## eri,

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

This is an accurate reproduction of the original electronic record as of 02/03/2009

**COMPLAINT** 

# 74073

Complaint Receiving Date

01/28/2009 ATL-DO

Accomplishing Organization District

How Received Telephone Complaint Source Consumer

Complaint Received By Complaint Status

Herbert, Dellarese Closed

Complainant Identification

Name

Address

ATL-DO

(6)(b)

Phone (W)

Phone (H) (b)

Source POC Name

Source Phone

Complaint/Injury

**Complaint Description** 

Adverse Event

Adverse Event

Injury / Illness

Result

Date

Consumer called to file a complaint on Austin's Peanut butter crackers. She stated that her 17 year old son consumed the product and experienced a series of symptoms.

Non-Life Threatening Injury/Illness - No Adverse Event Reporting

Gastrointestinal distress

Notify DEIO/EMOPS?

Notification Date

Attended

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

Reported

Need addnl.

Yes

01/28/2009

No

No

Yes

Not Reported to Unknown

Manufacture

r

Remarks

Complaint Symptoms

Sympton

System Affected

**Onset Time** 

Duration

Remarks

Diarrhea

**GASTROINTESTINAL** 

Vomiting

**GASTROINTESTINAL PSYCHOPHYSIOLOGI** 

Gastrointestinal, nausea (psychosomatic)

C

**Health Care Professional** 

**Provider Name** 

Address

Phone

Occupation

Hospital Informatio

**Hospital Name** 

Address

Phone

**Dates of Stay** 

Date: 02/03/2009

Page: 1 of 3

## Emergency Room/Outpatient Visit

Hospital Name

Address

Phone

**ER Date** 

1/15/2009

Product and Labeling

**Brand Name** 

**Product Name** 

**Product Cod** 

**Product Description** 

PAC

**UPC Code** 

Austin's

Peanut Butter Crackers

03GGT01

Peanut Butter Filled Crackers; Plastic, 03R801

7978340612

Synth; Packaged Food (Not

5

Commercially Sterile)

Qty / Unit / Package ·

Lot/ Serial # Exp/Use

Purchase Date

**Product** 

Amount

10 Count Other,

Po7249AV

by Date none

1/12/2009

Used No

Consumed/Used 4 count

identify in Label

Remarks

Date

Used

Date Amount Discontinued

**Imported** 

Country of Origin

Label

1/15/2009

1/15/2009

Remained 5 count

Product? No

Remarks individually wrapped

Retail

**Problem Ingredient Group** 

Address

Manufacturer/Distributor

FEI

Name & Address

**Home District** 

Firm Type

1026111

Kellogg's Snacks 1 Quality Lane Cary North Carolina United

ATL-DO

Manufacturer

States 27513-2001

Initial Evaluation/Initial Disposition

Problem Keyword

**Problem Keyword Details** 

Reaction

cramps, vomiting, nausea

**Initial Evaluation** 

Initial Disposition

Disposition Made By

**Disposition Date** 

Violation, Action in Process

Closed without further Investigation

Harris, Georgette P

01/29/2009

**Initial Disposition Remarks** 

recall

Referrals

Org Name

**HHS Mail Code** 

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

Date: 02/03/2009

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Complaint #74073

## 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 1026111 1 Quality Lane Cary North Kellogg's Snacks Manufacturer

Carolina United States 27513-

2001

Follow-Up Disposition Disposition Made By Disposition Date

Recall Harris, Georgette P 01/29/2009

**Disposition Remarks** 

Follow-Up Sent To

Organization Name HHS Mail Code