardiogram and determined he had DCM which she believes because of the sudden onset and no family history of cardiac issue. she determined it was due to eating a exotic grain free diet. I have since changed his food and started a taurine supplement 1000mg 2x daily. He is eating royal canine hydrolyzed protein. The cardiologist suggested we follow up in 6 months.	
	Date Problem Started: 08/29/2018	
	Concurrent Medical Problem: No	
	Outcome to Date: Unknown	
Product Information:	Product Name: Zignature kangaroo grain free	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Purchase Date: 07/27/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: In a plastic dog food container	
	Product Use Information:	Description: 2 cups 2x daily 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: American Pit Bull Terrier	
	Gender: Male	
	Reproductive Status: Neutered	
	Weight: 67 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:	
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:	Other	
Additional Documents:		

Report Details - EON-373907

ICSR:	2060192
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-12-14 18:06:33 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	We adopted B6 at one year of age with B6. The dermatology vet told us to put her on something exotic because of her possible reaction to common ingredients (chicken, lamb, beef, salmon, etc)...We had her on California Naturals Kangaroo Meat Dog Food for 6 1/2 years and she had no averse reaction...In February 2018, California Naturals discontinued the Kangaroo Meat and so we have been buying it from Zignature... On September 26, 2018 we noticed she had severe labored breathing and took her into our vet B6 B6 who took an X-ray and discovered her heart was abnormally enlarged...They sent us over to B6 to have an echo and they said she has about 3 months to live... She was in an oxygenated kennel for over 24 hours and was given Taurine B6. She has continued on that currently...She still plays and barks, but she's on borrowed time...
	Date Problem Started:	09/26/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	California Natural Adult Limited Ingredient Grain Free Kangaroo & Red Lentils Recipe Dog Food	
	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:	In a pet food storage container	
	Product Use Information:	Description:	We would give B6 1 cup in the morning and 1 cup in the evening
		First Exposure Date:	01/31/2014
		Last Exposure Date:	02/01/2018
		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	Definitely related		

		Relatedness to Adverse Event:	
		Other Foods or Products Given to the Animal During This Time Period:	Yes
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Chewy.com
		Address:	385 Milan Dr. McCarran Nevada 89434 United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Shepherd (unspecified)	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	60 Pound	
	Age:	7 Years	
	Assessment of Prior Health:	Excellent	
	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:	Referred veterinarian
		Date First Seen:	09/26/2018
		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:	Other	
Additional Documents:	Attachment: B6 page 30001.pdf Description: Discharge Orders Type: Other		
	Attachment: B6 page 20001.pdf Description: Day 2 hospital admittance and care Type: Other		
	Attachment: B6 page 10001.pdf Description: Admittance into B6 and care Type: Other		
	Attachment: B6 et 9-26-180001.pdf Description: Primary vet X-rayed B6 and sent us to B6 for echo Type: Other		

Report Details - EON-378266		
ICSR:	2062023	
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 18:48:09 EST	
Reported Problem:	Problem Description: patient was diagnosed with cardiomyopathy caused by taurine deficiency on 10/09 /2018 by cardiologist, patient has been eating 4 Health Grain free	
	Date Problem Started: 09/18/2018	
	Outcome to Date: Stable	
Product Information:	Product Name: 4 Health Grain Free	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Package Size: 30 Pound	
	Purchase Date: 10/01/2018	
	Number Purchased: 1	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: plastic container	
	Product Use Information:	Description: fed to patient twice daily
		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:		
Animal Information:	Name: B6	
	Type Of Species: Dog	
	Type Of Breed: Retriever - Golden	
	Gender: Female	
	Reproductive Status: Neutered	
	Weight: 97 Pound	
	Age: 8 Years	
	Assessment of Prior Health: Good	
	Number of Animals Given the Product: 3	
	Number of Animals Reacted: 1	

	Owner Information:	Owner Information provided:	Yes		
		Contact:	Name:	B6	
			Phone:		
			Email:		
	Address:	B6	United States		
	Healthcare Professional Information:				
Sender Information:	Name:				
	Address:	B6	United States		
	Contact:				
	Reporter Wants to Remain Anonymous:	Yes			
Additional Documents:					

Report Details - EON-378649

ICSR:	2062135
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:	2019-02-04 16:19:37 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Exclusively fed Iams ProActive Health Adult MiniChunks Dry Dog Food for 4 years. Initially no heart murmur. Normal weight for her size. Diagnosed with heart murmur grade 2 in 2018 . Today diagnosed with grade 3 murmur and severely enlarged heart (dilated cardiomyopathy). Given 2 weeks to 6 months to live. Heart size 13.4 (should not be over 10).
	Date Problem Started:	01/31/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Worse/Declining/Deteriorating

Product Information:	Product Name:	Iams ProActive Health Adult MiniChunks Dry Dog Food		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	30 Pound		
	Purchase Date:	05/23/2014		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	In plastic dog food container indoors.		
	Product Use Information:	Description:	2/3 cup twice a day	
		First Exposure Date:	05/24/2014	
		Last Exposure Date:	02/04/2019	
		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:		Yes		
Manufacturer /Distributor Information:				
Purchase Location Information:	Name:	chewy.com		
	Address:	unknown		

		unkwon unknown United States	
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Mixed (Dog)	
	Gender:	Female	
	Reproductive Status:	Neutered	
	Weight:	13.8 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:	Practice Name:	B6
		Contact Name:	forgot forgot
Phone:		B6	
Address:		B6 United States	
Type of Veterinarian:		Primary/regular veterinarian	
	Date First Seen:	02/04/2019	
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-378672

ICSR: 2062145
 Type Of Submission: Initial
 Report Version: FPSR.FDA.PETF.V.V1
 Type Of Report: Both
 Reporting Type: Voluntary
 Report Submission Date: 2019-02-04 21:00:02 EST
 Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: B6 was on Natures Recipe Grain Free food since birth. B6 called our vet as he was showing signs of labored breathing and coughing. He got in B6 at 3:30. Xrays showed an enlarged heart. Was told to come back the next morning for a cardiac workup. Apt at 8:15 am. That night was horrible and he became very lethargic and symptoms worsened. I received a phone call at 11am that he passed away at the vet before they could run any tests. Never once told me about the current issue with grain free dogs etc. I joined a facebook page after researching. Never one was told taruine could have been an issue.

Date Problem Started: B6
Concurrent Medical Problem: No
Outcome to Date: Died Naturally
Date of Death: B6

Product Information:
Product Name: Nature Recipe Grain Free Salmon and Sweet Potato
Product Type: Pet Food
Lot Number:
Package Type: BAG
Purchase Date: 07/02/2018
Number Purchased: 1
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: In a sealed food container.

