DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 0 7 2007

Dear Mr. Chairman:

Thank you for the letter of March 30, 2007, co-signed by five of your colleagues, regarding the response of the Food and Drug Administration (FDA or the Agency) to the recent recall of contaminated pet foods.

This letter is a partial response to your requests. We have re-stated each of your questions, followed by FDA's response. Documents are enclosed as noted in our responses. Please be advised that these documents contain trade secret, commercial confidential or other information protected from public disclosure under the Freedom of Information Act (Title 5, United States Code [U.S.C.], section 552), the Trade Secrets Act (Title 18, U.S.C., section 1905) and/or FDA regulations. This information should not be published or otherwise made public. We would be glad to discuss the protected status of any specific information with you or your staff.

1. **When did the FDA first become aware of the current outbreak of pet food contamination, and how did it learn of the contamination? Please provide copies of all records of how the FDA became aware of the contamination.**

Response: On March 15, 2007, Menu Foods notified the FDA Kansas City District of the company's decision to recall cat and dog food (cans and pouches only) that was manufactured by Menu Foods and sold under approximately 100 brand names (1000 UPC). These products are considered to be low-acid canned foods (LACF), and have been referred to as "cuts and gravy" style or "wet" pet foods.

Menu Foods informed FDA it was initiating a recall as it appeared its pet food may have been associated with 14 deaths of cats and dogs. Menu Foods explained that a kennel, with whom the company contracts to perform palatability studies, reported to them the deaths or illness of nine cats who had consumed pet food manufactured by Menu Foods during the palatability study. Menu Foods reported the cats showed evidence of renal failure. Menu Foods indicated it reviewed its own records and discovered five complaints of death or illness (cats and one dog) which it believed could be similarly related to renal failure associated with

Menu Food pet food consumption. Menu Foods indicated its investigation revealed the sole change in manufacturing for product associated with these deaths/illnesses was a change (December 2006) in their supplier of wheat gluten, an ingredient in the pet food. Menu Foods reported it had identified lots in which the suspect wheat gluten was used and made the decision to recall. The suspect wheat gluten was a part of a large shipment that was split between their Emporia, Kansas and Pennsauken, New Jersey manufacturing facilities. Menu Foods reported that cat and dog deaths and illnesses were linked to products manufactured by the Kansas plant. Nevertheless, Menu Foods decided to recall all "wet" pet food products from both plants in which the suspect wheat gluten was used as an ingredient. At approximately the same time Menu Foods informed us of its recall, the company indicated it had changed its suppliers of wheat gluten back to a previous supplier.

Menu Foods is headquartered in Ontario, Canada and has manufacturing facilities in Streetsville, Ontario; Emporia, Kansas; Pennsauken, New Jersey; and North Sioux City, South Dakota. Brand names include Iams, Purina, Wal-Mart and others. Product distribution includes the United States, Canada, and Mexico.

Enclosed at Tab A is an April 3, 2007, memorandum by Nadine Nanko Johnson, Compliance Officer for the Kansas City District Office. This memo is the record on how FDA became aware of the Menu Foods product contamination. Meeting notes from the FDA participants on the March 15 phone call with Menu Foods are attached to this memorandum. These notes have been redacted for personal privacy information.

2. **How many complaints of acute kidney failure in cats and dogs has the FDA received since February 20, 2007? Please provide copies of all summaries, analyses, memoranda, and reports the FDA may have prepared regarding those complaints.**

Response: To understand how the contamination affects dogs and cats, FDA scientists, in conjunction with academia and industry, are reviewing blood and tissue samples of affected animals to understand how wheat gluten contaminated with melamine contributed to the pet illnesses. We are also working with data from Banfield Pet Hospital (a nationwide network of veterinary hospitals), the Veterinary Information Network, Poison Control Centers, universities, and other organizations to assess the number of cats and dogs affected by the contaminated pet food. We are cooperating with the 50 state departments of agriculture, health authorities, veterinarians, and the Association of American Feed Control Officials.

