This is an accurate reproduction of the original electronic record as of 05/23/2012

COMPLAINT

126468

Complaint Receiving Date

Organization

Accomplishing District

How Received

Complaint Source

Complaint Received By

Complaint Status

05/23/2012 ATL-DO

ATL-DO

Telephone

Consumer

Harris, Georgette

Closed

Complainant Identification

Name

Address

(b) (6)(b) (6)(b) (6)(b) (6)(b)

Phone (W)

Phone (H)

Source POC Name

Source Phone

(b) (6)(b) (6)

Complaint/Injury

Complaint Description

Adverse Event Result

Death

Adverse Event Date

5/4/2012

Injury / Illness

Consumer reports death of dog due to consumption of dog food Dog, 14 yro, female, Chihuaha, weighing 5 lbs with a preexisting heart murmur, consumed a combination of Natural Balance, Taste of the Wild and Canadae dog foods. On a normal basis, 1.5 cups of food was consumed daily. Complainant operates a animal rescue service therfore dog food was received from various locations including local donations from varying sources. Dog displayed symptoms of loss of appetite, lethargy and diarrhea.

Notify Notification DEIO/EMOPS?

Date

Attended Required Health Professional? Hospitalization? Emergency Room / Outpatient Visit? Complaint To? FDA Contact?

Reported

Need addnl.

Yes

05/23/2012

Yes

Yes

Remarks

Complaint Symptoms

Sympton

System Affected

Onset Time

Duration

Remarks

Change in appetite

GASTROINTESTINAL 1 Months

Change in activity level (hyperactivity/lethargy)

NERVOUS

1 Months

Diarrhea

GASTROINTESTINAL 1 Months

Health Care Professional

 \mathbf{D}

Provider Name

Address

Phone

Occupation

Veterinarian

Hospital Information

Hospital Name

Address

Phone

Dates of Stay

Date: 05/23/2012

Emergency Room/Outpatient Visit

Hospital Name

Address

Phone

ER Date

(4)(b)(4)(b)(b) (4)(b) (4)(b)

4/8-9/2012

Product and Labeling

Brand Name

Product Name

Product Code Product Description

PAC

UPC Code

Natural Balance

Lamb Bison Venison

72BFH05

Comb Prod Pet Dog Food; Paper; Ntrl/Artfcl Dried 71R801

ukn

Qty / Unit / Package

Lot/ Serial #

ukn

Exp/Use by Date

ukn

Purchase Date

Product Used

Amount

Yes

Consumed/Used 1.5 cup daily

Date Used Date

Amount Remained

Imported **Product?**

Country of Origin

Label Remarks

Mar 2012

Discontinued Apr 2012

none

No

Retail

Problem Ingredient Group

Name

Address

ukn

Manufacturer/Distributor

FEI

Name & Address

Home District

Firm Type

3004348077

Diamond Pet Food Processors of SC, LLC Hwy 321 & Wood Trail ATL-DO

Manufacturer

Drive Gaston South Carolina United States 29053

Initial Evaluation/Initial Disposition

Problem Keyword

Problem Keyword Details

Death

Reaction

lethargy, loss of appetite, diarrhea

Initial Evaluation

Initial Disposition

Disposition Made By

Disposition Date

Violation, Action in Process

Closed without further Investigation

Harris, Georgette P

05/23/2012

Initial Disposition Remarks

No product remaining, no additional product information available.

Referrals

Org Name

HHS Mail Code

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

Date: 05/23/2012

Page: 2 of 3

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Operation Code

Number

Assignment Accomplishing Performing Organization

Sample Organization Number Status

Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer

Responsible Address Name

Firm Type

Responsible? FEI Follow-Up Disposition

Disposition Made By

Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name

HHS Mail Code

This is an accurate reproduction of the original electronic record as of 05/23/2012

COMPLAINT

126246

Complaint Receiving Date

Organization

Accomplishing District

How Received Complaint Source

Complaint Received By Harris, Georgette

Complaint Status

Closed

05/09/2012 ATL-DO

ATL-DO

Telephone

Complainant Identification

Name

Address

b)(6)(b) (6)(b) (6)(b) (6)(b)

Phone (W)

Phone (H)