Product Use Information:
Description: B6 was given 1 1/2 cups 2x day every day since he was old enough, from the breeder
First Exposure Date: 07/02/2018
Last Exposure Date: B6
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: Petco
Address: United States

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

	Gender: Male
	Reproductive Status: Neutered
	Weight: 86 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:	Practice Name: B6
	Contact: Name: B6
	Phone: B6
	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
	Email: B6
	Permission To Contact Sender: Yes
	Preferred Method Of Contact: Email
	Reported to Other Parties: None
Additional Documents:	

Report Details - EON-378844

ICSR:	2062217		
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 12:34:49 EST		
Reporter is the Animal Owner:	Yes		
Reported Problem:	Problem Description:	Veterinary exam for B6 Veterinarian heard heart murmur so did ProBNP. Lab value extremely elevated B6 so referred to veterinary cardiologist. He has been fed grain free Taste of The Wild most of his life. Cardiologist did cardiac ultrasound that showed significant dilated cardiomyopathy. EKG shows ventricular arrhythmia. Given 4 prescription medications and 2 supplements. Multiple Holter monitors to assess arrhythmias. Cardiologist said correlation between grain free food and DCM.	
	Date Problem Started:	11/13/2018	
	Concurrent Medical Problem:	No	
	Outcome to Date:	Stable	
Product Information:	Product Name:	Taste of the Wild Grain High Prairie with Roasted Bison and Roasted Venison A Grain Free Diet. Taste of the Wild Pacific Stream A Grain Free Diet. Taste of the Wild Sierra Mountain	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	30 Pound	
	Purchase Date:	10/01/2018	
	Number Purchased:	1	
	Possess Unopened Product:	No	
	Possess Opened Product:	No	
	Storage Conditions:	Stored in the original bag in a plastic storage bin	
	Product Use Information:	Description:	Fed 2 cups twice a day.
		First Exposure Date:	10/01/2018
		Last Exposure Date:	11/01/2018
		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: 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: 9 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: 11/13/2018 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: Other	
Additional Documents:		

Report Details - EON-379640					
ICSR:	2062632				
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:	2019-02-13 14:54:02 EST				
Reporter is the Animal Owner:	Yes				
Reported Problem:	Problem Description: B6 started to become finicky about her food, then she started coughing and losing weight, and her stomach became bloated. I took her into the vet and she was experiencing congestive heart failure as a result of Dilated Cardiomyopathy. She ate Acana brand grain-free dog food and sometimes in the last year Stella & Chewy's kibble.				
	Date Problem Started: 01/07/2019				
	Concurrent Medical Problem: Yes				
	Pre Existing Conditions: B6				
	Outcome to Date: Stable				
Product Information:	Product Name: Acana Grasslands Kibble , Stella & Chewy's Raw Kibble Lamb				
	Product Type: Pet Food				
	Lot Number:				
	Package Type: BAG				
	Possess Unopened Product: No				
	Possess Opened Product: Yes				
	Storage Conditions: Stored the original bag put inside a big plastic container bin.				
	Product Use Information: <table border="1"> <tr> <td>Description:</td> <td>I have fed B6 with Acana kibble since I adopted her at 2 years old and she will be 9 in April 2019. I fed her the Grasslands kibble twice per day. Over the last year I would sometimes feed her the Stella and Chewy's Freeze Dried Raw Kibble Lamb as well, switching off with Acana.</td> </tr> <tr> <td>Other Foods or Products Given to the Animal During This Time Period:</td> <td>Yes</td> </tr> </table>	Description:	I have fed B6 with Acana kibble since I adopted her at 2 years old and she will be 9 in April 2019. I fed her the Grasslands kibble twice per day. Over the last year I would sometimes feed her the Stella and Chewy's Freeze Dried Raw Kibble Lamb as well, switching off with Acana.	Other Foods or Products Given to the Animal During This Time Period:	Yes
	Description:	I have fed B6 with Acana kibble since I adopted her at 2 years old and she will be 9 in April 2019. I fed her the Grasslands kibble twice per day. Over the last year I would sometimes feed her the Stella and Chewy's Freeze Dried Raw Kibble Lamb as well, switching off with Acana.			
	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>B6</td> </tr> <tr> <td>Address:</td> <td></td> </tr> </table>	Name:	B6	Address:		
Name:	B6				
Address:					
Animal Information:	Name: B6				
	Type Of Species: Dog				
	Type Of Breed: Pit Bull				
	Gender: Female				
	Reproductive Status: Neutered				
	Weight: 65 Pound				
	Age: 8 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: B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Phone
	Reported to Other Parties:	Store/Place of Purchase

Additional Documents:

Report Details - EON-380143

ICSR: 2062879
Type Of Submission: Initial
Report Version: FPSR.FDA.PETF.V.V1
Type Of Report: Both
Reporting Type: Voluntary
Report Submission Date: 2019-02-19 13:13:47 EST

Reported Problem:
Problem Description: B6 started with a ventricular arrhythmia (2016) which progressed to dilated cardiomyopathy (2018).
Date Problem Started: 12/08/2016
Concurrent Medical Problem: Yes
Pre Existing Conditions: B6
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Wellness
Product Type: Pet Food
Lot Number:
Package Type: BAG
Storage Conditions: We're unsure
Product Use Information:
Description: She was fed Wellness for most of her 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: Female
Reproductive Status: Neutered
Weight: 66 Pound
Age: 12 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

			B6 United States
Healthcare Professional Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	B6
		Email:	
	Address:	B6	
		United States	
Sender Information:	Practice Name:	B6	
	Contact:	Name:	B6
		Phone:	B6
	Type of Veterinarian:	Referred veterinarian	
	Practice Name:	B6	
	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		
Additional Documents:			

Report Details - EON-380785

ICSR: 2063152
 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 12:05:51 EST

Reported Problem:

Problem Description: HISTORY **B6** a 6 Yrs. 0 Mos., Spayed Female, Dalmatian Mix was presented on **B6** for cardiac evaluation following presentation to our ER service today for abdominal distension, coughing and labored breathing. An abdominal ultrasound was performed showing peritoneal effusion and hepatomegaly concerning for right-sided heart failure. Thoracic radiographs were taken showing generalized cardiomegaly and mild interstitial pattern concerning for pulmonary edema. VHS 11.2. No unusual sneezing, vomiting or diarrhea. No polyuria /polydypsia. Appetite and activity level normal. Owner feeds Science Diet grain free diet. **B6**

F Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, no murmur on auscultation, rapid regular rhythm, lungs- fine crackles bilateral cranial thorax with mildly increased respiratory effort, pulses fair. Skin - shaved abdomen. Abdominal distension with mild fluid wave. Normal peripheral lymph nodes Diagnostics: ECG: Sinus tachycardia with average heart rate of 215 beats/minute. **B6**

B6

B6 Chamber size: severely increased end-diastolic and end-systolic dimensions - Free wall thickness: decreased - IVS thickness: decreased - Shortening fraction: decreased - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: severely dilated Right ventricle: - Chamber size: moderately to severely dilated - Global wall movement: hypokinetic Right atrial size: moderately to severely dilated Mitral valve leaflets: mildly thickened 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. Mild volume of peritoneal effusion CFD/PWD/CWD: - Mitral regurgitation: mild with decreased velocities - Mitral inflows: summated velocity wave profiles - Mitral annulus motion (TDI): summated - Tricuspid regurgitation: mild to moderate with mildly increased velocities - LVOT: normal flow pattern with decreased velocities. - Aortic insufficiency: none - RVOT: normal flow pattern with decreased velocities. - Pulmonic insufficiency: none Diagnosis: Dilated cardiomyopathy - r/o idiopathic DCM vs. tachycardia-induced vs. taurine deficiency Suspect congestive heart failure (peritoneal effusion, pulmonary edema) Mild pulmonary hypertension Sinus tachycardia Treatment/Medications Place IV catheter and draw blood for whole blood Taurine levels. Monitor heart rates overnight via continuous ECG. If heart rate remains persistently elevated consider **B6** therapy. Start the following medications. **B6**

B6 Taurine 1.5 grams PO BID.