FDA is looking closely at cases of animals with kidney disease (renal failure) diagnosed by a veterinarian; where the animal has died from the renal failure; the veterinary records are available; the pet food was implicated in the illness and was consumed within the two weeks prior to death, and was the only food consumed by the pet and the consumer has the product that was fed to the pet available for sampling in the original packaging. FDA is interested in collecting veterinary records, including lab reports and necropsy records (if a necropsy was performed).

The American Association of Veterinary Laboratory Diagnosticians is helping with the analysis of the tissue samples and toxicology screening and the Banfield Pet Hospitals have offered data

from their hospital records system for disease surveillance. This has helped our investigation tremendously, and we are very positive that this framework will continue to provide valuable information.

As of May 2, 2007, FDA has received over 17,800 consumer complaints relating to this emergency which included reports of approximately 2,168 deaths in cats and 2,457 deaths in dogs. These reports were recorded as received from the complainant, without additional verification at the time by FDA. To put the complaint volume in perspective, generally, FDA receives about 6,000 complaints for all products in a typical year in our consumer complaint reporting system.

FDA considers the 14 animal deaths initially reported by Menu Foods as confirmed deaths. The Agency recognizes the interest in having updated reports of confirmed animal deaths, and we intend to analyze consumer complaints along with the results of any available blood and tissue samples on affected pets as time and the quality of the data permits. Our priorities from the very beginning of this emergency have been to fully investigate the situation; follow all leads to determine the cause, scope, and needed actions; monitor the effectiveness of recalls; and communicate with the public to support and protect animal and human health. The efforts of FDA and pet food manufacturers have led to the expansion of the pet food recalls well beyond the initial Menu Foods recall that began on March 15, and we believe this has prevented many additional animal injuries and deaths.

Documents responsive to this request are still being collected and will be provided in a subsequent submission.

3. **How many times has the FDA inspected Menu Foods, Inc. pet food processing facilities over the past five years? Please provide a list of all Menu Foods pet food processing facilities, including their locations, and all records of any such inspections.**

Response: Prior to FDA's initiation of the pet food contamination investigation on March 15, 2007, the Agency and/or state agencies under contract to FDA have inspected Menu Foods pet food processing facilities as listed below:

- Menu Foods Midwest Corporation, 1400 E. Logan, Emporia, Kansas.
  Inspection date: 10/02/2006 – Kansas state inspection. BSE inspection.

- Menu Foods Inc, 9130 Griffith Morgan Lane, Pennsauken, New Jersey.
  Inspection dates: 6/10/2002, 9/30/2003, 2/03/2004, 3/9/2005, and 5/9/2006 – All FDA inspections.

- Menu Foods South Dakota Inc., 630 North Derby Lane, North Sioux City, South Dakota.
  Inspection date: 7/26/2005 – FDA inspection.

- Menu Foods Limited, 8 Falconer Drive, Streetville, Ontario, Canada.
  No inspections on file.

Records related to the listed inspections are enclosed at Tab B. Additional documents are being collected and will be submitted in a subsequent submission.

Since March 15, 2007, FDA has conducted inspections at all of these facilities. Documents related to these inspections will be provided in a subsequent submission to an extent consistent with FDA's ongoing, broader investigation related to these matters, which may result in further action.

4. **What steps has the FDA taken to identify the source of the contamination in the current outbreak?**

Response: FDA is conducting a thorough investigation of the pet food contamination. Since March 15, 2007, when FDA became aware of this outbreak, we have aggressively worked to identify the source and scope of the contamination, to assure removal of all contaminated products from the supply chain and store shelves, and to keep the public informed. We continue to pursue leads for this pet food contamination investigation. Our goal is to limit the risk of animal injury and death related to the contamination and to actively investigate any potential risk to the human food supply.

