

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

This is an accurate reproduction of the original electronic record as of 01/12/2015

| | |
|------------------|-----------------|
| COMPLAINT | # 139723 |
|------------------|-----------------|

| Complaint Date | Receiving Organization | Accomplishing District | How Received | Complaint Source | Complaint Received By | Complaint Status |
|-----------------------|-------------------------------|-------------------------------|----------------------------|-------------------------|------------------------------|-------------------------|
| 01/08/2015 | NYK-DO | NYK-DO | Other, identify in Remarks | Consumer | Allen, Vera L | Follow Up Requested |

Complainant Identification

| Name | Address |
|-------------|----------------|
| | (b) (6) |

| Phone (W) | Phone (H) | Source POC Name | Source Phone |
|------------------|------------------|------------------------|---------------------|
| | (b) (6) | | |

Complaint/Injury

| Complaint Description | Adverse Event Result | Adverse Event Date | Injury / Illness |
|---|---------------------------------|---------------------------|-------------------------|
| CVM forwarded EON-192800 to NYK-DO for follow up. Complainant believes Primal Pronto Formula Wholesome Raw Foods for Cats (Turkey) is cause for her cat's symptoms. (b) (6) is 11 year old male Domestic Shorthair Neutered cat weighing 12.9lbs having known skin allergies effecting him off and on. There is another pet in the household which consumed same foods however did not experience any symptoms. Information about second pet was not provided in the report. Product is raw. Prior to feeding, complainant thawed product in refrigerator for several hours then fed the product to her pets. After two days of feeding, (b) (6) had lost of appetite and appeared disoriented. He experienced what complainant thought to be a seizure. He went form a standing position to the floor with his paws out to his side, shaking and crying out in pain. Complainant visited ER where many tests were performed to include MRI. All results were negative and/or normal. After no brain tumor or cancer was noted, Doctors diagnosed Thiamine deficiency. (b) (6) was treated with Thiamine supplements. Symptoms ceased and he responded well to treatment. | Life Threatening Injury/Illness | 10/12/2014 | Seizures |

| Notify DEIO/EMOPS? | Notification Date | Attended Health Professional? | Required Hospitalization? | Emergency Room / Outpatient Visit? | Reported Complaint To? | Need addnl. FDA Contact? |
|---------------------------|--------------------------|--------------------------------------|----------------------------------|---|-------------------------------|---------------------------------|
| Yes | 01/08/2015 | No | No | Yes | Not Reported to Manufacturer | r |

Remarks
EON-192800

Complaint Symptoms

| Symptom | System Affected | Onset Time | Duration | Remarks |
|----------------------|------------------|------------|----------|---|
| Change in appetite | GASTROINTESTINAL | 2 Days | 2 Days | Seemed disinterested in his food |
| Other Neurological | NERVOUS | 2 Days | 2 Days | Appeared disoriented |
| Seizures/convulsions | NERVOUS | 2 Days | 1 Days | From standing position to paws out to sides, shaking and crying out |

Health Care Professional

| Provider Name | Address | Phone | Occupation |
|---------------|---------|-------|------------|
|---------------|---------|-------|------------|

Hospital Information

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

Emergency Room/Outpatient Visit

| Hospital Name | Address | Phone | ER Date |
|---------------|---------|-------|---------|
| | | | (b) (6) |

Product and Labeling

| Brand Name | Product Name | Product Code | Product Description | PAC | UPC Code |
|-----------------------|---------------------------------------|--------------|---|--------|--------------|
| Primal Pronto Formula | Wholesome Raw Foods For Cats (Turkey) | 70YY-99 | Animal Feeds, N.E.C.;Not Elsewhere Classified (NEC) | 71R801 | 850334004140 |

| Qty / Unit / Package | Lot/ Serial # | Exp/Use by Date | Purchase Date | Product Used | Amount Consumed/Used |
|----------------------|---------------|-----------------|---------------|--------------|----------------------|
| 3 Pounds Plastic Bag | 5033400414 | 06/08/2015 | 10/04/2014 | Yes | 1 1/2 BAG |

| Date Used | Date Discontinued | Amount Remained | Imported Product? | Country of Origin | Label Remarks |
|------------|-------------------|-----------------|-------------------|-------------------|---------------|
| 10/10/2014 | 10/12/2014 | 1 Unopened Bag | No | United States | |
| - | 12/12/2014 | | | | |

Retail

| Name | Address |
|------|---------|
| | (b) (6) |

Problem Ingredient Group

Manufacturer/Distributor

| FEI | Name & Address | Home District | Firm Type |
|-----|----------------|---------------|------------------------|
| | (b) (4) | SEA-DO | Manufacturer |
| | | SAN-DO | Corporate Headquarters |

Initial Evaluation/Initial Disposition

Problem Keyword

Problem Keyword Details

Reaction

Lost of appetite, disoriented, partial seizure

Initial Evaluation

Initial Disposition

Disposition Made By

Disposition Date

Initial Disposition Remarks

Manu confirmed from CC 120816***

CVM tasked NYK-DO with collecting remaining product from complainant and a matching retail lot sample if possible from retail store. Samples should be tested for thiamine and any other testing the District deems appropriate.