Tentatively plan to discharge tomorrow and recheck in 1-2 weeks to assess thoracic radiographs, blood work and HR/rhythm. A repeat echocardiogram is recommended in 6 months.

Date Problem Started: **B6**

Concurrent Medical Problem: Unknown

Outcome to Date: Died Euthanized

Date of Death: **B6**

Product Information:

Product Name: Hill's Science Diet Adult Grain Free

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:	40.3 Kilogram
	Age:	6 Years
	Assessment of Prior Health:	Unknown
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided:
Healthcare Professional Information:	Practice Name:	B6
	Contact:	Name: B6 Phone:
	Address:	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:	Phone
Reported to Other Parties:	None	
Additional Documents:		

Report Details - EON-365913

ICSR: 2055091
 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 07:30:45 EDT

Reported Problem:

Problem Description: Submitted as RFR EON-365670. FDA CVM Resubmitting as PFR. Dogs have been eating Acana Heritage Poultry since late June 2018. Last bag lot # 3008631-81802. Taurine levels on both dogs were critically low but they had no symptoms. Echocardiogram of [B6] reveals mild systolic dysfunction which is consistent with critically low taurine levels although primary dilated cardiomyopathy or normal variant for this patient cannot be ruled out. Echo of [B6] (second dog) is pending.

Date Problem Started: 09/13/2018

Concurrent Medical Problem: Unknown

Outcome to Date: Unknown

Product Information:

Product Name: Acana Heritage Poultry

Product Type: Pet Food

Lot Number: Lot Number: 3008631-81802

Package Type: BAG

Product Use Information:

First Exposure Date: 06/30/2018

Last Exposure Date: 09/13/2018

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

Manufacturer /Distributor Information:

Purchase Location Information:

Animal Information:

Name:

Type Of Species: Dog

Type Of Breed: Unknown

Gender: Unknown

Reproductive Status: Unknown

Number of Animals Given the Product: 2

Number of Animals Reacted: 2

Owner Information: Owner Information provided: No

Healthcare Professional Information:

Practice Name: [B6]

Contact: Name: [B6]
 Phone: [B6]
 Email: [B6]

Address: [B6]

		B6
		United States
	Type of Veterinarian:	Primary/regular veterinarian
Sender Information:	Name:	B6
	Contact:	B6
	Reporter Wants to Remain Anonymous:	No
	Permission To Contact Sender:	Yes
	Preferred Method Of Contact:	Email

Additional Documents:

Report Details - EON-366184

ICSR:	2055155
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-09-19 18:57:40 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Our four year old Golden Retriever was diagnosed with severe DCM on [B6] at UC Davis. His Taurine levels were critical low (dangerously low) whole blood was [B6] and plasma was [B6]. Blood work and echocardiogram were done at UC Davis by Dr. Joshua Stern. Our Golden had been eating Acana Lamb and Apple singles for 39 months of his life and he is only just turned four in June. My husband and I are just devastated with this news. Our dog means the world to us and now we have an uphill battle with this disease. We have switched him to RC Golden Retriever along with taurine supplements, L-Carnitine [B6]. We go back to UC Davis the third week of November for a follow up appointment with Dr. Stern for more blood work and echocardiogram. Our Golden Retriever showed no symptoms, our vet called and asked what food [B6] was eating and we told her The Acana Lamb and Apple singles and she instructed us to get blood work done and have his Taurine levels checked by sending the sample to the UC Davis amino acid lab. Devastated!!!!
	Date Problem Started:	08/28/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Unknown

Product Information:	Product Name:	Acana Lamb and Apple singles
	Product Type:	Pet Food
	Lot Number:	
	Purchase Date:	08/10/2018
	Possess Unopened Product:	No
	Possess Opened Product:	Yes
	Product Use Information:	
	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:	Neutered
	Weight:	80 Pound
	Age:	4 Days
	Assessment of Prior Health:	Excellent
	Number of Animals Given the Product:	1
Number of Animals Reacted:	1	

Owner Information:	Healthcare Professional Information:		Practice Name:	UC Davis Vetrenary Medicine	
	Contact:	Name:	Joshua Stern		
		Phone:	(530) 752-1393		
		Other Phone:	530 514 4555		
	Address:	1 Shields Ave Davis California 95616 United States			
	Type of Veterinarian:	Referred veterinarian			
	Date First Seen:	08/29/2018			
	Permission to Release Records to FDA:	Yes			
	Practice Name:	B6			
	Contact:	Name:	B6		
		Phone:	B6		
		Other Phone:	B6		
	Address:	B6 United States			
	Type of Veterinarian:	Primary/regular veterinarian			
Date First Seen:	08/28/2018				
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:	Phone				
Reported to Other Parties:	Manufacturer				
Additional Documents:	Attachment:	B6	Discharge Instructions	B6	pdf
	Description:	Discharge Instructions from UC Davis Exam B6			
	Type:	Medical Records			
	Attachment:	Dr. Stern Facebook post.pdf			
Description:	Facebook post by Dr. Stern refrencing B6 the evening of his examination B6				

Type: Other

Attachment:

B6

Exam-UC Davis

B6

pdf

Description: Examination report at UC Davis by Dr. Joshua Stern

Type: Medical Records

Report Details - EON-381419

ICSR:	2063514
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:	2019-03-04 12:09:48 EST
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	We noticed he started to have labored breathing and a bad cough. Vet thought it could be kennel cough. After more diagnostic tests they found him to have Dilated cardiomyopathy (DCM). It was suggested we take him off of his grain free food, Acana Lamb and Apple, and move him to a grain inclusive food. We transitioned him to Fromm's Gold Large Breed and started him on medications prescribed by a local veterinary cardiologist. After 6 months of new food and medications his heart significantly improved. The vet believes that the new diet along with meds shows this disease was caused from a grain free diet.
	Date Problem Started:	08/30/2018
	Date of Recovery:	03/04/2019
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Better/Improved/Recovering

Product Information:	Product Name:	ACANA SINGLES LIMITED INGREDIENT DIET LAMB AND APPLE FORMULA GRAIN FREE DRY DOG FOOD		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	25 Pound		
	Purchase Date:	08/01/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	No		
	Storage Conditions:	Stored in airtight plastic container in my home.		
	Product Use Information:	Description:	He was given 2 cups a day divided between morning and evening.	
		Last Exposure Date:	09/08/2018	
		Product Use Stopped After the Onset of the Adverse Event:	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: Address:	B6 United States	
Animal Information:	Name:	B6		
	Type Of Species:	Dog		
	Type Of Breed:	Pit Bull		
	Gender:	Male		
	Reproductive Status:	Neutered		
	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:	Practice Name:	B6	
		Contact:	Name:	B6
			Phone:	
			Email:	
		Address:	B6 United States	
		Type of Veterinarian:	Referred veterinarian	
		Date First Seen:	09/11/2018	
		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:	Store/Place of Purchase		
Additional Documents:				

Report Details - EON-366468

ICSR:	2055216
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-09-21 16:58:06 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Our dog, B6 had been on the Nature's Domain grain-free turkey and sweet potato kibble for about 5 years. He was diagnosed with a heart murmur in April 2018, given an echo, then further diagnosed with dilated cardiomyopathy (DCM). He was put on B6 in B6 he died suddenly in his sleep, presumably from the DCM. I came to find out later that there is an investigation linking his grain-free food to DCM, and I'd like to contribute his details to any studies or investigations.
	Date Problem Started:	04/10/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Naturally
	Date of Death:	B6