Source POC Name

Source Phone

(b) (6)(b) (6

Complaint/Injury

Complaint Description

Adverse Event Result Death

Injury / Illness Adverse Event

Date

Apr 6, 2012

Consumer reports 1 death and 1 illness of dogs due to consumption of dog food product. Dog #1, 5 mo, male, not nutured, weighing 18-20 lbs, is an Austrialian Border Collie. Within 2 days of consuming product, he began to experience loss of appetite and bloody diarrhea. Symptoms persisted until death on Apr 6, 2012. Dog was "free-feed" and ate about 4-5 times a day. Dog #2, a Lab mix, spayed female, weighing 80 lbs, age ukn has begun to experience same symptoms as dog #1. She consumed Kirkland Lamb Rice and Vegetable dog food, Lot #KLV0201A2XMS, UPC #096619253500, EXP DT: Mar 26, 2013 from a 40 lb bag. Ate 3 cups of product daily. Symptoms, bloody diarrhea and loss of appetite started on 5/5/2012. Neither dog was seen by a vet. Both products purchased from the (b) (4) on the same day.

Notify Notification DEIO/EMOPS? Date

Attended

Required Health Professional? Hospitalization? Emergency Room /

Reported Need addnl. Outpatient Visit? Complaint To? FDA Contact?

Yes

05/09/2012

No

No

No

Remarks

Complaint Symptoms

Sympton

Diarrhea

System Affected

Onset Time

Duration

Remarks

Change in appetite

GASTROINTESTINAL 2 Days GASTROINTESTINAL 2 Days

until death

bloody

Health Care Professional

Provider Name

Address

Phone

Occupation

Hospital Information

Hospital Name

Address

Phone

Dates of Stay

Date: 05/23/2012

Emergency Room/Outpatient Visit

Hospital Name

Address

Phone

ER Date

Product and Labeling

Brand Name

Product Name

Product Code Product Description

PAC

UPC Code

Kirklands

Puppy Chicken and

Lot/

72BFH05

Comb Prod Pet Dog Food; Paper; Ntrl/Artfcl Dried 71R801

0966191303

13

Rice

Exp/Use

Purchase

Product

Amount

Serial #

by Date

Date

Used

Consumed/Used

20 Pounds Paper Bag

Oty / Unit / Package

KCP0204D32 XRN

Feb 28, 2013

Mar 26, 2012

Yes

some

Date Used Date Discontinued Amount Remained **Imported** Product?

Country of Origin

Label Remarks

Mar 27, 2012

Apr 6, 2012

some

No

Problem Ingredient Group

Retail

Name (b) (4) Address

(b) (4)

Manufacturer/Distributor

FEI

Name & Address

Home District

Firm Type

3004348077

Diamond Pet Food Processors of SC, LLC Hwy 321 & Wood Trail ATL-DO

Manufacturer

Drive Gaston South Carolina United States 29053

Initial Evaluation/Initial Disposition

Problem Keyword

Problem Keyword Details

Reaction

bloody diarrhea, loss of appetite

Initial Evaluation

Initial Disposition

Disposition Made By

Disposition Date

Violation, Action in Process

Closed without further Investigation

Harris, Georgette P

05/09/2012

Initial Disposition Remarks

recalled product

Referrals

Org Name

HHS Mail Code

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

Date: 05/23/2012

Page: 2 of 3

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Operation Assignment Accomplishing Performing Sample PAF Status Status Id Code Number Organization Organization Number Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible Address Name Firm Type

Responsible? FEI

No 3004348077 Hwy 321 & Wood Trail Drive Diamond Pet Food Processors Manufacturer of SC, LLC

Gaston South Carolina United of SC, LL States 29053

Follow-Up Disposition Disposition Made By Disposition Date

Recall Harris, Georgette P 05/09/2012

Disposition Remarks

Follow-Up Sent To

Date: 05/23/2012

Organization Name HHS Mail Code

This is an accurate reproduction of the original electronic record as of 05/23/2012

COMPLAINT

126212

Complaint Receiving Date

Accomplishing Organization District

How Received

Complaint Source

Complaint Received By Complaint Status

05/08/2012 ATL-DO

ATL-DO

Telephone

Consumer

Harris, Georgette

Closed

Complainant Identification

Name

Address

(b) (6)(b) (6)(b) (6)(b) (6)(b)

Phone (W)

Phone (H)

(b) (6)

Source POC Name

Source Phone

Complaint/Injury

Complaint Description

Adverse Event

Result

Death

Adverse Event

Injury / Illness

Date

Consumer reports the death of her dog and cat from what she believes is the consumption of a dog food product. Both consumed the same product. Within a week of consuming product both dog and cat displayed the same symptoms, lethargy, loss of appetite and increased water intake. Dog, 11 yro

Weimariner weighing 50 lbs died on 4/8/2012. Cat, who also occasionally consumed cat food was a 12 yro mixed Siamese, died on 4/27/2012. Neither received medical attention.

