How Poisoning Cats and Dogs Changed the FDA

American Society for Quality, Section 509 Seminar
July 26, 2012
FDA/Center for Veterinary Medicine
How Poisoning Cats and Dogs Changed the FDA (or at least how it changed CVM)

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Menu Foods notifies KAN-DO of recall
10 “taste” animals died from kidney failure
Numerous complaints about their feed
Diethylene glycol negative
Believes caused by wheat gluten
KAN-DO will inspect tomorrow
Timeline

- March 16 – Firm announces recall
Timeline

• March 16 – Firm announces recall
• March 23 – NYS Ag announces aminopterin
Timeline

• March 16 – Firm announces recall
• March 23 – NYS Ag announces aminopterin
• March 30 – FDA/Cornell announces melamine
Melamine
Timeline

- March 16 – Firm announces recall
- March 23 – NYS Ag announces aminopterin
- March 30 – FDA/Cornell announces melamine
- April 15 – Firm informs FDA of suspicious rice protein
Suspicious Rice Protein Shipment
Timeline

• March 16 – Firm announces recall
• March 23 – NYS Ag announces aminopterin
• March 30 – FDA/Cornell announces melamine
• April 15 – Firm informs FDA of rice protein
• April 21 – FDA informed pet food feed to pigs
Timeline

- March 16 – Firm announces recall
- March 23 – NYS Ag announces aminopterin
- March 30 – FDA/Cornell announces melamine
- April 15 – Firm informs FDA of rice protein
- April 21 – FDA informed pet food feed to pigs
- April 24 – Cyanuric acid identified
Melamine

Cyanuric Acid
Timeline

- March 16 – Firm announces recall
- March 23 – NYS Ag announces aminopterin
- March 30 – FDA/Cornell announces melamine
- April 15 – Firm informs FDA of rice protein
- April 21 – FDA informed pet food feed to pigs
- April 24 – Cyanuric acid identified
- April 24 – No Import Alert needed/screening is used
Timeline

- March 16 – Firm announces recall
- March 23 – NYS Ag announces aminopterin
- March 30 – FDA/Cornell announces melamine
- April 15 – Firm informs FDA of rice protein
- April 21 – FDA informed pet food feed to pigs
- April 24 – Cyanuric acid identified
- April 24 – No Import Alert needed/screening is used
- April 26 – Bioterrorism Act invoked for first time
Timeline

• March 16 – Firm announces recall
• March 23 – NYS Ag announces aminopterin
• March 30 – FDA/Cornell announces melamine
• April 15 – Firm informs FDA of rice protein
• April 21 – FDA informed pet food feed to pigs
• April 24 – Cyanuric acid identified
• April 24 – No Import Alert needed/screening is used
• April 26 – Bioterrorism Act invoked for first time
• April 27 – Import Alert - all Chinese vegetable protein
Timeline

- March 16 – Firm announces recall
- March 23 – NYS Ag announces aminopterin
- March 30 – FDA/Cornell announces melamine
- April 15 – Firm informs FDA of rice protein
- April 21 – FDA informed pet food feed to pigs
- April 24 – Cyanuric acid identified
- April 24 – No Import Alert needed/screening is used
- April 26 – Bioterrorism Act invoked for first time
- April 27 – Import Alert - all Chinese vegetable protein
- May 1 – FDA informed pet food fed to chickens
Timeline

- March 16 – Firm announces recall
- March 23 – NYS Ag announces aminopterin
- March 30 – FDA/Cornell announces melamine
- April 15 – Firm informs FDA of rice protein
- April 21 – FDA informed pet food feed to pigs
- April 24 – Cyanuric acid identified
- April 24 – No Import Alert needed/screening is used
- April 26 – Bioterrorism Act invoked for first time
- April 27 – Import Alert - all Chinese vegetable protein
- May 1 – FDA informed pet food fed to chickens
- **May 1 – Melamine/Cyanuric Acid complex identified**
Melamine – everyday use

it's all about me! personalize it!

Make Your Own Melamine Plate
BPA-Free
$16.00

Qty: 1

Here is a keepsake that children will enjoy creating and parents can treasure for a lifetime. Seriously, here at MODERN LOLA we have one that is 18 years old and still looks great. Not to mention is a regular at the table. (Check out Sam picture!)

Make a new one every year and have a colorful unique collection made by your very own petite designer. A MODERN LOLA favorite!