Product Information:	Product Name:	Kirkland Signature Nature's Domain Turkey Meal and Sweet Potato Formula for Dogs		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	35 Pound		
	Purchase Date:	05/01/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	In a sealed container in our pantry.		
	Product Use Information:	Description:	As directed - 1 Cup twice a day	
		Last Exposure Date:	06/09/2018	
		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:		Not Applicable		
Product Use Started Again:		No		
Perceived Relatedness to Adverse Event:		Definitely related		
Other Foods or Products Given to the Animal	No			

		During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name:	Costco
		Address:	United States
Animal Information:	Name:	B6	
	Type Of Species:	Dog	
	Type Of Breed:	Retriever - Labrador	
	Gender:	Male	
	Reproductive Status:	Neutered	
	Weight:	100 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:	B6
		Address:	B6
			United States
		Type of Veterinarian:	Primary/regular veterinarian
		Date First Seen:	03/01/2018
		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	
	Reported to Other Parties:	None	
Additional Documents:			

Report Details - EON-364756	
ICSR:	2054795
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:	2018-09-10 11:19:37 EDT
Reported Problem:	Problem Description: Presented for increased respiratory rate and effort at rest and exercise intolerance; was diagnosed with DCM and ventricular premature complexes of left bundle branch block morphology; was started on B6 and Taurine supplementation.
	Date Problem Started: 08/13/2014
	Date of Recovery: 11/03/2014
	Concurrent Medical Problem: No
	Outcome to Date: Stable
Product Information:	Product Name: Zignature Fish
	Product Type: Pet Food
	Lot Number:
	Package Type: BAG
	Product Use Information:
	First Exposure Date: 08/10/2014
	Last Exposure Date: 12/19/2014
	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: Merrick Lamb, Peas, and Ancient Grains
	Product Type: Pet Food
	Lot Number:
Package Type: BAG	
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:	Yes	
	Manufacturer /Distributor Information:			
	Purchase Location Information:			
	Product Name:	Natural Balance Lamb and Brown Rice		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Product Use Information:	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:	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:	Retriever - Golden		
	Gender:	Male		
	Reproductive Status:	Neutered		
	Weight:	35.1 Kilogram		
	Age:	10 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:		B6	
	Address:			
			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-366679

ICSR:	2055284
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2018-09-24 16:02:45 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	I am the breeder to this puppy. [B6] went to her new home at seven weeks old. Puppy was fed Nature's Domain Puppy Chicken and Pea Formula starting at three weeks old. Her dam was also fed the Nature's Domain Puppy Chicken and Pea Formula starting two weeks before she was born. I switched to this puppy food after Costco stopped carrying the other puppy food I had fed with no problems for over twenty years. [B6] started coughing, decreased appetite, and enlarged heart when she was 11 months old. Died when she was just 14 1/2 months old. Her full sister also died at 10 months of age. Also fed the same food. Sire and dam to this litter have had multiple litters together and with other matings, all normal puppies until this litter on this puppy food. Both sire and dam to this litter have their hearts cleared by a veterinary specialist and are OFA Cardiac Clear. Again, no heart issues with any of their other litters or puppies until this litter. The only that changed is the puppy food! I do not have the records from [B6] regular vet, however I do have copies of her records from [B6] [B6] I also do have permission from [B6] s owner for you to contact them as well as their regular veterinarian. [B6] owner kept her on the Nature's Domain Puppy Chicken and Pea Formula until she was 5-6 months old and then switched her to Taste Of The Wild.
	Date Problem Started:	02/01/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Died Euthanized
	Date of Death:	[B6]

Product Information:	Product Name:	Nature's Domain Puppy Chicken and Pea Formula		
	Product Type:	Pet Food		
	Lot Number:			
	Package Type:	BAG		
	Package Size:	20 Pound		
	Possess Unopened Product:	Unknown		
	Possess Opened Product:	Unknown		
	Product Use Information:	Perceived Relatedness to Adverse Event:	Definitely related	
	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:	22.6 Kilogram
	Age:	14 Months

	Assessment of Prior Health:	Excellent																																						
	Number of Animals Reacted:	5																																						
	Owner Information:	<table border="1"> <tr> <td data-bbox="665 209 885 312">Owner Information provided:</td> <td data-bbox="885 209 1554 312">Yes</td> </tr> <tr> <td data-bbox="665 312 885 431">Contact:</td> <td data-bbox="885 312 1554 431"> <table border="1"> <tr> <td data-bbox="885 312 1047 355">Name:</td> <td data-bbox="1047 312 1554 355">B6</td> </tr> <tr> <td data-bbox="885 355 1047 398">Phone:</td> <td data-bbox="1047 355 1554 398"></td> </tr> <tr> <td data-bbox="885 398 1047 431">Email:</td> <td data-bbox="1047 398 1554 431"></td> </tr> </table> </td> </tr> <tr> <td data-bbox="665 431 885 592">Address:</td> <td data-bbox="885 431 1554 592"> <table border="1"> <tr> <td data-bbox="885 431 1112 549">B6</td> <td data-bbox="1112 431 1554 549"></td> </tr> <tr> <td colspan="2" data-bbox="885 549 1554 592">United States</td> </tr> </table> </td> </tr> </table>	Owner Information provided:	Yes	Contact:	<table border="1"> <tr> <td data-bbox="885 312 1047 355">Name:</td> <td data-bbox="1047 312 1554 355">B6</td> </tr> <tr> <td data-bbox="885 355 1047 398">Phone:</td> <td data-bbox="1047 355 1554 398"></td> </tr> <tr> <td data-bbox="885 398 1047 431">Email:</td> <td data-bbox="1047 398 1554 431"></td> </tr> </table>	Name:	B6	Phone:		Email:		Address:	<table border="1"> <tr> <td data-bbox="885 431 1112 549">B6</td> <td data-bbox="1112 431 1554 549"></td> </tr> <tr> <td colspan="2" data-bbox="885 549 1554 592">United States</td> </tr> </table>	B6		United States																							
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Date First Seen:	04/13/2018																																							
Permission to Release Records to FDA:	Yes																																							
Sender Information:		<table border="1"> <tr> <td data-bbox="665 1530 966 1573">Name:</td> <td data-bbox="966 1530 1554 1573"></td> </tr> <tr> <td data-bbox="665 1573 966 1724">Address:</td> <td data-bbox="966 1573 1554 1724"> <table border="1"> <tr> <td data-bbox="966 1573 1169 1692">B6</td> <td data-bbox="1169 1573 1554 1692"></td> </tr> <tr> <td colspan="2" data-bbox="966 1692 1554 1724">United States</td> </tr> </table> </td> </tr> <tr> <td data-bbox="665 1724 966 1821">Contact:</td> <td data-bbox="966 1724 1554 1821"> <table border="1"> <tr> <td data-bbox="966 1724 1047 1767">Phone:</td> <td data-bbox="1047 1724 1554 1767"></td> </tr> <tr> <td data-bbox="966 1767 1047 1821">Email:</td> <td data-bbox="1047 1767 1554 1821">B6</td> </tr> </table> </td> </tr> <tr> <td data-bbox="665 1821 966 1886">Permission To Contact Sender:</td> <td data-bbox="966 1821 1554 1886">Yes</td> </tr> <tr> <td data-bbox="665 1886 966 1951">Preferred Method Of Contact:</td> <td data-bbox="966 1886 1554 1951">Email</td> </tr> <tr> <td data-bbox="665 1951 966 2028">Reported to Other Parties:</td> <td data-bbox="966 1951 1554 2028">Store/Place of Purchase Manufacturer</td> </tr> </table>	Name:		Address:	<table border="1"> <tr> <td data-bbox="966 1573 1169 1692">B6</td> <td data-bbox="1169 1573 1554 1692"></td> </tr> <tr> <td colspan="2" data-bbox="966 1692 1554 1724">United States</td> </tr> </table>	B6		United States		Contact:	<table border="1"> <tr> <td data-bbox="966 1724 1047 1767">Phone:</td> <td data-bbox="1047 1724 1554 1767"></td> </tr> <tr> <td data-bbox="966 1767 1047 1821">Email:</td> <td data-bbox="1047 1767 1554 1821">B6</td> </tr> </table>	Phone:		Email:	B6	Permission To Contact Sender:	Yes	Preferred Method Of Contact:	Email	Reported to Other Parties:	Store/Place of Purchase Manufacturer																		
Name:																																								
Address:	<table border="1"> <tr> <td data-bbox="966 1573 1169 1692">B6</td> <td data-bbox="1169 1573 1554 1692"></td> </tr> <tr> <td colspan="2" data-bbox="966 1692 1554 1724">United States</td> </tr> </table>	B6		United States																																				
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Phone:																																								
Email:	B6																																							
Permission To Contact Sender:	Yes																																							
Preferred Method Of Contact:	Email																																							
Reported to Other Parties:	Store/Place of Purchase Manufacturer																																							