Notify DEIO/EMOPS?

Notification Date

Attended

No

Required Health Professional? Hospitalization? Emergency Room / Outpatient Visit? Complaint To? FDA Contact?

Reported

Need addnl.

Yes

05/08/2012

No

No

· No

Remarks

Complaint Symptoms

Sympton

System Affected

Onset Time

Duration

Remarks

Change in appetite

GASTROINTESTINAL 1 Weeks **NERVOUS**

1 Weeks

until death until death

Change in activity level (hyperactivity/lethargy)

Change in thirst or water intake

METABOLIC

1 Weeks

until death

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

Date: 05/23/2012

Product and Labeling

Brand Name

Product Name

Product Code Product Description

PAC

UPC Code

Diamond

Maintenance Adult Dog 72BFH05 Food

Comb Prod Pet Dog Food; Paper; Ntrl/Artfcl Dried 71R801 ukn

Qty / Unit / Package

Lot Serial # Exp/Use by Date

02/22/2013

Product Used

Amount

most

40 Pounds Paper Bag

DMD0104C21

Date ukn

Purchase

Yes

Consumed/Used

XAG 1806

Date Used Date Discontinued Amount Remained

Imported Product?

Country of Origin

Label Remarks

04/02/2012

04/08/2012

little

No

Retail

Problem Ingredient Group

Name

(b) (<u>4</u>)(b) (4)

Address (b)(4)

Manufacturer/Distributor

FEI

Name & Address

Home District

Firm Type

3004348077

Diamond Pet Food Processors of SC, LLC Hwy 321 & Wood Trail ATL-DO

Manufacturer

Drive Gaston South Carolina United States 29053

Initial Evaluation/Initial Disposition

Problem Keyword

Problem Keyword Details

Reaction

decreased appetite, lethargy, excessive thrist

Initial Evaluation

Initial Disposition

Disposition Made By

Disposition Date

Violation, Action in Process

Closed without further Investigation

Harris, Georgette P

05/08/2012

Initial Disposition Remarks

no UPC provided

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 Operation Assignment Accomplishing Performing Sample PAF Status Status Id Code Number Organization Organization Number Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible Address Name Firm Type

Responsible? FEI

Follow-Up Disposition Disposition Made By Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name HHS Mail Code

This is an accurate reproduction of the original electronic record as of 05/17/2012

COMPLAINT

125899

Date

Complaint Receiving Organization District

Accomplishing

How Received Complaint Source

Complaint Received By

Complaint Status

04/18/2012 ATL-DO

ATL-DO

Telephone

Consumer

Harris, Georgette

Follow Up Requested

Complainant Identification

Name

Address

(b)(6)(b) (6)(b)(6)(b) (6)(b)

Phone (W)

Phone (H)

Source POC Name

Source Phone

Date

(b) (6)

Complaint/Injury

Complaint Description

Adverse Event

Adverse Event

Injury / Illness

Result

Apr 8, 2012

Complainant reports death of dog due to consumption of dog food Death product. Dog, Alaskan Husky, female, 9 yro, weighing 40 lbs had no pre-existing health concerns. Within 2 days of consuming food she experienced diarrhea, vomiting, lethargy, fever (106) and increased water intake. All symptoms persisted until death on Apr 8, 2012. Also consumed occasional table scraps. No

nacropsy performed.

Notify DEIO/EMOPS?

Notification

Attended

Required

Emergency Room / Health Professional? Hospitalization? Outpatient Visit? Complaint To? FDA Contact?

Reported

Yes

Date 04/18/2012

Yes

Remarks

Complaint Symptoms

Sympton

Vomiting

System Affected

CARDIOVASCULAR

Onset Time

Duration

Remarks

Change in activity level (hyperactivity/lethargy)

NERVOUS

lethargy

Change in thirst or water intake

METABOLIC

2

GASTROINTESTINAL 2

106

Change in body temperature **Health Care Professional**

Provider Name

Address

Phone

Occupation

(b) (4)(b) (4)

Veterinarian

Hospital Information

Hospital Name

Address

Phone

Dates of Stay

Date: 05/17/2012

Emergency Room/Outpatient Visit

Hospital Name

Address

Phone

ER Date

Product and Labeling

Brand Name

Product Name

Product Code Product Description

PAC

UPC Code

Diamond

Lamb & Rice Formula

72BFB99

Pet Dog Food

71R801

0741986081

N.E.C.;Paper;Heat/Pastor/Retort

77

Qty / Unit / Package

Lot/ Serial # Exp/Use by Date

Purchase Date

Product Used

Amount Consumed/Used

40 Pounds Paper Bag

DLR0102A31

1/10/2013

Mar 2012

Yes

10 lbs

XAN

Date Used Date

Amount Remained Imported Product?