How it works:
- Simply have your child color his/her favorite picture onto each of the 5 pre-cut paper circle templates, keeping in mind not to draw close to the edge.
- Pick your favorite drawing (1pc only) and place it inside the enclosed envelope.
- Fill out the “Official Processing Certificate” and enclose.
Cyanuric Acid – everyday use
May 1, 2007

Melamine

Cyanuric Acid
Melamine:Cyanurate Complex
Triazine Crystals
Triazone Crystals
Triazine Crystals
Triazines

Melamine

Cyanuric Acid

Ammeline

Ammelide
Triazines in Wheat Gluten

Normal  Contaminated
FDA’s Response

• FDA Amendments Act (FDAAA) of 2007
FDA’s Response

• FDA Amendments Act (FDAAA) of 2007
  – Effective Recall Communication
  – Reportable Food Registry
  – Early Warning Surveillance System for Pet Animals
  – Pet Food Ingredient Definitions
  – Pet Food Processing Standards
  – Pet Food Labeling Standards
FDA’s Response

- FDA Amendments Act (FDAAA) of 2007
- Food Safety Modernization Act (FSMA) of 2011
FDA’s Response

- Food Safety Modernization Act (FSMA) of 2011
  - Preventative Controls
  - Inspection and Compliance
  - Imported Food Safety
  - Response
  - Enhanced Partnerships
FDA’s Response

• FDA Amendments Act (FDAAA) of 2007
• Food Safety Modernization Act (FSMA) of 2011
• CERT/CORE
Creation of the Complaint /Emergency/ Recall/ Team (CERT)

- CVM hired two Emergency Response Coordinators (ERC) in late 2008 to prevent and coordinate emergencies such as melamine in pet food.
- CVM’s Emergency Response Coordinators work closely with ORA emergency staff, CORE staff, centers emergency staff and the Office of Emergency Operations staff to ensure that communication and coordination occurs when an emergency occurs.
Creation of the Complaint /Emergency/Recall Team (CERT)

- In 2010 CVM Office of Compliance reconfigured
- As a result, the CERT was created, with the addition of import duties, now the team is named ICERT
- The ICERT team is responsible for Imports, Complaints, Emergencies and Recalls in CVM
- In addition, the ICERT team has an active role Public Health Act issues related to CVM
Coordinated Outbreak Response and Evaluation Network (CORE)

- On August 1, 2011, FDA officially launched CORE, the
- CORE Network was created to manage surveillance, response, and post-response activities related to incidents of illness linked to FDA-regulated human and animal food
- CORE works closely with CVM to determine when an incident meets the threshold to be transferred to CORE to coordinate the incident
FDA’s Response

- FDA Amendments Act (FDAAA) of 2007
- Food Safety Modernization Act (FSMA) of 2011
- CERT/CORE
- Safety Reporting Portal and EON
Two ways to report a pet food related adverse event or product problem:
Safety Reporting Portal or CCC through FDA District Offices.
Safety Reporting Portal

- Opened May 2010.
- 1002 reports (PFRs). Also used for 1005 (RFR) reports, drug reports from manufacturers, certain NIH clinical trial reports.
- Allows owners, veterinarians or concerned citizens to enter pet food reports online through a structured questionnaire.
- Accepts reports about adverse events, product problems or both.
- Only for pet foods at this time, not for large animal reports, or not for adverse drug event reports from consumers.
Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).

Whatever your role, (manufacturer, health care professional, researcher, public health official, or concerned citizen), when you submit a safety report through this Portal, you make a vital contribution to the safety of America's food supply, medicines, and other products that touch us all.

Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances:

- Food Manufacturers, Processors, Packers, and Holders
- Researchers
- Drug Manufacturers

Others, including concerned citizens, health professionals, and public health officials, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to a product.

Learn more about mandatory and voluntary reporting.

Reports You Can Submit Through this Portal

FDA safety issues involving:

- Human or animal reportable foods
- Animal drugs
- Pet foods

NIH safety issues involving:

- NIH gene-transfer research

For other issues, find out where to submit your report.
Reporter is guided through required and optional questions
What happens after a report is submitted? Transmitted to EON