Additional Documents:

Attachment:	B6	page 1 of 4.jpg
Description:	Medical Records from	B6
	page 1 of 4.	
Type:	Medical Records	
Attachment:	B6	page 3 of 4.jpg
Description:	Medical Records from	B6
	page 3 of 4.	
Type:	Medical Records	
Attachment:	B6	page 2 of 4.jpg
Description:	Medical Records from	B6
	page 2 of 4.	
Type:	Medical Records	
Attachment:	B6	page 4 of 4.jpg
Description:	Medical Records from	B6
	page 4 of 4.	
Type:	Laboratory Report	

Report Details - EON-381161

ICSR: 2063366
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: 2019-02-28 17:18:58 EST

Reported Problem:
Problem Description: HISTORY: B6 a 9 Yrs. 0 Mos., Neutered Male, Pinscher, Doberman, owned by B6 was presented on 5/10/2018 for cardiac evaluation after an intermittent arrhythmia was noted following presentation to his pDVM for lameness. B6 has a history B6 disease. No clinical signs or symptoms of cardiac disease have been noted by the owner. No unusual coughing, sneezing, vomiting or diarrhea. No polyuria /polydypsia. Appetite and activity level normal. B6 is fed Taste of the Wild grain-free diet. Current Medications: B6 Fish oil Physical Exam Weight: 94.2 lb (42.8 kg) HR- 110; RR- 22 Pertinent PE Findings: mm pink, CRT < 2 seconds, no jugular venous distention or abnormal jugular pulses, grade I /VI left apical systolic murmur, mostly regular rhythm with occasional dropped beat; lungs clear, pulses good with occasional deficits. Diagnostics ECG: normal sinus rhythm with occasional single monomorphic vpc's of LV origin; average heart rate of 100 bpm. B6

B6

There is severe left ventricular dilation and severe left ventricular hypokinesis. The left atrium remains normal in size. The right heart remains normal in size. There is mild mitral regurgitation likely secondary to annular dilation. Pulmonary arterial pressure appear normal in exam. 2D/M-MODE: Left ventricle: Chamber size: severely dilated - Free wall thickness: normal - IVS thickness: normal - Shortening fraction: severely depressed - Ejection fraction: decreased - Global wall movement: hypokinetic - E point to septal separation: increased Left atrial size: normal Right ventricle: Chamber size: normal - Global wall movement: normal Right atrial size: normal Mitral valve leaflets: normal 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 - 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: mild with normal velocities Diagnosis: Occult Dilated cardiomyopathy leading to severe left ventricular dilation; no current left atrial or right-sided dilation Occasional Ventricular arrhythmia - 24 hour Holter monitor placed prior to discharge Treatment/Medications Start the following: -

B6

B6 Recheck renal values/lytes in 1-2 weeks with pDVM. Discussed transitioning off a grain free diet given recent development of DCM noted with some patients that are fed grain free diets. Discussed adding in Taurine and L-Carnitine supplementation (give 2 grams of each PO BID). B6 therapy would be recommended if ventricular ectopy appears hemodynamically significant on 24 hour Holter exam (results should be back next week). A repeat echocardiogram and 24 hour Holter monitor are tentatively recommended every 6 months indefinitely.

Date Problem Started: 05/10/2018
Outcome to Date: Died Euthanized
Date of Death: B6

Product Information:
Product Name: Taste of The Wild (rotated different varieties)
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:	42.8 Kilogram
	Age:	9 Years
	Number of Animals Reacted:	1
	Owner Information:	Owner Information provided: No
	Healthcare Professional Information:	Practice Name:
Contact:		Name: B6
		Phone: B6
Sender Information:	Name:	B6
	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-379400

ICSR: 2062495
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 16:56:26 EST

Reported Problem:

Problem Description:	Initial FDA report linking possible cause of DCM linked in certain foods. This canine B6 was diagnosed with Dilated Cardiomyopathy on 6/12/2017. She was being fed Blue Wilderness (unknown variety) grain free high in legume ingredients. energy level had declined over the past two weeks and had become more lethargic. Rapid atrial fibrillation with average heart rate of 200-220 bpm. There is severe global cardiac dilation and severe generalized hypokinesia consistent with dilated cardiomyopathy. Diagnoses: Rapid atrial fibrillation, Dilated cardiomyopathy, Congestive Heart Failure
Date Problem Started:	06/12/2017
Outcome to Date:	Unknown

Product Information:

Product Name:	Blue Wilderness Grain Free (unknown variety)
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:	Female
Reproductive Status:	Unknown
Number of Animals Reacted:	1
Owner Information:	Owner Information provided: No
Healthcare Professional Information:	

Sender Information:

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

Additional Documents:

Report Details - EON-379304

ICSR: 2062478
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 08:09:45 EST

Reported Problem:

Problem Description: Submitted as RFR EON-379142. CVM resubmitting as PFR. Possible cause of Dilated Cardiomyopathy 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. 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) Reported product Blue Wilderness. Manufacturer reported as Champion Petfoods which manufactures Origen and Acana.

Date Problem Started: 06/12/2017
Outcome to Date: Unknown

Product Information:

Product Name: Blue Wilderness
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: Unknown
Gender: Female
Reproductive Status: Unknown
Number of Animals Reacted: 1
Owner Information: Owner Information provided: No
Healthcare Professional Information:

Sender Information:

Name:
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:	Unknown

Additional Documents:

Report Details - EON-379775

ICSR: 2062681
 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: 2019-02-14 14:08:57 EST

Reported Problem:

Problem Description: Presented on 12/22/18 for acute onset cough. Was started on [B6] 100mg, 2 caps po bid for 10 days; cough improved slightly. D [B6] was unable to hear his heart that day as he was moaning a lot. Presented for recheck on 1/11/19. Grade II/VI murmur auscultated that day. Chest rads revealed generalized cardiomegaly. Echocardiogram done on 1/16/19 which revealed CHF due to DCM, mitral and tricuspid insufficiency (could be secondary to dilation of annulus/DCM).

Date Problem Started: 12/05/2018

Concurrent Medical Problem: Yes

Pre Existing Conditions: [B6]

Outcome to Date: Stable

Product Information:

Product Name: Dick Van Patten's Natural Balance Limited Ingredient Diets Grain Free Potato & Duck Formula Single Animal Protein Source

Product Type: Pet Food

Lot Number:

UPC: 723633420723

Package Type: BAG

Package Size: 26 Pound

Purchase Date: 11/28/2018

Number Purchased: 1

Possess Unopened Product: No

Possess Opened Product: Yes

Storage Conditions: In original packaging in pantry closet rolled tightly closed

Product Use Information:

Description:	Pet food-ingested
First Exposure Date:	11/28/2018
Last Exposure Date:	12/19/2018
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:	Possibly related
Other Foods or	Yes

		Products Given to the Animal During This Time Period:	
	Manufacturer /Distributor Information:		
	Purchase Location Information:	Name: Amazon.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:	77 Pound	
	Age:	10 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:	Practice Name: B6	
	Contact:	Name: B6	
		Phone: B6	
		Email: B6	
	Address:	B6	
		United States	
	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:		
		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	fdacase4.jpeg
	Description:	medical records page 4	
	Type:	Medical Records	
	Attachment:	B6	fdacase9.jpeg
	Description:	medical record page 9	
	Type:	Radiographs	
	Attachment:	B6	fdacase8.jpeg
	Description:	medical record page 8	
	Type:	Echocardiogram	
	Attachment:	B6	fdacase5.jpeg
	Description:	medical records page 5	
	Type:	Medical Records	
	Attachment:	B6	fdacase3.jpeg
	Description:	medical records page 3	
	Type:	Medical Records	

Report Details - EON-379181

ICSR:	2062451
Type Of Submission:	Followup
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-02-08 19:52:50 EST
Initial Report Date:	07/12/2018
Reporter is the Animal Owner:	Yes
Parent ICSR:	2051919
Follow-up Report to FDA Request:	Yes

Reported Problem:	Problem Description:	In CY 2012, my B6 was part of a targeted cardiac study conducted at B6 as part of the study. B6 wore a Holter vest and received an echocardiogram. The results of his screening indicated no heart issues/defects - his heart was healthy. On February 12, 2018, B6 was diagnosed by both my vet and a veterinary cardiologist as having congestive heart failure, severely advanced dilated cardiomyopathy, heart arrhythmia and a grossly enlarged left heart ventricle (left ventricle was nearly 2x it's normal size while the right ventricle was normal sized). He was placed on a host of cardiac medications that helped improve his quality of life for several weeks, but the disease had progressed too far. On B6 we made the decision to euthanize him. Prior to his diagnosis in February 2018, B6 was aging gracefully and was an overall healthy, active dog. He developed a cough one morning and upon vet check we received the shocking diagnosis. For several years we had been feeding B6 Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Grain-Free dog food. Occasionally we alternated between this food and the chicken based grain free dog food (same brand). Purchased in large 35 lb bags at Costco. Neither the cardiologist who diagnosed B6 nor the team at B6 were able to explain to me why it was that he developed such serious, severe heart disease at age 11/12 after being cardiac cleared in CY 2012 (B6 did have two litter-mates who died very young from arrhythmia (they died under the age of four); but the rest of the dogs in the litter were heart healthy as was B6). I read the FDA report issued today, July 12, 2018 (FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease) with great shock and sadness. Based upon what I have read and my own experience with my dog, I am extremely concerned that the Kirkland brand grain-free dog food I have used for years (containing peas, potatoes and potato starch as high-content ingredients), may have led to to my dog's severe heart disease, suffering and eventual death. Until he awoke with a cough that morning in February 2018, we had no indication whatsoever that he was so sick with advanced heart disease. The FDA report encouraged pet owners to report cases of DCM in dogs suspected of having a link to diet - this is why I am reaching out to you today regarding my experience. If B6 records regarding his heart disease from my vet B6 or the cardiologist will be helpful in your research to identify/confirm that these grain-free diets are a contributing factor or are the root cause of DCM in these dogs, please let me know. Thank you.
	Date Problem Started:	02/12/2018
	Concurrent Medical Problem:	Yes
	Pre Existing Conditions:	B6
	Outcome to Date:	Died Euthanized
	Date of Death:	B6
Product Information:	Product Name:	Kirkland Signature Nature's Domain Salmon Meal & Sweet Potato Dog Food (Grain Free)
	Product Type:	Pet Food
	Lot Number:	
	Package Type:	BAG
	Package Size:	35 Pound

	Possess Unopened Product:	No
	Possess Opened Product:	No
	Storage Conditions:	Stored in a plastic dog food bin (sealed lid) in hall closet.
	Product Use Information:	Description: Fed daily for several years to my dog.
		First Exposure Date: 05/01/2016
		Last Exposure Date: 04/23/2018
		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: Yes
	Manufacturer /Distributor Information:	
	Purchase Location Information:	Name: Costco (bought in-store and online)
		Address: B6 United States
Animal Information:	Name:	B6
	Type Of Species:	Dog
	Type Of Breed:	Saluki
	Gender:	Male
	Reproductive Status:	Neutered
	Weight:	60 Pound
	Age:	12 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:	04/12/2018
	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:	02/12/2018	
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:	B6	20180213_075336.pdf	
	Description:	Cardiac diagnosis report	B6	
	Type:	Medical Records		
	Attachment:	5C14F3B1-F917-4B5F-B58B-B479814F7458.jpeg		
	Description:	My dog	B6	
	Type:	Photograph		
	Attachment:	SCAN_20180221_084141686.pdf		
	Description:	B6	Cardiac Study	B6
	Type:	Medical Records		
	Attachment:	70BC47D9-3853-42B0-B985-51F8176728D4.jpeg		
	Description:	Cardiac x Ray side view		
	Type:	Radiographs		
	Attachment:	BA23EA91-190D-4A5C-8A5C-60316B0B40A5.jpeg		
	Description:	Cardiac x Ray		
	Type:	Radiographs		

Report Details - EON-380736

ICSR:	2063128
Type Of Submission:	Initial
Report Version:	FPSR.FDA.PETF.V.V1
Type Of Report:	Both
Reporting Type:	Voluntary
Report Submission Date:	2019-02-24 23:50:26 EST
Reporter is the Animal Owner:	Yes

Reported Problem:
Problem Description: There were no symptoms. B6 had a tumor that I was debating if we should remove as it was small and his age. I wanted to see other options and decided to see a holistic vet. After she examined B6 regarding the small tumor she told me that he had a heart problem and that I should see a cardiologist asap. We went B6 (where my other dog was diagnosed with CHF back in Sept. of 2017) B6 had an echo-cardiogram was diagnosed with DCM on November 1, 2018 just 7 months after we lost our B6 our old english sheepdog (not from the same litter) to congested heart failure.

