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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

JUL 09 2007

Dear Mr. Chairman:

Thank you for the letter of June 5, 2007, co-signed by three of your colleagues, requesting information related to the adequacy of the efforts of the Food and Drug Administration (FDA) to ensure the safety of food imported from China.

We have re-stated each of your requests in bold type, followed by FDA's response. Supporting documents are enclosed as noted. The tables provide data on both human food and animal food and feed. We note that your letter requested import information going back to 2001. However, as discussed with your staff, prior to 2002, FDA's importation records are not readily accessible within FDA's automated import tracking system, the Operational and Administrative System for Import Support (OASIS). Therefore, the information we are providing goes back only to 2002.

1. "The number of food imports from China. Please include both the number of entries and the number of lines."

Response: A table providing information responsive to this request is enclosed at Tab A. Because the only meaningful way to report import data categorized by country of origin or by product category is at the line level, we are providing data for line entries (lines) only.

We note that import entries are not product or country of origin specific. Entries often include a combination of foods, drugs, cosmetics, devices and other FDA-regulated products, as well as products not regulated by FDA, and they can include products from a number of different countries of origin. A line entry, however, refers to each portion of an import entry that is listed as a separate item on an entry document. Line entries do contain data elements for country of origin as well as product category.

2. "The declared value of all food imports from China."

Response: Information responsive to this request is included in the table enclosed at Tab A.

3. "The number of imports from China that were detained pending laboratory examination."

Response: A table providing information responsive to this request is enclosed at Tab B. The table provides information on line entries in product categories related to human and animal food that were held under Detention Without Physical Examination (DWPE).

It is important to note that detentions are undertaken pending the refusal or release of an import line entry. We detain shipments offered for import based on an appearance of a violation under 801(a) of the Federal Food, Drug, and Cosmetic Act. Laboratory analysis is only one of many ways to overcome the appearance of a violation and may not be sufficient standing alone in many instances.

4. "The number of Chinese food samples analyzed by private laboratories."

Response: Enclosed at Tab C is a table that details the number and types of analytical packages received by FDA from outside laboratories that include an analysis of Chinese food samples.

5. "The number of Chinese food samples analyzed by FDA laboratories."

Response: The following two tables represent the number of Chinese food samples analyzed by FDA laboratories for fiscal years 2002 – 2006.

The table below tabulates import samples, which are samples of a commodity collected from a shipment made by a foreign firm into the U.S. before they are released into commerce.

Number of Import Chinese Food Samples Analyzed			
FISCAL YEAR	***IMPORTED HUMAN FOOD***	***IMPORTED ANIMAL FOOD AND FEED***	**GRAND TOTAL**
FY 2002	1,343	13	**1,356**
FY 2003	2,354	17	**2,371**
FY 2004	2,295	35	**2,330**
FY 2005	2,538	44	**2,582**
FY 2006	2,452	44	**2,496**
GRAND TOTAL	**10,982**	**153**	**11,135**

The following table tabulates domestic import samples, which are samples of an imported article collected after release from import status.

Number of Domestic Import Chinese Food Samples Analyzed			
FISCAL YEAR	*IMPORTED HUMAN FOOD*	*IMPORTED ANIMAL FOOD AND FEED*	GRAND TOTAL
FY 2002	158		**158**
FY 2003	124	4	**128**
FY 2004	110		**110**
FY 2005	105		**105**
FY 2006	91		**91**
GRAND TOTAL	**588**	**4**	**592**

6. "The number of Chinese food samples determined to be violative."

Response: The following two tables represent the number of Chinese food samples determined to be violative for fiscal years 2002 – 2006.

Number of Violative Import Chinese Food Samples Analyzed			
FISCAL YEAR	*IMPORTED HUMAN FOOD*	*IMPORTED ANIMAL FOOD AND FEED*	GRAND TOTAL
FY 2002	161	3	**164**
FY 2003	239		**239**
FY 2004	204		**204**
FY 2005	175	1	**176**
FY 2006	148	1	**149**
GRAND TOTAL	**927**	**5**	**932**

(Collected before release into commerce).

Number of Violative Domestic Import Chinese Food Samples Analyzed			
FISCAL YEAR	*IMPORTED HUMAN FOOD*	*IMPORTED ANIMAL FOOD AND FEED*	GRAND TOTAL
FY 2002	66		**66**
FY 2003	16	1	**17**
FY 2004	18		**18**
FY 2005	9		**9**
FY 2006	25		**25**
GRAND TOTAL	**134**	**1**	**135**

(Collected after release into commerce).

7. "The number of violative Chinese food shipments that were reexported."

8. "The number of violative Chinese food shipments that were destroyed."

Response (to both questions): Under the FD&C Act, an import shipment refused admission must be exported or destroyed within 90 days. Enforcement of this requirement is handled by U.S. Customs and Border Protection. FDA does not systematically collect or compile numerical data on the disposition of refused shipments.

9. "The percentage of Chinese food samples found to be violative in each district and each laboratory."

Response: Enclosed at Tab D are five tables that are responsive to your request. These tables represent the percentage of Chinese food samples found to be violative in fiscal years 2002 through 2006. The tables are divided into Analyzing Laboratory and Collecting District. Within each laboratory or district, the data is further divided between human food and animal food and feed. Finally, the data is divided between those samples collected in import status and those samples collected in domestic commerce after having been imported and released into commerce in the United States.

10. "The number of FDA personnel (by full-time equivalent) conducting Chinese food import work for each district, each laboratory, and at headquarters."

Response: We are unable to provide a breakdown of full-time equivalents performing Chinese food import work. FDA does not assign work or hire staff to specifically conduct work based upon the country of origin of regulated products. The duties of FDA staff are assigned by management based upon the yearly work plan, emergencies, and other needs that arise during any given year.

Thank you for your interest in this matter. If you have any further questions or concerns, please let us know. A similar response has been sent to the co-signers of your letter.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures