

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 | # **189300**

| Complaint Date | Receiving Organization | Accomplishing District | How Received | Complaint Source | Complaint Received By | Complaint Status |
|----------------|------------------------|------------------------|--------------|------------------|-------------------------|------------------|
| 08/16/2024 | 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-590171 | |

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 (b) (6), (b) (7)(C) dog. (b) (6), (b) (7)(C) 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 (b) (6), (b) (7)(C) pets that had eaten this food and became ill.

Narrative (b) (6), (b) (7)(C) was presented to (b) (6), (b) (7)(C) following four vets concurring (b) (6), (b) (7)(C) housemate, (b) (6), (b) (7)(C), had experienced a toxic event due to an unknown poison in the dog food on May 20th 2024 despite having no clinical symptoms. See Pet Safety Report ID 393974. Following a workup by (b) (6), (b) (7)(C) was diagnosed with acquired fanconi syndrome, elevated liver enzymes, liver hepatopathy and severe anemia. (b) (6), (b) (7)(C) was brought home and received supportive care without patient labs until (b) (6), (b) (7)(C) showed clinical signs of illness in June attributed to prolonged side effects of the suspected toxin by (b) (6), (b) (7)(C). (b) (6), (b) (7)(C) was released from the hospital and on recheck was hospitalized again due to low platelets. (b) (6), (b) (7)(C) recommended (b) (6), (b) (7)(C) have a liver biopsy performed to isolate the toxin. They improperly submitted the request to the surgical department and failed to contact toxicology and it was never performed. By the time they got around to addressing the issue they theorized the toxin had cleared (b) (6), (b) (7)(C) system. (b) (6), (b) (7)(C) was released and on subsequent rechecks by (b) (6), (b) (7)(C) liver enzyme elevations have resolved along

Non-Life
Threatening
Injury/Illness

05/20/2024

Other - identify
in Remarks

with (b) (6),
 acquired fanconi syndrome symptoms and anemia. Toxicology is
 pending at
 (b) (6), (b) (7)(C) at (b) (6), (b) (7)(C) but one of the varieties of answers pet food
 (b) (6), was on
 did show nicotine, caffeine and theobromine on mass
 spectrometry." 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 | No | | |

Remarks

Continued from Description - "The caffeine and theobromine can be attributed to a manufacturing error in the cultivation of the green tea kombucha used to ferment the food as they are both present in green tea leaves used to make the kombucha referenced on the answers pet food website. (b) (6), (b) (7)(C) does not do quantitative analysis and has hoped the FDA would step in and do additional testing. Calls have been being made to the regional manager for the FDA for three months' time with no follow up. I will be doing additional independent testing once preliminary results are in from (b) (6), (b) (7)(C). All dogs in these cases are suspected to have been progressively poisoned by their pet food over a long duration but I am listing each dog's problem start date as the date of diagnosis for suspected toxin ingestion."

Illness Acquired Fanconi 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 dog also ate the same brand but different flavor-Answers Pet Food Raw Beef Straight and Raw Beef Detailed formulas
 purchased on 4/13/2024.

Complaint Symptoms

| Symptom | System Affected | Onset Time | Duration | Remarks |
|---------|-----------------|------------|----------|---------|
|---------|-----------------|------------|----------|---------|

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) | Veterinarian |

Hospital Information

| | | | |
|----------------------|----------------|---------------------|----------------------|
| Hospital Name | Address | Phone | Dates of Stay |
| (b) (6), (b) (7)(C) | | (b) (6), (b) (7)(C) | |

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 ChickenStraight 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 | 004 135347 | Jan 02 2026 | 03/29/2024 | No | |

| | | | | | | |
|------------------|--------------------------|------------------------|--------------------------|--------------------------|--------------------------|--|
| Date Used | Date Discontinued | Amount Remained | Imported Product? | Product Recalled? | Country of Origin | Label Remarks |
| 4/02/2024 | 05/08/2024 | | No | No | | Expiration date obtained from Sample collection at Distributor 8/22/24. Second sample for same product expiration Mar 11 2026. |

Retail

| | |
|-------------|----------------|
| Name | Address |
| (b)(4) | |

Problem Ingredient Group**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 | acquired Fanconi Syndrome |

| | | | |
|---------------------------|--------------------------------------|----------------------------|-------------------------|
| 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

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)(C) dogs. This complaint states a dog became ill after consuming Answer Pet Food brand raw, ready-to-eat Straight Chicken Formula pet food. These complaints were received during the inspection. The FDA sampled two (2) lots from a distributor in (b) (4). The results were reported as follows:

Sample 1270740 is Straight Chicken Lot Jan 02, 2026, was positive for Salmonella Kentucky.

Sample 1270741 is Straight Chicken Lot Mar 11, 2026, was positive for Salmonella Typhimurium.

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 |
|-------------------|---------------|
|-------------------|---------------|