

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 # 189299

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
08/14/2024	SAN-DO	PHI-DO	Email	FDA Center	CFSAN_CMS,Int erface	Closed

Complainant Identification**Name** **Address**

(b) (6), (b) (7)(C) (b) (6), (b) (7)(C)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6), (b) (7)(C)	CVM EON-590079 and EON 590080	

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
-----------------------	----------------------	--------------------	------------------

Product Frozen Raw pet food

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. She is one of (b) (6), (b) (7)(C) pets that had eaten this food and became ill. Narrative (b) (6), (b) (7)(C) was placed on supportive care for suspected toxicosis caused by ingestion of an environmental toxin was confirmed on two of her housemates on the same food. Vets speculated that since she had previous incidents of undefined GI upset at the same time on different batches of the same brand and subtype of food acute poisoning was intermittent but on going and may have caused mitral valve degeneration along with GI Upset. Many symptoms of illness are only able to be visible on diagnostic testing like bloodwork, urinalysis and ultrasound and show no physical symptoms until the dogs condition progresses to a point death is imminent. (b) (6), (b) (7)(C) had been on a rotation of Answers food products prior to and up to her diagnosis of Toxicosis. Her diagnosis was officially made once she received her blood test and urinalysis two weeks after starting supportive care for acquired fanconi syndrome and was based on elevated liver enzymes, pancreatitis and hepatopathy of the liver in conjunction with prior diagnosis of mitral valve

Non-Life
Threatening
Injury/Illness

05/16/2024

Other - identify
in Remarks

degeneration, unspecified GI Upset, Polydipsia, weight loss, and anorexia consistent with the symptoms of the other dogs affected. Liver enzymes have been improving, pancreatitis is now believed to have developed into a chronic condition following the repeated insults to pancreas from the food.

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		

Remarks

Continued from Description-Nicotine, Theobromine and Caffeine have been identified in one of the types of answers pet food she was on leading up to injury. the majority of results are not in. (b)(4) is doing preliminary toxicology. see companion pet safety report ID 393974 and 403130. date listed as date problem started is date of diagnosis for toxicosis on the first dog identified."

Illness - suspected toxicosis, possible Fanconi's syndrome

Product Handling- Arrived Frozen, Thawed in refrigerator for 2-4 hours and portioned into sealed single use 2 oz cups. then placed in a ziplock bag in the freezer. individual portions removed and left to thaw at room temperature one hour prior to feeding. fed in a stainless-steel bowl that was washed with hot water and dawn dish soap between feedings. fed two 2 oz meal daily in rotation with other answers products listed on this form

This pet also ate the Chicken variety of the food, Answers Pet Food Raw Chicken Straight Formula. This food was consumed 3/29/24-5/01/24 and reaction onset time was the same - 5 minutes. She also ate the Raw Beef Detailed consumed 05/15/2024 - 05/17/2024 and reaction onset time was the same.

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Other gastrointestinal	GASTROINTESTINAL	immediate		undefined GI upset

Health Care Professional

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

Hospital Information

Hospital Name	Address	Phone	Dates of Stay
---------------	---------	-------	---------------

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
----------------------	----------------	--------------	----------------

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Answers Pet Food	Raw Beef Detailed Formula	72BFD01	Meat (Mammalian Muscle) Prod Pet Dog Food;Paper;Raw - Fresh, Frozen, Natural State	71R801	856554002102

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
4 Pounds Box		Nov 8 2025	4/13/2024	No	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Product Recalled?	Country of Origin	Label Remarks
April and May 2024	5/13/24		No	No		Expiration date supplied by complainant.

RetailProblem Ingredient Group

Name	Address
-------------	----------------

(b) (6), (b) (7)(C)

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b)(4)	(b)(4)	(b)(4)	Manufacturer
(b)(4)	(b)(4)	(b)(4)	Manufacturer

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	GI problems

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

Initial Disposition RemarksReferrals

Org Name	HHS Mail Code
-----------------	----------------------

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
--------------------------	-----------------	---------	------	-----------

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 the dog became ill with lethargy and gastrointestinal symptoms including being close to death after consuming Answer Pet Food brand raw, ready-to-eat Detailed Beef pet food. These complaints were received during the inspection. The FDA sampled one lot of Detailed Beef from a distributor in (b)(4). The results were reported as follows:

Sample 1270738 is Detailed Beef Lot May 06, 2026, was positive for Salmonella newport and Listeria monocytogenes. This product was produced two (2) days before a firm initiated environmental (b)(4) swabbing event that was reported positive for Listeria sp. The firm did not appreciate the positive result.

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
-------------------	---------------