Referrals

Org Name

HHS Mail Code

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

| Operation Id | Operation Code | Assignment Number | Accomplishing Organization | Performing Organization | Sample Number | PAF | Status | Status Date |
|---------------------|-----------------------|--------------------------|-----------------------------------|--------------------------------|----------------------|------------|---------------|--------------------|
| 7772664 | 13 | 11504645 | NYK-DO | | | | Assigned | 01/09/2015 |
| 7772672 | 31 | 11504645 | NYK-DO | NYK-IB | 832982 | | In Progress | 01/09/2015 |
| 7772674 | 31 | 11504645 | NYK-DO | NYK-IB | 832981 | | In Progress | 01/09/2015 |

Disposition Summary

| Is Consumer Responsible? | Responsible FEI | Address | Name | Firm Type |
|---------------------------------|------------------------|----------------|-------------|------------------|
|---------------------------------|------------------------|----------------|-------------|------------------|

| Follow-Up Disposition | Disposition Made By | Disposition Date |
|------------------------------|----------------------------|-------------------------|
|------------------------------|----------------------------|-------------------------|

Disposition Remarks

Follow-Up Sent To

| Organization Name | HHS Mail Code |
|--------------------------|----------------------|
|--------------------------|----------------------|

| Report Details - EON-192800 | | |
|--|--|--|
| ICSR: | 1037281 | |
| Type Of Submission: | Initial | |
| Report Version: | FPSR.FDA.PETF.V.V1 | |
| Type Of Report: | Adverse Event (a symptom, reaction or disease associated with the product) | |
| Reporting Type: | Voluntary | |
| Report Submission Date: | 2015-01-07 17:03:53 EST | |
| Reporter is the Animal Owner: | Yes | |
| Reported Problem: | Problem Description: On October 12th, (b) (6) seemed disinterested in his food and appeared disoriented. He later cried out as if in pain, and I went to touch him to comfort him and see what was wrong. He fell from a standing position to the floor with his paws out to the sides and began to shake and cry out. What I observed looked like a seizure or partial seizure. Although he had never had an episode like this in his life. He had another so my friend and I took him to the (b) (6) which fortunately is within 2 miles of my home. He was given many tests, and treated, however they referred us to another Specialty Hospital for an MRI of his brain. Brain tumor was suspected. We were referred to the Neurologist on staff. He performed many tests which included the MRI, but found no brain tumor or cancer. He suspected that (b) (6) might have Thiamine deficiency. Once he supplemented (b) (6) with Thiamine, his symptoms ceased to exist. They sent out his test to confirm the diagnosis of thiamine deficiency, and it took close to 6 weeks to get it back. It was however confirmed that the Doctor was correct. He said that the food must have been deficient, even though it says it is a complete feline diet. Thankfully (b) (6) is well, and no longer eating that food, which he was before. | |
| | Date Problem Started: 10/12/2014 | |
| | Date of Recovery: 10/14/2014 | |
| | Concurrent Medical Problem: Yes | |
| | Pre Existing Conditions: He had some skin allergies on and off. | |
| | Outcome to Date: Recovered Completely | |
| Product Information: | Product Name: Primal Formula for Cats (Raw Diet) Turkey | |
| | Product Type: Pet Food | |
| | Lot Number: Lot Number: 5033400414 Expiration Date: 06/08/2015 | |
| | UPC: 8 5033400414 0 | |
| | Package Type: BAG | |
| | Package Size: 3 Pound | |
| | Purchase Date: 10/04/2014 | |
| | Number Purchased: 3 | |
| | Possess Unopened Product: Yes | |
| | Possess Opened Product: Yes | |
| | Storage Conditions: It was stored in the freezer after I bought it. It stayed in the freezer until I needed to defrost some. | |
| | Product Use Information: | Description: It is a raw diet, so you need to defrost the food in the refridge several hours before feeding. I did that and fed him, in his bowl. |
| | | First Exposure Date: 10/10/2014 |
| | | Last Exposure Date: 10/12/2014 |
| Time Interval between Product Use and Adverse Event: 2 Days | | |

| | | | | |
|--|---|-----------------------|---------------|---------|
| | 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: | (b) (6) | | |
| | Address: | | | |
| Animal Information: | Name: | (b) (6) | | |
| | Type Of Species: | Cat | | |
| | Type Of Breed: | Domestic Shorthair | | |
| | Gender: | Male | | |
| | Reproductive Status: | Neutered | | |
| | Weight: | 12.9 Pound | | |
| | Age: | 11 Years | | |
| | Assessment of Prior Health: | Good | | |
| | Number of Animals Given the Product: | 2 | | |
| | Number of Animals Reacted: | 1 | | |
| | Owner Information: | | | |
| | Healthcare Professional Information: | Practice Name: | (b) (6) | |
| | | Contact: | Name: | (b) (6) |
| | | | Phone: | |
| Other Phone: | | | | |
| Email: | | | | |
| Address: | | (b) (6) | | |
| Type of Veterinarian: | | Referred veterinarian | | |
| Date First Seen: | 10/13/2014 | | | |
| Permission to Release Records to FDA: | Yes | | | |
| Sender Information: | Name: | (b) (6) | | |
| | Address: | | | |

| | | | |
|-------------------------------------|--|---------------------|---------|
| | | (b) (6) | |
| | Contact: | Phone: | (b) (6) |
| | | Other Phone: | |
| | | Email: | |
| | 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 Manufacturer | | |
| Additional Documents: | | | |