Country of Origin

Label

~Apr 4,

Discontinued

30 lbs

~Apr 6, 2012

2012

No

Remarks

Retail

Name

(b) (4)(b) (4)

Address (b) (4)

Manufacturer/Distributor

FEI

Name & Address

Home District

Firm Type

Problem Ingredient Group

3004348077

Diamond Pet Food Processors of SC, LLC Hwy 321 & Wood Trail ATL-DO

Manufacturer

Drive Gaston South Carolina United States 29053

Initial Evaluation/Initial Disposition

Problem Keyword

Problem Keyword Details

Death

Apr 8, 2012

Initial Evaluation

Initial Disposition

Disposition Made By

Disposition Date

FDA Action Indicated

Immediate Follow-Up

Harris, Georgette P

04/23/2012

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.

Date: 05/17/2012

Page: 2 of 3

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
6098855	31	1401780	ATL-DO	ATL-IB-PH	749114		Completed	05/11/2012
6098855	31	1401780	ATL-DO	ATL-IB-PH	749114		Completed	05/11/2012
6098855	31	1401780	ATL-DO	ATL-IB-PH	749114		Completed	05/11/2012
6133161	13	1407979	ATL-DO	ATL-IB-PH			Completed	05/15/2012

Disposition Summary

Is Consumer Responsible Address

Name

Firm Type

Responsible? FEI

Disposition Made By Follow-Up Disposition

Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name

HHS Mail Code

This is an accurate reproduction of the original electronic record as of 05/23/2012

COMPLAINT

126326

Complaint Receiving Date Organizat

Receiving Accomplishing Organization District

How Received Complaint Source

Complaint Received By Complaint Status

05/14/2012 FLA-DO

ATL-DO

Telephone

Consumer

Adverse Event

Result

Death

Milan,Stephanie

Assigned

Injury / Illness

Gastrointestinal

distress

Complainant Identification

Name

Address

(b) (6)(b) (6)(b) (6)(b) (6)(b) (6)(b) (6)(b) (6)(b) (6)

Phone (W)

Phone (H)

Source POC Name

Source Phone

(b) (6)(b) (6)(b) (6)(b) (6)(b) (6)

727-492-5352

Date

Adverse Event

04/13/2012

Complaint/Injury

Complaint Description

In Mid march the owner's dog a (1/2 German Shepard & 1/2 Golden Retriever) was introduced to "Kirkland Signature Adult Dog Food" for an approximate two week time span. The owner noticed that his dog had started having diarrhea and acting lethargic.

The dog owner went on vacation to GA and took the dog with him; however, the owner left the "Kirkland Signature Adult Dog Food" at home. During the vacation the dog ate an unknown brand of dog food and the dog's health greatly improved. While in GA the owner had his niece, a veterinarian run test on the dog and the dog was given a clean bill of health, (the owner can provide medical records).

Upon returning home the dog was reintroduced to "Kirkland Signature Adult Dog Food". Within a week and a half the dog became ill, lethargic, had diarrhea, had lost of bowels, went into convulsions, and died at (b) (4)(b) (4)(b) (4)(b) (4)

The owner stated he had not made a connection between the dog's food and the dog's death, until this weekend when he received a recall notification from Costco on the "Kirkland Signnature Adult Dog Food". The notification informed him that he may have purchased a recalled lot of "Kirkland Signature Adult Dog Food". He checked the bag of "Kirkland Signature Adult Dog Food" and has a recalled lot.

Notify	Notification	Attended	Required	Emergency Room /	Reported	Need addnl.
DEIO/EMOPS?	Date	Health Professional?	Hospitalization?	Outpatient Visit?	Complaint To?	FDA Contact?
Yes	05/14/2012	Yes	No	No	Not Report to Other Source	

Remarks

The owner and his wife experienced some diarrhea during the time span that they were feed the dog the "Kirkland Signature

Date: 05/23/2012

Adult Dog Food". However, they are not sure if it was just normal everyday incidents or linked to the dog food. Prior to the dog"s death, the dog became lethargic, had diarrhea, lost of bowels, convulsions. No medical test were conducted to link the dog's death to salmonella Infantis.

Complaint Symptoms				,
Sympton	System Affected	Onset Time	Duration	Remarks
Diarrhea	GASTROINTESTINAL			The dog did not have a history of gastrointestinal illness. Dog was on a very strict diet, and no human food. The dog was not allowed outside without supervison.
Death	CARDIOVASCULAR			The dog was rushed to the veterinarian to seek medical treatment; no medical test could be conducted, since the dog died to quickly after arrival at the veterinarian. A necropsy was not conducted.
Change in appetite	GASTROINTESTINAL			The dog stopped eating approximately 3 day's before his death.
Abdominal swelling	BLOOD OR LYMPHATIC		:	The owner stated that when he picked up the dog, to carry the dog to the car and into the veterinarian he noticed that the dogs abdomin appeared to be swollen.
Seizures/convulsions	NERVOUS			On 04/13/2012, the owner came home from work and found the dog on the floor appearing to be having a seizure or in convulsions.
Involuntary Bowel Movement	GASTROINTESTINAL			On 04/13/2012, when the owner lifted the dog to place the dog into the car the dog lost bowl function.
Change in activity level (hyperactivity/lethargy)	NERVOUS			Please see "Complaint Description" for details
Health Care Professional				

Date: 05/23/2012

Address

Provider Name

Occupation 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

Kirkland

Adult Dog Food

72BFH05

Comb Prod Pet Dog Food;Paper;Ntrl/Artfcl Dried 71R801

Signature

Exp/Use

Purchase

Product

Amount

Lot/ Serial #

by Date

Date

Used Yes

Consumed/Used

50 Pounds Paper Bag

Qty / Unit / Package

March 2012

1/4 of the 50lb bag

Date Used Date Discontinued

Amount Remained Imported Product?

Country of Origin

Label Remarks

04/13/2012

3/4 bag

Lableing expected from

consyumer by 05/15/2012

Retail

Problem Ingredient Group

Name (b)(4)(b)

Manufacturer/Distributor

FEI

Name & Address

Home District

Firm Type

3004348077

Diamond Pet Food Processors of SC, LLC Hwy 321 & Wood Trail ATL-DO

Manufacturer

Drive Gaston South Carolina United States 29053

Initial Evaluation/Initial Disposition

Problem Keyword

Problem Keyword Details

Death

Initial Evaluation

Initial Disposition

Disposition Made By

Disposition Date

FDA Action Indicated

Referred to Other FDA District

Milan, Stephanie C

05/15/2012

Initial Disposition Remarks

Potential dog death associated with Salmonella infantis, Diamond Dog Food recalled produict.

Referrals

Org Name

HHS Mail Code

ATL-IB

HFR-SE150

There are no Cosmetics details for this Complaint.

Date: 05/23/2012

Page: 3 of 5

Complaint # ADVERSE EVENT DETAILS Adult Dog Food **Product Name** Product Code 72BFH05

Birth Date Age Gender Race Previous Adv Effects of Product?

Male Yes

Consumption Site Recommended Dosage/Serving Size

Label Indications for Use Home Unknown Photos of label coming

Recommended Duration of Use Product Label Available? Sample Available?

Oral- dog food Yes

Product Ingredients

Duration of Product Used Frequency of Product Used How was Product Taken? Other Other Dog food oral consumption

Remarks

The dog was introduced to "Kirkland Signature Adult Dog Food" for approximate two week, the dog was removed from "Kirkland Signature Adult Dog Food" for two weeks, and then The "Kirkland Signature Adult Dog Food" was reintroduced. During the time spans when the dog was consuming the "Kirkland Signature Adult Dog Food" the dog became ill and eventually died.

Symptoms Occurence

Did event abate after Did symptoms recur after Did symptoms recur after stopping use of product? product reintroduction? using products with same ingredients?

Yes Yes No

Did adverse event result in Did adverse event require intervention Congenital Anomaly? to prevent permanent impairment / damage?

No Yes

Medications / Other Products Used

Medical Test Performed Results

Medical History

Preexisting Conditions Treatment Remarks

Arthritis

Owner will provide Other, identify Owner will provide Hip Dysplasia

Medical Diagnosis Medical Treatment Death

The dog was rushed to the vet to seek medical treatment; no medical test could be conducted, since the dog died to quickly after arrival at the vet. A

necropsy was not conducted.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Operation Assignment Accomplishing Performing Sample PAF Status Status Id Code Number Organization Organization Number Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible Address Name Firm Type

Responsible? FEI

Follow-Up Disposition Disposition Made By Disposition Date

Disposition Remarks

Follow-Up Sent To

Date: 05/23/2012

Organization Name HHS Mail Code