

United States Food and Drug Administration**Consumer Complaint / Injury Report**

This is an accurate reproduction of the original electronic record as of 04/30/2025

COMPLAINT # 189298

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
08/13/2024	SAN-DO	PHI-DO	Email	FDA Center	CFSAN_CMS,Int erface	Closed

Complainant Identification

Name	Address
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(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)
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Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6), (b) (7)(C)	CVM EON-590052	

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
<p>Product -raw frozen pet food</p> <p>The complainant contacted the Pet Safety reporting Portal to report the ongoing illness of her dog. She attributes the illness to the food the dog was eating. The dog is a (b) (6), (b) (7)(C) named (b) (6), (b) (7)(C). The complainant stated that prior to this illness the dog was in excellent health. (b) (6), (b) (7)(C) is one of (b) (6), (b) (7)(C) pets that had eaten this food and became ill.</p> <p>Narrative- (b) (6), (b) (7)(C) was admitted to (b) (6), (b) (7)(C) after failure to eat, lethargy and collapse. (b) (6), (b) (7)(C) was diagnosed with acquired fanconi syndrome, gall stones, anemia, elevated liver enzymes and liver hepatopathy amongst other issues attributed to an environmental toxin in the pet food. When (b) (6), (b) (7)(C) closed (b) (6), (b) (7)(C) was transferred to (b) (6), (b) (7)(C) that confirmed the same. On their recommendation for an albumin transfusion (b) (6), (b) (7)(C) was transferred to the (b) (6), (b) (7)(C). They ran more tests but could not perform the transfusion so they transferred him to the ER at (b) (6), (b) (7)(C). (b) (6), (b) (7)(C) diagnosed (b) (6), (b) (7)(C) with elevated liver enzymes secondary to a toxin, pancreatitis, low blood proteins, severe anemia (requiring two transfusions), acute diarrhea, fluid in (b) (6), (b) (7)(C) abdomen, elevated bilirubin, low blood sugar, low potassium, low phosphorous, ketones in (b) (6), (b) (7)(C) urine, protein in (b) (6), (b) (7)(C) urine, glucose in (b) (6), (b) (7)(C) urine, acquired fanconi syndrome, bladder and gallstones, blood clots resulting from two strokes, left ventricular dialation, systolic dysfunction, arrhythmias, Lyphangiectasia/PLE, liver hepatopathy, muscle</p>	<p>Life Threatening Injury/Illness</p>	<p>05/16/2024</p>	<p>Other - identify in Remarks</p>

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wasting, vasculitis
and more all subsequent to the toxin. (b) (6) was also diagnosed with
a staph
infection of (b) (6) skin that lead to chemical burns from treatment
and cellulitis
from treatment. (b) (6), (b) (7)(C) has resolved the clot in (b) (6) right front leg
but not
regained full feeling and mobility. (b) (6) has permanent scarring from
catherization. (b) (6), (b) (6) ears toenails and toes are falling off
progressively Continued in Remarks

Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
No	08/16/2024	Yes	Yes	Yes		

Remarks

continued from Description: (b) (6), (b) (7)(C) is currently doing preliminary toxicology. Additional reports will be made for additional animals diagnosed. I requested a call back numerous times to the FDA regional manager as I was in (b) (6), (b) (7)(C) for two months with the dogs in the hospital without a laptop. Never got a call. I cannot attach all the vets that have confirmed this case is related to a toxin in the pet food. I cannot attach all the medical records to this case. (b) (6), (b) (7)(C) cannot perform all the testing to isolate the toxin and said you would reach out to them if you wanted more testing. All vets claim they have made reports with the FDA. No one received any form of communication from the FDA."

Product handling:
product was purchased frozen and delivered to my home.
It was thawed in the refrigerator for 3 hours and portioned
into plastic cups with lids, placed into a zip lock bag and
then placed in the freezer. it was thawed in individual two
ounce containers for one hour immediately prior to
feeding. it was served in a stainless-steel bowl washed
with hot water and dawn dish soap in between use.
(b) (6), (b) (7)(C) was being fed 2 ounces of food up from (b) (6)
previous 1 ounce due to weight loss for several weeks
prior to diagnosis.

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Change in activity level (hyperactivity/lethargy)	NERVOUS			lethargy
Change in appetite	GASTROINTESTINAL			failure to eat
Unconsciousness/coma	NERVOUS			collapse

Health Care Professional

Provider Name	Address	Phone	Occupation
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	Veterinarian
(b) (6), (b) (7)(C) - (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	Veterinarian

Hospital Information

Hospital Name	Address	Phone	Dates of Stay
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Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
(b) (6), (b) (7)(C)		(b) (6), (b) (7)(C)	

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Answers Pet Food	Straight Formula Beef	72BFD01	Meat (Mammalian Muscle) Prod Pet Dog Food;Paper;Raw - Fresh, Frozen, Natural State	71R801	

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
4 Pounds Box		Jan 31 2026	4/13/2024	No	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Product Recalled?	Country of Origin	Label Remarks
April and May 2024	05/16/2024		No	No		Expiration date obtained from Sample collection at Distributor 8/22/24

Retail

Name	Address
(b) (6), (b) (7)(C)	

Problem Ingredient Group**Manufacturer/Distributor**

FEI	Name & Address	Home District	Firm Type
(b)(4)	(b)(4)	(b)(4)	Manufacturer
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	Manufacturer

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	acquired fanconi syndrome, gall stones, anemia, elevated liver enzymes and liver hepatopathy amongst

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Surveillance Information for Next EI	Anderson,Danielle	09/30/2024
Initial Disposition Remarks			

Referrals

Org Name	HHS Mail Code
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There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

Related Complaints

COMPLAINTS FOLLOW - UP**Grouped Follow - Up Operations**

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
12231377	12	12347001	HAFE2	HAFE2-GRP5			Completed	10/11/2024

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
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Follow-Up Disposition	Disposition Made By	Disposition Date
Recall	Cheung,Raymond L	10/11/2024

Disposition Remarks

Consumer complaint numbers 189298, 189299, and 189300 were filed with the FDA and derives from the same owner spanning (b) (6), (b) (7) dogs. This complaint states a dog became ill with malaise, lethargy, vomiting and diarrhea after consuming Answer Pet Food brand raw, ready-to-eat Straight Beef Formula pet food. The pet was reported to be hospitalized for supportive care and diagnostic testing. These complaints were received during the inspection. The FDA sampled two (2) lots of ready-to-eat (b)(4) pet food from a distributor in (b)(4). Sample 1270739 is (b)(4) Lot Jan 31, 2026, was positive for *Listeria monocytogenes*.

On 10/03/2024, Investigators Covill and Nardelli reviewed the batch records for these lots. Discrepancies with the firm's production and sanitation procedures are documented on a Form FDA 483.

According to Mr. Shawver and Mr. Strawser, they were not aware of the consumer complaints until the compliance calls with FDA on 08/27/2024. They have requested left over samples from these lots from the FDA. They sent samples to (b)(4) for analysis. The results are pending.

Follow-Up Sent To

Organization Name	HHS Mail Code
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