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 27 2007

Dear Mr. Chairman:

Thank you for the letter of May 25, 2007, co-signed by Chairman Bart Stupak, Subcommittee on Oversight and Investigations, requesting information related to the adequacy of the efforts of the Food and Drug Administration (FDA) to assure the safety and security of the nation's food supply.

We have re-stated each of your requests in bold type, followed by FDA's response. Documents are enclosed as noted. 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 This information should not be published or otherwise made public.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. The Establishment Inspection Report of Menu Foods prepared in the Kansas City District Office.

Response: Documents responsive to the request are enclosed at Tab A. Limited redactions have been made for information relating to open investigations and personal privacy.

2. All records since January 1, 2001, relating to the import or attempted import into the United States of seafood packed in an atmosphere containing carbon monoxide, contaminated with metals such as mercury, and rejected as unfit for human consumption.

Response: Enclosed at Tab B are two charts responsive to this request. The first chart provides information on 174 seafood products refused admission into the U.S. during the time period of January 1, 2001, through June 4, 2007, because they appear to contain heavy metals. The second chart provides information on 14 seafood products refused admission into the U.S. during the time period of January 1, 2001, through May 30, 2007, because they appear to have been treated with carbon monoxide without an appropriate label declaration.

3). All records since January 1, 2001, relating to inspections of firms that process or distribute fresh, leafy greens, that have resulted in VAI (voluntary action indicated) or OAI (official action indicated).

Approximately 1,000 inspections occurred during this period of time that were classified as VAI or OAI. Of these, sixty-eight were classified as OAI. Per an agreement with your staff, we are presently providing three sample Establishment Inspection Reports for inspections that were classified as OAI. Enclosed at Tab C is an example from FDA's Florida District Office. Enclosed at Tab D is an example from FDA's Chicago District Office. Tab E contains an example from our Los Angeles District Office. We will await further instructions from your staff before providing additional documents.

4. A report on the status of the inspection of establishments that import vegetable proteins subject to the Import Alert dated April 27, 2007, and the inspection of establishments that process such proteins into human or pet food or animal feed including, but not limited to, the nationwide assignments issued by the Agency on or about April 30, 2007. This report should include the number and types of inspections by District and the number of samples processed by FDA, State, university, and private laboratories. In addition, it should include the names and contract information for each laboratory, together with the cost to FDA for the processing of samples in non-FDA labs. For private labs whose sampling work is paid by the importer, please provide the audits that FDA has performed on each of those labs since January 1, 2006.

Response: On April 30, 2007, FDA issued a domestic vegetable protein surveillance assignment (PSA), in conjunction with our state and local regulatory partners, aimed at testing a variety of protein concentrates commonly found in the U.S. food and animal feed supply for the presence of melamine. So far, the PSA has targeted ingredients and finished products including raw protein extract products including grain meals; flour and grains derived from soy, wheat, rice and corn; infant formula and baby cereals; dietary conventional foods and meal replacements; fish feed imported from China; and domestic infant formula. The assignment is expected to run until late July and will also target whey, gelatin, meat substitutes, fish meal and domestic animal feed.

Under this assignment, 287 firms have been assigned, inspection information has been received on 172 firms, and 168 samples have been collected for analysis. For this assignment, FDA and state regulators perform limited scope inspections, including food defense activities, reconciliation exams, and sample collections and determine whether the firms have the ability to identify immediate suppliers, transporters and consignees of the assigned products. All 168 samples tested as part of the PSA have been negative for melamine and associated analogs. The inspections performed by each District are as follows:

Baltimore	3	New Jersey	9	Florida	5
Cincinnati	3	Philadelphia	2	Los Angeles	48
Detroit	9	Seattle	2	New England	3
Kansas	5	Chicago	16	New York	31
Minneapolis	4	Dallas	6	San Francisco	17
Denver	2	New Orleans	4	San Juan	1

Eight State Food Emergency Response Network (FERN) laboratories are involved in the analysis of samples collected in accordance with the PSA. Monies awarded to the FERN laboratories are not itemized on a "per sample basis." Instead, the costs incurred by the laboratories to analyze these samples are covered by the FERN cooperative agreements. FERN cooperative agreement funding includes the costs associated with training, sample analysis (including surge capacity to assist FDA), equipment, supplies/reagents, personnel support and facility upgrades. The specific state FERN laboratories involved in the analysis of samples collected in accordance with the PSA include:

- Arizona Department of Health Service (AZ)
- Regents of the University of California (CA)
- Connecticut Agricultural Experiment Station (CT)
- Florida Department of Agriculture and Consumer Services (FL)
- University of Iowa (IA)
- Minnesota Department of Agriculture (MN)
- New Hampshire Department of Public Health (NH)
- Virginia Division of Consolidated Labs (VA)

The eight laboratories identified above submitted applications for, and were awarded grants, in the form of cooperative agreements, in response to a Federal Register (FR) Notice issued on May 25, 2005. A copy of the FR Notice is enclosed at Tab F.

The grant number, specific dollar amount awarded per grant awardee for Fiscal Years 2005 through 2007, and point of contact for each grant is included in the chart enclosed at Tab G.