Within 24 hours of learning from Menu Foods of the illnesses and deaths, our FDA investigators were on-site at the Menu Foods Emporia, Kansas plant searching for the source of the problem. FDA began a large-scale investigation and the Agency's Office of Crisis Management activated the Emergency Operations Center, which has worked seamlessly with the Agency's Center for Veterinary Medicine, district offices and laboratories, the Office of Public Affairs and Office of International Programs. FDA has reached out to our state counterparts requesting their assistance in the investigation and in determining the effectiveness of the pet food recalls.

FDA has dedicated personnel in each of its 20 district offices to take consumer calls and conduct inspections and investigations. Eighteen of FDA's district offices have inspected manufacturing and distribution facilities. Within 24 hours of receiving the initial samples of pet food and wheat gluten, FDA's Forensic Chemistry Center had confirmed the presence of melamine.

A records review allowed FDA to identify the importer and initial distributor of the contaminated wheat gluten. FDA determined the supplier as a Chinese firm, Xuzhou Anying Biologic Technology Development Company. FDA made known to the Chinese government that the Agency needed to conduct a foreign inspection and invited Chinese authorities to participate in the investigation. During the first week of May 2007, three FDA officials traveled to China to further investigate this contamination.

On April 16, 2007, FDA invoked Section 414(a) of the Federal Food Drug and Cosmetic Act, which grants records access authority when there is a reasonable probability that food for humans or animals is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. FDA issued this request for records to Menu Foods in Emporia, Kansas.

Additionally, on April 16, 2007, FDA began an additional investigation into rice protein concentrate imported by an importer and distributor of agricultural products, Wilbur-Ellis of San Francisco, California. The Agency detected the presence of melamine and melamine analogs in the imported rice protein concentrate that was used to manufacture pet food. The contaminants in question include melamine and the melamine analogs cyanuric acid, ammelide, and ammeline, the combination of which has been linked to the acute renal failure in cats and dogs that have eaten the suspect pet foods. About the same time, FDA became aware of a South African pet food manufacturer recalling dry cat and dog food due to corn gluten contaminated with melamine.

All of the Agency's district offices continue to take complaints from consumers and veterinarians who report illness potentially associated with the contaminated pet food. The complaints are an important aspect of our ongoing investigation. These complaints have assisted the Agency in tracking down additional pet food products affected by the contamination. This investigation is an ongoing priority for FDA, and our work continues unabated.

5. **Has the FDA conducted in-house laboratory analyses of the suspect pet food to determine the nature of the contamination? If so, please provide copies of the laboratory analyses. If not, why not?**

Response: As of May 31, over 1,500 samples have been collected and analyzed by FDA laboratories. A total of 444 finished product samples, consisting primarily of consumer complaint samples which met the criteria for sample collection, were found positive for melamine and/or melamine analogues. Additionally, 49 samples of wheat gluten, and 51 samples related to rice protein concentrate, were found positive for melamine and/or melamine analogues. A spreadsheet summarizing the results is enclosed at Tab C.

Although still under investigation, it now appears that the combination of melamine and cyanuric acid has been linked to the acute renal failure in cats and dogs that have eaten the suspect pet foods.

6. **Has the FDA obtained any laboratory analyses or other reports from State agencies or private organizations regarding the nature of the contamination? If so, please provide copies of all such records.**

Response: FDA has been working closely with state laboratories under contract with FDA to perform analyses related to food emergencies as part of the Food Emergency Response Network (FERN Cooperative Agreement laboratories). These labs have been testing raw materials and finished products for melamine and related compounds, similarly to what FDA laboratories have been doing. FDA also has been providing information regarding analytical methodology to other state and local laboratories through national conference calls involving FDA's technical experts.