Date Problem Started:	11/01/2018
Concurrent Medical Problem:	Yes
Pre Existing Conditions:	B6
Outcome to Date:	Stable

Product Information:	Product Name:	Zignature Kangaroo dog food	
	Product Type:	Pet Food	
	Lot Number:		
	Package Type:	BAG	
	Package Size:	27 Pound	
	Possess Unopened Product:	No	
	Possess Opened Product:	Yes	
	Storage Conditions:	in original bag inside a container	
	Product Use Information:	Description:	dry food given three times a day total of 3 cups
		Last Exposure Date:	01/04/2019
		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:	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:	<table border="1"> <tr> <td data-bbox="672 116 878 153">Purchase Location Information:</td> <td data-bbox="878 116 1019 153">Name:</td> <td data-bbox="1019 116 1214 153">chewy.com</td> <td data-bbox="1214 116 1534 153">B6</td> </tr> <tr> <td></td> <td data-bbox="672 153 878 189">Address:</td> <td data-bbox="878 153 1045 189">B6</td> <td data-bbox="1045 153 1534 189"></td> </tr> <tr> <td></td> <td></td> <td data-bbox="878 189 1045 226">United States</td> <td data-bbox="1045 189 1534 226"></td> </tr> </table>	Purchase Location Information:	Name:	chewy.com	B6		Address:	B6				United States																																																													
Purchase Location Information:	Name:	chewy.com	B6																																																																							
	Address:	B6																																																																								
		United States																																																																								
Animal Information:	Name: Type Of Species: Type Of Breed: Gender: Reproductive Status: Weight: Age: Assessment of Prior Health: Number of Animals Reacted: Owner Information: Healthcare Professional Information:	<table border="1"> <tr> <td data-bbox="672 239 878 275">Name:</td> <td colspan="3" data-bbox="878 239 1534 275">B6</td> </tr> <tr> <td data-bbox="672 275 878 312">Type Of Species:</td> <td colspan="3" data-bbox="878 275 1534 312">Dog</td> </tr> <tr> <td data-bbox="672 312 878 349">Type Of Breed:</td> <td colspan="3" data-bbox="878 312 1534 349">Sheepdog - Old English</td> </tr> <tr> <td data-bbox="672 349 878 385">Gender:</td> <td colspan="3" data-bbox="878 349 1534 385">Male</td> </tr> <tr> <td data-bbox="672 385 878 422">Reproductive Status:</td> <td colspan="3" data-bbox="878 385 1534 422">Neutered</td> </tr> <tr> <td data-bbox="672 422 878 459">Weight:</td> <td colspan="3" data-bbox="878 422 1534 459">90 Pound</td> </tr> <tr> <td data-bbox="672 459 878 495">Age:</td> <td colspan="3" data-bbox="878 459 1534 495">11 Years</td> </tr> <tr> <td data-bbox="672 495 878 569">Assessment of Prior Health:</td> <td colspan="3" data-bbox="878 495 1534 569">Good</td> </tr> <tr> <td data-bbox="672 569 878 642">Number of Animals Reacted:</td> <td colspan="3" data-bbox="878 569 1534 642">2</td> </tr> <tr> <td data-bbox="672 642 878 679">Owner Information:</td> <td colspan="3" data-bbox="878 642 1534 679"></td> </tr> <tr> <td data-bbox="672 679 878 715">Practice Name:</td> <td colspan="3" data-bbox="878 679 1534 715">B6</td> </tr> <tr> <td data-bbox="672 715 878 752">Contact: Name:</td> <td data-bbox="878 715 1045 752">B6</td> <td data-bbox="1045 715 1534 752"></td> <td data-bbox="1045 715 1534 752"></td> </tr> <tr> <td data-bbox="672 752 878 789">Phone:</td> <td colspan="3" data-bbox="878 752 1534 789">B6</td> </tr> <tr> <td data-bbox="672 789 878 825">Address:</td> <td colspan="3" data-bbox="878 789 1534 825">B6</td> </tr> <tr> <td></td> <td colspan="3" data-bbox="878 825 1534 862">United States</td> </tr> <tr> <td data-bbox="672 862 878 899">Type of Veterinarian:</td> <td colspan="3" data-bbox="878 862 1534 899">Referred veterinarian</td> </tr> <tr> <td data-bbox="672 899 878 935">Date First Seen:</td> <td colspan="3" data-bbox="878 899 1534 935">11/01/2018</td> </tr> <tr> <td data-bbox="672 935 878 1009">Permission to Release Records to FDA:</td> <td colspan="3" data-bbox="878 935 1534 1009">Yes</td> </tr> </table>	Name:	B6			Type Of Species:	Dog			Type Of Breed:	Sheepdog - Old English			Gender:	Male			Reproductive Status:	Neutered			Weight:	90 Pound			Age:	11 Years			Assessment of Prior Health:	Good			Number of Animals Reacted:	2			Owner Information:				Practice Name:	B6			Contact: Name:	B6			Phone:	B6			Address:	B6				United States			Type of Veterinarian:	Referred veterinarian			Date First Seen:	11/01/2018			Permission to Release Records to FDA:	Yes		
Name:	B6																																																																									
Type Of Species:	Dog																																																																									
Type Of Breed:	Sheepdog - Old English																																																																									
Gender:	Male																																																																									
Reproductive Status:	Neutered																																																																									
Weight:	90 Pound																																																																									
Age:	11 Years																																																																									
Assessment of Prior Health:	Good																																																																									
Number of Animals Reacted:	2																																																																									
Owner Information:																																																																										
Practice Name:	B6																																																																									
Contact: Name:	B6																																																																									
Phone:	B6																																																																									
Address:	B6																																																																									
	United States																																																																									
Type of Veterinarian:	Referred veterinarian																																																																									
Date First Seen:	11/01/2018																																																																									
Permission to Release Records to FDA:	Yes																																																																									
Sender Information:	Name: Address: Contact: Permission To Contact Sender: Preferred Method Of Contact: Reported to Other Parties:	<table border="1"> <tr> <td data-bbox="672 1181 878 1218">Name:</td> <td colspan="3" data-bbox="878 1181 1534 1218">B6</td> </tr> <tr> <td data-bbox="672 1218 878 1254">Address:</td> <td colspan="3" data-bbox="878 1218 1534 1254">B6</td> </tr> <tr> <td></td> <td colspan="3" data-bbox="878 1254 1534 1291">United States</td> </tr> <tr> <td data-bbox="672 1291 878 1328">Contact: Phone:</td> <td colspan="3" data-bbox="878 1291 1534 1328">B6</td> </tr> <tr> <td data-bbox="672 1328 878 1364">Email:</td> <td colspan="3" data-bbox="878 1328 1534 1364">B6</td> </tr> <tr> <td data-bbox="672 1364 878 1401">Permission To Contact Sender:</td> <td colspan="3" data-bbox="878 1364 1534 1401">Yes</td> </tr> <tr> <td data-bbox="672 1401 878 1438">Preferred Method Of Contact:</td> <td colspan="3" data-bbox="878 1401 1534 1438">Phone</td> </tr> <tr> <td data-bbox="672 1438 878 1474">Reported to Other Parties:</td> <td colspan="3" data-bbox="878 1438 1534 1474">Manufacturer</td> </tr> <tr> <td></td> <td colspan="3" data-bbox="878 1474 1534 1511">Store/Place of Purchase</td> </tr> <tr> <td></td> <td colspan="3" data-bbox="878 1511 1534 1548">Distributor</td> </tr> </table>	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:	Manufacturer				Store/Place of Purchase				Distributor																																		
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Additional Documents:																																																																										