Pursuant to Import Alert (IA) #99-29, "Detention without Physical Examination (DWPE) of All Vegetable Protein Products from China for Animal or Human Food Use Due to the Presence of Melamine and/or Melamine Analogs," dated April 27, 2007, firms or shippers can request removal from DWPE status by providing:

1. Documentation showing that a minimum of five consecutive entries have been released by FDA based on third party laboratory analyses using FDA recommended methods and that all shipments did not contain the presence of melamine and/or melamine analogs; and

2. A certificate, such as from China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), indicating that an inspection of the manufacturer was conducted and adequate controls are in place. Information should also include:

   a. a copy of the inspectional reports and compliance status of the manufacturer; and

   b. if products were sampled during the course of the inspection, test results indicating that the products are free of melamine and/or melamine analogs.

Import Alert #99-29 has been in effect for approximately eight weeks and is ongoing. Therefore, FDA has not compiled data identifying private laboratories that have submitted documentation to the Agency in support of removal from DWPE or the release of specific entry

lines. To do so would require a manual review of import detention data. Identifying FDA audit-related activity of these laboratories would require an additional manual check of this information against audit records residing in the field.

FDA has compiled general data on audit-related activities that the Agency has performed with respect to private labs whose sampling work is paid for by importers. While not specific to the sampling work resulting from IA #99-29, these audit-related activities are indicative of the type of reviews that FDA would perform with respect to private laboratories analyzing samples from IA #99-29.

FDA performs several types of audit-related activities, as described below, to assess private laboratories and/or the analytical packages the Agency receives from them. These audit-related activities fall into three broad categories and are considered by FDA when evaluating whether to release a product that is subject to DWPE. They are also illustrative of the types of activities that FDA would conduct relative to those private laboratories submitting data in support of the release of specific entry lines.

1). On-site Assessments: This activity involves a visit by FDA investigational and laboratory personnel to the private laboratory to conduct an assessment of the equipment, personnel, and procedures in order to ascertain whether a private laboratory has the capability and capacity to accurately perform the analyses it presents to FDA. Since October 1, 2005, the Agency has performed three on-site assessments of private laboratories. It should be noted that FDA does not have specific statutory authority to conduct such on-site assessments.

2). Review of Private Laboratory Analytical Packages: FDA staff have conducted comprehensive reviews of 6,706 analytical packages related to import entries of human food, animal feed and dietary supplements that were submitted by private laboratories from October 1, 2005, through June 1, 2007. A table summarizing the number of reports submitted by each of the private laboratories listed is enclosed at Tab H.

3). Collection and Analysis of Audit Samples: FDA requested, collected and analyzed 175 audit samples related to human food, animal feed and dietary supplement import entry lines for which private laboratory analytical results had been submitted to the Agency. To verify the analytical results submitted by the private laboratory, FDA attempts to collect audit samples from the same container or lot as the original sample collected by the importer and tested by the private laboratory. The FDA analytical results for these audit samples, in conjunction with private laboratory analytical data, are evaluated by Compliance Officers situated in FDA District Offices, to make admissibility decisions. Current FDA databases do not readily "link" audit sample results with the corresponding data submitted by the private laboratories.

5. **Copies of all drafts of fiscal year 2007 and 2008 budget proposals for imported and domestic food-related related activities performed or programmed by FDA. This includes all internal estimates of the need and cost of inspections, laboratory work, regulatory efforts, and administration. Please break down the salaries and full-time staff equivalents for each fiscal year of Headquarters,**

Regional, and District level personnel by assigned office or laboratory. This report should also include, but not be limited to, all plans to cope with the growth of imported food, all declassified documents that detail funding for security threats from imported food, as well as the number of inspections, samples, and Oasis entries planned for each fiscal year.

Enclosed at Tab I are copies of sections of FDA's Fiscal Year (FY) 2007 and FY 2008 Congressional Justification budget requests that relate to food safety and food defense. These documents include the Agency's FY 2007 requested increases for food defense/counter-terrorism related activities, the FY 2007 Foods Program Congressional budget justification, the FY 2008 "Strengthening Food Safety" initiative, and the FY 2008 Foods Program Congressional budget justification. The full text of the FY 2007 and FY 2008 Congressional Justification also appear on the FDA web site at *http://www.fda.gov/oc/oms/ofm/budget/documentation.htm.*

Please note that the documents at Tab I do not estimate the need and cost of inspections, laboratory work, regulatory efforts, or administration. Although the specific documents include estimates of full-time staff equivalents, they do not include estimates at the regional or district level. In addition, although these documents include estimates of the number of inspections and samples, the budget documents do not include Operational and Administrative System for Import Support (OASIS) entries or declassified documents that relate to security threats. The items listed in your request are not items that FDA prepared when writing the enclosed FY 2007 or FY 2008 Congressional Justifications.

Draft copies of budget justifications prior to the submission of the President's Budget to the Congress are not provided, as there is a longstanding executive branch practice of protecting the confidentiality of the budget formation process. See Office of Management and Budget Circular A-11, Section 22. However, the Agency would be interested in working with the Committee to find ways of accommodating its needs consistent with this practice.

Thank you again for your interest in this matter. A similar response without enclosures has been sent to Chairman Stupak.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures