

U.S. Food and Drug Administration
**Office of Emergency
Operations**

Consumer Complaints

Joan Trankle

National Consumer Complaint Coordinator

Consumer Complaints

- Post marketing surveillance
- Lead to product recalls
- Provide surveillance information for future inspections
- Preventative actions by manufacturers

Complaints about....

- Filth, foreign objects, off odor/ color/ taste
- Rodent parts
- Illness
- Suspected tampering
- Labeling issues

Consumers contact:

- 19 FDA District Offices – nationwide
- 1 consumer complaint coordinator per District
- Consumers contact local FDA office
- Consumers contact FDA HQ – Office of Emergency Operations (OEO)

Consumers contact:

- Office of Emergency Operations manages FDA's 24 hr. telephone number
- Tel. 301-443-1240 or 1-888-463-6332
- OEO Emergency Coordinators and HQ volunteers handle "emergency" calls received after hours.

Follow up needed?

- Illness/injury that appears to be attributed to specific product.
- What is the health hazard?
- Is the problem likely to be isolated or widespread?
- Is more information needed to evaluate the complaint?

Follow up needed

- Infant formula and baby food complaints
- Suspected product tampering
- Allergic reactions – undeclared allergens
- Illness – if suspect food identified

Complaint follow up

- FDA complaint follow up

Product samples – consumers, retailers, manufacturers

Investigations

- visit / interview consumer
- visit store where purchased
- collect medical records

Inspections – manufacturing plants

Determine manufacturer

- maintain informal list of firms code breakdowns
- maintain contact names and phone numbers for companies
- information needed to identify manufacturing plants.

FACTS complaint reports

Electronic reporting into FACTS --
National operational database for:

- consumer complaints
- sample collections
- inspections/investigations

FACTS Complaints

- Complaint report should include:
 - complete description of the product;
 - lot number and expiration date;
 - firm identified on label

Need this information to identify manufacturing plant and production date.

FACTS Complaints

- Once entered into FACTS, complaint can be viewed by anyone with FACTS account
- Complaint is linked to manufacturing plant
- View each manufacturer's complaints
- Spot complaint trends

When to alert Office of Emergency Operations (OEO)

- ALL infant formula and baby food
- Food illness or injury of significance
- Food allergic reactions
- Dietary supplement adverse events
- Suspect tampering

OEO Complaint Review

- Review complaints daily
 - Product/problem clearly identified
 - Follow up assigned?
 - Correct mfr. identified?
 - Does complaint warrant CFSAN notification?

OEO Complaint Review

- Identify complaint trends
 - multiple complaints / same product/problem
- Alert field and headquarters to trends and need for follow up

FY 2006 Complaints

- 4,942 complaints (all regulated products)
- 1,641 (33%) were adverse events
- Range from 4,600 to 6,000 per year
- Over 18,000 pet food complaints in FY 07 to date – melamine related

Complaints – FY 06

Foods	70%
Drugs	9%
Medical Devices	4%
Dietary supplements	4%
Veterinary medicine	3%
Cosmetics	2%
Unclassified	6%

Recent incidents

- Sept. 2006: E. coli 0157H7 (spinach)
- Feb. 2007: Salmonella Tennessee (peanut butter)
- March 2007: Melamine and melamine-compounds (pet food and other products)

E. Coli 0157H7, Spinach – Sept. 2007

- Complaints received by FDA: 194
- 205 confirmed illnesses & 3 deaths
- Fields identified where spinach grown
(Environmental samples in field matched outbreak strain.)
- Risk factors: wild pigs, proximity of irrigation wells, and surface waterways exposed to feces from cattle and wildlife

Salmonella Tennessee, peanut butter – Feb. 2007

- Peter Pan and Great Value brands
- Complaints received by FDA: 557
- Timeline:
 - **Feb. 13** (4:30 pm) – CDC notification
 - **Feb. 13** evening – mfr. plant identified
 - **Feb. 14** FDA initiates inspection
 - **Feb. 14** – FDA issues press

Salmonella Tennessee, peanut butter – Feb. 2007

- **Feb. 15** – FDA learns product shipped to 64 countries. Foreign countries notified.
- **Feb. 21** – FDA laboratory conference call: CDC, state/local H.D./FDA labs – discuss sample results and methodology.

Salmonella Tennessee, peanut butter – Feb. 2007

- **Feb. 23** – FDA learns bulk peanut butter sold for mfr. of ice cream toppings
- **April 6** – firm reports leaky roof and faulty sprinkler were likely root cause of salmonella contamination
- **June 4** – CDC reports number ill: 628

Pet food – melamine – March 2007

- **March 2007** – Pet Food
- Complaints received by FDA: 18,000+ in less than 3 months
- Wheat gluten from China
- Rice Protein Concentrate from China
- Melamine and Cyanuric acid combination and other related compounds

Pet food – melamine – March 2007

- Acute kidney failure and death
- 58% of complaints reported into FACTS involve pet deaths
- continue to receive complaints and collect consumer samples
- Agency needs on-line complaint reporting system

The (Food)Borne Identity:

As presented by Joan Trankle at the Great Lakes Border Health Initiative Conference, June 15, 2007.

THANK YOU!

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U.S FDA

Office of Emergency Operations

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FDA's Consumer Complaint Coordinators

To report adverse reactions or other problems with FDA-regulated products, contact the FDA district office consumer complaint coordinator for your geographic area. If you require the use of a Relay Service, please call the Federal Relay Services (1-800-877-8339). This is a toll free relay service to call Federal agencies from TTY devices.

Alabama--866-289-3399
Alaska--(425) 483-4949
Arizona--(949) 608-3530
Arkansas--(214) 253-5200, ext. 5233
California (Northern)--(510) 337-6741
California (Southern)--(949) 608-3530
Colorado--(303) 236-3044
Connecticut--(781) 596-7700
Delaware--(215) 597-9064
District of Columbia--(410) 779-5713
Florida -- (866) 337-6272
Georgia--(404) 253-1161
Hawaii--(510) 337-6741
Idaho--(425) 483-4949
Illinois--(312) 353-7840
Indiana--(313) 393-8100
Iowa--(913) 752-2440
Kansas--(913) 752-2440
Kentucky--(513) 679-2700, ext. 124
Louisiana--866-289-3399
Maine--(781) 596-7700
Maryland--(410) 779-5713
Massachusetts--(781) 596-7700
Michigan--(313) 393-8100
Minnesota--(612) 758-7221
Mississippi--866-289-3399
Missouri--(913) 752-2440
Montana--(425) 483-4949
Nebraska--(913) 752-2440
Nevada--(510) 337-6741
New Hampshire--(781) 596-7700
New Jersey-- (973) 331-4917
New Mexico--(303) 236-3044
New York -- (718) 340-7000 ext 5588
North Carolina--(404) 253-1161
North Dakota--(612) 758-7221
Ohio--(513) 679-2700, ext. 124
Oklahoma--(214) 253-5200, ext. 5233
Oregon--(425) 483-4949

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South Dakota--(612) 758-7221
Tennessee-- 866-289-3399
Texas--(214) 253-5200 ext. 5233
Utah--(303) 236-3044
Vermont--(781) 596-7700
Virginia--(410) 779-5713
Washington--(425) 483-4949
West Virginia--(410) 779-5713
Wisconsin--(612) 758-7221
Wyoming--(303) 236-3044
Puerto Rico, U.S. Virgin Islands--800-332-0127