Report Details - EON-359648

ICSR:	2052309
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:	2018-07-18 11:43:34 EDT
Reporter is the Animal Owner:	Yes

Reported Problem:	Problem Description:	Decreased energy Lethargy Coughing Difficulty Breathing Diagnosed with cardiomyopathy
	Date Problem Started:	03/15/2018
	Concurrent Medical Problem:	No
	Outcome to Date:	Stable

Product Information:	Product Name:	Acana Pork and Squash Singles Formula
	Product Type:	Pet Food
	Lot Number:	
	UPC:	6499251325
	Package Type:	BAG
	Package Size:	25 Pound
	Purchase Date:	01/08/2018
	Storage Conditions:	Original package

Product Use Information:	Description:	Feed to affected dog 2 xs a day
	First Exposure Date:	01/08/2018
	Last Exposure Date:	04/10/2018
	Product Use Stopped After the Onset of the Adverse Event:	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:	
	Type Of Species:	Dog
	Type Of Breed:	Retriever - Golden
	Gender:	Male
Reproductive Status:	Intact	

	Weight: 88 Pound
	Age: 7 Years
	Assessment of Prior Health: Excellent
	Number of Animals Reacted: 1
	Owner Information:
Healthcare Professional Information:	Contact: Name: B6
	Phone:
	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
Additional Documents:	Attachment: Vet bill pdf.pdf
	Description: This was the initail bill for first visit
	Type: Medical Records

Report Details - EON-359672		
ICSR:	2052321	
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:	2018-07-18 14:10:30 EDT	
Reporter is the Animal Owner:	Yes	
Reported Problem:	Problem Description: Just read FDA report of 7/12/18 about dog foods containing peas or lentils. Our standard poodle was fed these foods most of her life: California Naturals Venison with green lentils, California Naturals Salmon and peas, and California Naturals Kangaroo and red lentils. She developed DCM at about 8 years of age, then it advanced into CHF. She was under the care of a cardiologist from the first diagnosis of heart murmur, was treated with a variety of drugs, which extended her life for a couple of years. There was no genetic history of heart problems. We believe that the grain-free food we fed her was the proximate cause of her cardiac problems and ultimately her early death.	
	Date Problem Started: 09/01/2009	
	Concurrent Medical Problem: No	
	Outcome to Date: Died Other	
	Date of Death: B6	
Product Information:	Product Name: California Naturals Salmon	
	Product Type: Pet Food	
	Lot Number:	
	Package Type: BAG	
	Possess Unopened Product: No	
	Possess Opened Product: No	
	Storage Conditions: It was stored in an airtight plastic container.	
	Product Use Information:	Description: We fed this food to our dog.
		First Exposure Date: 09/01/2009
		Last Exposure Date: 04/01/2018
		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: online sites	
	Address: United States	
Animal Information:	Name: B6	
	Type Of Species: Dog	

	Type Of Breed: Poodle - Standard
	Gender: Female
	Reproductive Status: Neutered
	Weight: 50 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: UCDavis
	Contact: Name: [Redacted]
	Phone: [Redacted]
	Other Phone: [Redacted]
	Email: [Redacted]
	Address: [Redacted] San Diego California 92121 United States
	Type of Veterinarian: Referred veterinarian
	Date First Seen: 09/23/2016
Permission to Release Records to FDA: Yes	
Sender Information:	Name: [Redacted]
	Address: [Redacted] United States
	Contact: Phone: [Redacted]
	Other Phone: [Redacted]
	Email: [Redacted]
	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-359689

ICSR: 2052329
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: 2018-07-18 16:23:26 EDT
Reporter is the Animal Owner: Yes

Reported Problem:
Problem Description: B6 began swelling in the belly area, and appeared to be losing weight. we thought it was from the puppy making him active and playing that we got 6 months prior to obtaining diagnosis. upon learning it was dilated cardiomyopathy, our vet stated this condition was rare to the labrador breed, and could not give definitive answers to what caused this condition. we have been giving him the trio of very expensive meds (can only remember the B6
Date Problem Started: 07/05/2017
Concurrent Medical Problem: No
Outcome to Date: Worse/Declining/Deteriorating

Product Information:
Product Name: Iams Proactive Health Minichunks Adult 1+
Product Type: Pet Food
Lot Number:
Package Type: BAG
Package Size: 15 Pound
Possess Unopened Product: No
Possess Opened Product: No
Storage Conditions: in an air tight pet food container on wheels
Product Use Information:
Description: currently being given as the meal source
Last Exposure Date: 07/18/2018
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: walmart
Address: B6
United States

Animal Information: Name: B6

	Type Of Species: Dog
	Type Of Breed: Retriever - Labrador
	Gender: Male
	Reproductive Status: Neutered
	Weight: 89 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
	United States
	Type of Veterinarian: Primary/regular veterinarian
	Date First Seen: 07/01/2018
	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:	

Report Details - EON-361853

ICSR:	2053565			
Type Of Submission:	Initial			
Report Version:	FPSR.FDA.PETF.V.V1			
Type Of Report:	Both			
Reporting Type:	Voluntary			
Report Submission Date:	2018-08-10 16:26:51 EDT			
Reporter is the Animal Owner:	Yes			
Reported Problem:	Problem Description:	Taurine level critically low at B6 for plasma for one dog and B6 for another		
	Date Problem Started:	08/10/2018		
	Concurrent Medical Problem:	No		
	Outcome to Date:	Not Applicable		
Product Information:	Product Name:	Nutrisource Chicken and Pea Formula Grain free dog food, chicken and Chicken meal Protein		
	Product Type:	Pet Food		
	Lot Number:	Lot Number:	8D03P16233	
		Expiration Date:	10/02/2019	
	UPC:	073893290018		
	Package Type:	BAG		
	Package Size:	15 Pound		
	Purchase Date:	07/09/2018		
	Number Purchased:	1		
	Possess Unopened Product:	No		
	Possess Opened Product:	Yes		
	Storage Conditions:	Original bag in cool/dry place		
	Product Use Information:	Description:	Given as normal feeding twice per day	
		First Exposure Date:	08/06/2018	
		Last Exposure Date:	08/06/2018	
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:		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	
Product Name:	Nutrisource Lamb Meal and Peas Formula, Grain Free Dog Food, Lamb Meal and Salmon Meal Protein		
Product Type:	Pet Food		
Lot Number:	Lot Number:	8B20P12272	
	Expiration Date:	08/21/2019	
UPC:	073893291008		
Package Type:	BAG		
Package Size:	30 Pound		
Purchase Date:	08/02/2016		
Number Purchased:	1		
Possess Unopened Product:	No		
Possess Opened Product:	Yes		
Storage Conditions:	Stored in original bad in cool/dry place		
Product Use Information:	Description:	Dog food given twice per day	
	First Exposure Date:	08/02/2016	
	Last Exposure Date:	08/06/2018	
	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:	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 - Golden		
	Gender:	Mixed Population of Female and Male		
	Reproductive Status:	Mixed		
	Pregnancy Status:	Not pregnant		
	Lactation Status:	Not lactating		
	Weight:	60 Pound		
	Age:	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:	07/27/2018			
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:	Attachment:	B6	pdf	
	Description:	Lab report of critically low taurine level for plasma		
	Type:	Laboratory Report		
	Attachment:	B6	pdf	
	Type:	Laboratory Report		