FDA's Forensic Chemistry Center, at the outset of this event, received communications from Cornell University, the University of Guelph, and Proctor and Gamble regarding analytical results these organizations had obtained. These were not formal reports, but primarily e-mail

communications of findings, sometimes with PowerPoint attachments. At the time, FDA and these outside organizations were all working to determine the cause of the animal illnesses. Although still under investigation, these collaborative efforts and communications have helped to link the combination of melamine and cyanuric acid to the acute renal failure in cats and dogs that have eaten the suspect pet foods.

Documents responsive to this request are being collected and will be provided in a subsequent submission.

7. **A recent Associated Press (AP) report, which appeared in the web edition of Newsweek on March 21, 2007, quoted David Elder, director of the FDA's Office of Surveillance and Compliance, Center for Veterinary Medicine, as saying that inspections of pet food processing facilities are "based on risk." Moreover, the AP report states that the Emporia, Kansas, processing plant where some of the contaminated food was manufactured has never been inspected by the FDA. If true, this indicates a very serious shortcoming in the FDA's approach to ensuring the safety of pet food. Has the Emporia, Kansas, food processing plant ever been inspected by the FDA? If so, please list all dates of inspections and provide copies of all records pertaining to the inspections. This should include all inspections up to the date of this letter.**

Response: David Elder is the Director of the Office of Enforcement within FDA's Office of Regulatory Affairs, but the quote is otherwise generally accurate. The context of the quote related to the prioritization of pet food inspections within the overall animal drugs and animal feeds programs. A risk-based approach is used to prioritize resources, including inspection resources. Prior to the most recent inspection related to the ongoing FDA investigation at Menu Foods Inc. in Emporia, Kansas, the State of Kansas had inspected the facility under our state contract program. The inspection was conducted on October 2, 2006, and was focused on the FDA's BSE inspection program. A copy of the inspection report is included along with other inspections of Menu Foods' facilities provided under Tab B.

8. **Are inspections of pet food processing facilities based on risk? If so, please provide copies of the risk analysis used by the FDA prior to February 20, 2007, in determining when, where, and how such inspections are carried out.**

Response: FDA's field inspection resources are prioritized to maximize the Agency's ability to assure a safe and reliable supply of food and drugs. Resources for the inspection of animal feed facilities are prioritized to guard against problems such as the spread of bovine spongiform encephalopathy and other diseases that have a direct impact on humans. FDA's inspection program and oversight is augmented by a network of partners involved in product safety, particularly state regulatory partners who accomplish inspections under their own state programs and also on FDA's behalf under contracts and partnerships. Historically, pet food facilities have been inspected "for cause," in response to complaints. FDA does not use a formal risk analysis process to determine whether or not an inspection is needed; however, the Agency is working on various models to help it analyze potential risks and identify facilities that may need additional attention.

9. **Please list all pet food manufacturing facilities inspected by the FDA for 2001 through 2006. For each of these inspections, please indicate whether the inspection was routine or whether it was conducted for cause. For inspections conducted for cause, please indicate the cause.**

Response: From the beginning of fiscal year 2001 through the end of fiscal year 2006, FDA and states under partnership or contract with FDA have conducted 918 inspections at pet food processing facilities. Pet food processing facilities are establishments defined as either manufacturers or repackers of pet food. Of the 918 inspections, 55 have been identified as having been conducted for "for cause." An alphabetically sorted list of the 918 inspections, with a column indicating whether the inspection was "for cause," and the reason, if applicable, is enclosed at Tab D.

Please note that FDA does not record or code the data to identify "for cause" inspections. The information provided here was obtained by a manual review of the text fields associated with each of the 918 inspections to determine if the inspection was "for cause" and the reason. Examples of "for cause" inspections include, among other things, those initiated by an import alert, recall, violative sample, follow-up to a previous inspection, or consumer complaint.

Thank you again for your interest in this matter. We will provide the additional documents responsive to your request as soon as possible. A similar response has been sent to the co-signers of your letter. A copy of the enclosures has been provided to the Ranking Member of the full Committee.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures