The (Food)Borne Identity:

**U.S. Food and Drug Administration**

**Office of Emergency Operations**

**Consumer Complaints**

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National Consumer Complaint Coordinator

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**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

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Foods</td>
<td>70%</td>
</tr>
<tr>
<td>Drugs</td>
<td>9%</td>
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<tr>
<td>Medical Devices</td>
<td>4%</td>
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<tr>
<td>Dietary supplements</td>
<td>4%</td>
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<tr>
<td>Veterinary medicine</td>
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<td>Cosmetics</td>
<td>2%</td>
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<tr>
<td>Unclassified</td>
<td>6%</td>
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</tbody>
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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
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
Pennsylvania--(215) 597-9064
Rhode Island--(781) 596-7700
South Carolina--(404) 253-1161
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