- Emergency Operations Network
- Shared by CFSAN and CVM
- Contains RFR and PFR reports
- Search capabilities
- Ability to download individual reports
Welcome to the FDA's Emergency Operations Network (EON)
<table>
<thead>
<tr>
<th>Event ID</th>
<th>Event Type</th>
<th>Date</th>
<th>Type</th>
<th>Breed</th>
<th>Gender</th>
<th>Age</th>
<th>Weight</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCN-9011</td>
<td>PFR Event Created for Blue Wilderness Duck Recipe</td>
<td>07/05/12</td>
<td>Dog</td>
<td>Mixed</td>
<td>Male</td>
<td>11</td>
<td></td>
<td>Housed, Unspayed, 11 Years - Mixed Population of Female and Male</td>
</tr>
<tr>
<td>BCN-9012</td>
<td>PFR Event Created for Wellness Chicken &amp; Herring Formula Grain-Free</td>
<td>06/05/12</td>
<td>Cat</td>
<td>Domestic Longhair</td>
<td>Female</td>
<td>14</td>
<td></td>
<td>Female, 8 Pounds, Removed Completely</td>
</tr>
<tr>
<td>BCN-9013</td>
<td>PFR Event Created for Blue Wilderness Duck Recipe</td>
<td>06/05/12</td>
<td>Dog</td>
<td>Shepherd Australian</td>
<td>Male</td>
<td>3</td>
<td></td>
<td>Shepherd, Dog, Australian, 3 Years, Male, 20 Pounds</td>
</tr>
<tr>
<td>BCN-9014</td>
<td>PFR Event Created for Blue Wilderness Duck Recipe</td>
<td>06/05/12</td>
<td>Dog</td>
<td>Mixed (Dog)</td>
<td>Male</td>
<td>1</td>
<td></td>
<td>Mixed (Dog), Male, 1 Year, 80 Pounds</td>
</tr>
<tr>
<td>BCN-9015</td>
<td>PFR Event Created for Blue Wilderness Duck Recipe</td>
<td>06/05/12</td>
<td>Dog</td>
<td>Tender - Yakutsk</td>
<td>Male</td>
<td>7</td>
<td></td>
<td>Tender - Yakutsk, 7 Year, Male, 10 Pounds</td>
</tr>
<tr>
<td>BCN-9016</td>
<td>PFR Event Created for Blue Wilderness Duck Recipe</td>
<td>06/05/12</td>
<td>Dog</td>
<td>Ener - Golden</td>
<td>Male</td>
<td>1</td>
<td></td>
<td>Ener - Golden, 1 Year, Male, 75 Pounds</td>
</tr>
</tbody>
</table>

**EON**
## Individual PFR report

### Report Details - EON-90109

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICSR</td>
<td>1025260</td>
</tr>
<tr>
<td>Type Of Submission</td>
<td>Initial</td>
</tr>
<tr>
<td>Profile ID</td>
<td>FPFR.FDA.PETF.V.V1</td>
</tr>
<tr>
<td>Type Of Report</td>
<td>Both</td>
</tr>
<tr>
<td>Reporting Type</td>
<td>Voluntary</td>
</tr>
<tr>
<td>Report Date</td>
<td>06/May/12</td>
</tr>
<tr>
<td>AE/PP As Reported</td>
<td>A 3#3 day old bag of healthy benefits dog food, gave it to my dog. On May 3rd, vomiting started during night. He did not eat for another day, then ate a little on Sat May 5th, started vomiting all up again during the night, and am still up tending to him now.</td>
</tr>
<tr>
<td>AE/PP Found Date</td>
<td>03/May/12</td>
</tr>
<tr>
<td>Concurrent Medical Problem</td>
<td>No</td>
</tr>
<tr>
<td>Outcome Reaction</td>
<td>Worsening/Declining/Deteriorating</td>
</tr>
<tr>
<td>Result Assessment</td>
<td>Source Of Assessment: Reaction Result: Definitely related</td>
</tr>
<tr>
<td>Name</td>
<td>Judy Turner</td>
</tr>
<tr>
<td>Address</td>
<td>United States</td>
</tr>
<tr>
<td>Contact</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:jst19960@aol.com">jst19960@aol.com</a></td>
</tr>
<tr>
<td>No Identity Disclosure</td>
<td>False</td>
</tr>
<tr>
<td>Permission To Contact Sender</td>
<td>Yes</td>
</tr>
<tr>
<td>Preferred Method Of Contact</td>
<td>Email</td>
</tr>
<tr>
<td>Reported to Other Sources</td>
<td>None</td>
</tr>
<tr>
<td>Name</td>
<td>Patches</td>
</tr>
<tr>
<td>Type Of Species</td>
<td>Dog</td>
</tr>
<tr>
<td>Type Of Breed</td>
<td>Terrier - Yorkshire</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td>Reproductive Status</td>
<td>Neutered</td>
</tr>
<tr>
<td>Weight</td>
<td>10 Pound</td>
</tr>
<tr>
<td>Age</td>
<td>7 Years</td>
</tr>
<tr>
<td>Assessment Of Health</td>
<td>Excellent</td>
</tr>
<tr>
<td>Number of Animals Treated With Product</td>
<td>1</td>
</tr>
<tr>
<td>Number of Animals Reacted With Product</td>
<td>1</td>
</tr>
<tr>
<td>Healthcare Professional</td>
<td>Practice Name:</td>
</tr>
<tr>
<td></td>
<td>Practice Name:</td>
</tr>
<tr>
<td>Name</td>
<td>Purina Beneficial Healthy Fiesta dry dog food</td>
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<tr>
<td>Product Group</td>
<td>Pet Food</td>
</tr>
<tr>
<td>Lot Number</td>
<td>20101084 2123L11</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>13/Jan/12</td>
</tr>
</tbody>
</table>
Number of reports to date
FACTS vs. EON

- FACTS reports come through District Offices.
- Only way for reports to come in prior to May, 2010.
- In 2010, most still came in through FACTS, then about 50%, and now about 25% FACTS, 75% EON roughly.
FDA’s Response

- FDA Amendments Act (FDAAA) of 2007
- Food Safety Modernization Act (FSMA) of 2011
- CERT/CORE
- Safety Reporting Portal and EON
- Veterinary Laboratory Response Network (Vet-LRN)
Vet-LRN - Mission

• TO PROMOTE HUMAN and ANIMAL HEALTH by collaborating with veterinary diagnostic laboratories in order to
  - provide scientific information
  - build laboratory capacity
  - train scientists

• TO INVESTIGATE POTENTIAL PROBLEMS with CVM regulated products - animal foods and animal drugs

• CVM Vet-LRN Staff
• Over 40 investigations FY2011
• Current Investigations
Vet-LRN Program Goals

• Coordinate facilities, equipment, and professional expertise of government and non-government veterinary diagnostic laboratories throughout the United States and Canada
• Enable rapid, strengthened response to high priority chemical and microbial animal food and drug contamination events.
• Establish protocols to report diagnostic information about adverse events to FDA. (eLEXNET)
• Increase veterinary diagnostic laboratory capacity and surge capabilities domestically and internationally.
• These efforts can contribute to overall food and drug safety as animal food and drug events may signal potential issues in the human food and drug system.
Vet-LRN

Works with other networks but Vet-LRN needs to be at CVM

1 Program Director
- Writes RFA’s
- Interacts with the labs on CVM projects
- Receives data from the projects
- Writes reports

1 Support Scientist
- Assists in these projects
- Conducts in-house investigations
  - microbiology/chemistry
Vet-LRN

1 Liaison with OSC

Monitors incoming complaints
Interacts with emergency response groups
Assists in response study coordination

1 Contract chemist

Responsible for setting up new laboratory equipment dedicated to Vet-LRN
Developing validation and proficiency protocols
Conducting in-house testing

1 Commissioners' Fellow (Oct 2011- 2 year term)

Major responsibility 2012 Chicken Jerky Testing
Coordination and evaluation

These are all tasks that cannot be done by outside networks
Vet-LRN Member Laboratories

- 25 State and University/College Veterinary Diagnostic Laboratories around the country
- Benefits:
  - confidential information exchange
  - scientific training
  - harmonization of analytical method
  - opportunities to use veterinary diagnostic samples to fill data gaps.
  - opportunities to obtain cooperative agreement
  - funding for projects to investigate chemical, toxicological, microbial, and pathological aspects of cases with potential adverse food or drug responses.
FDA’s Response

- FDA Amendments Act (FDAAA) of 2007
- Food Safety Modernization Act (FSMA) of 2011
- CERT/CORE
- Safety Reporting Portal and EON
- Veterinary Laboratory Response Network (Vet-LRN)
- Pet Event Tracking Network (PETNet)
Pet Event Tracking Network (PETNet)

• Lack of a federal oversight for monitoring food-borne illness/disease outbreak in companion animals
• Criticism of FDA’s information sharing during the recall discussed by break-out group during the 2008 50-state meeting
• Break-out group recommended the development of a Pet Event Tracking Network or “PETNet”
• Vision for an early reporting system that would have foundations in surveillance, laboratory support, and epidemiology
• CVM asked to lead a workgroup, established under the Partnership for Food Protection umbrella, to develop PETNet
• Workgroup included members from FDA, state agencies, CDC, USDA, and the Department of Homeland Security (DHS)
Pet Event Tracking Network (PETNet)

- Allow exchange of information about pet-food related incidents, such as illness associated with the consumption of pet food or pet food product defects.
- PETNet gives equal data access to all members
- Using the shared information, State and Federal agencies can work together to quickly determine what regulatory actions are needed to prevent or quickly limit adverse effects associated with pet food products.
Pet Event Tracking Network (PETNet)

How PETNet Works:

1. PETNet is a secure, web based system.
2. A PETNet member completes a reporting form and submits the completed form electronically to PETNet.
3. The report is entered into a searchable database which is accessible to members.
4. All PETNet members will be able to input data into and extract data from the network.
5. PETNet members can customize the system to send them email alerts notifying them of new reports.
Pet Event Tracking Network (PETNet)
Highlights of Event

• Largest FDA recall ever
• Largest number of consumer complaints ever
• Involved complex chemical reactions hitherto unknown
• Revealed nature of pet food manufacturing
• Revealed global nature of food supply
• Revealed vulnerability of pet animals
• Revealed how food animals are fed waste product
• Revealed US vulnerability to intentional adulteration
• Revealed the gaps in the FDA and CVM