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March 11, 2009

Dr. Frank Torti
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20903

Dear Dr. Torti:

On February 11, 2009, the Subcommittee on Oversight and Investigations under the House Committee on Energy and Commerce held a hearing entitled "Salmonella Outbreak: The Continued Failure to Protect the Food Supply." This hearing explored the issues related to the most recent salmonella outbreak involving peanut butter and peanut-containing products. Two issues emerged from the investigation concerning the Food and Drug Administration's (FDA) food safety responsibilities.

The first issue concerns FDA's oversight of the state inspection programs. For more than a decade, FDA has made both contract arrangements and partnership agreements with individual states to conduct inspections of food processing firms on their behalf. Contracting out food firm inspections has become common practice for FDA. For Fiscal Year 2008, approximately 59 percent of FDA's inspections of food firms were conducted by the States.

The adequacy of the oversight of those inspections has come into question before. In 2000, the Inspector General's Office (OIG) from the Department of Health and Human Services (HHS) released a report entitled "FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability."[1] The OIG concluded that FDA's oversight of State food firm inspections done under contract is limited. The report stated that FDA does minimal assessment of the quality of inspection reports and provides limited feedback to the State on how to conduct an FDA-contract inspection. The OIG recommended that FDA work with the States to achieve basic equivalency in food safety standards, laws, and inspection programs.

[1] http://www.oig.hhs.gov/oei/reports/oei-01-98-00400.pdf

The second issue concerns FDA's Reportable Food Registry. Pursuant to Section 417 of the Food Drug and Cosmetic Act (FDCA), the Secretary must establish a Reportable Food Registry under the Food and Drug Administration (FDA) within one year of the date of enactment. To date and to our knowledge, this Food Registry has not been established.

Under FDAAA, a "responsible party" must submit to the Food Registry any event that involves a "reportable food", which is a food for which there is a "reasonable probability" that exposure to the food will cause serious adverse health consequences or death. The responsible party must submit the report electronically to FDA's Food Registry as soon as practicable (but no later than 24 hours) after the party becomes aware of a reportable food. In such an instance, the responsible party also must investigate the cause of the event. As soon as FDA receives the report, it is required to review the report to determine what protective actions need to be taken. FDA has authority under Section 417 to publicize a reported event if such action is necessary.

In light of these ongoing concerns raised by the hearing, we ask that FDA respond to the following questions within two weeks from the date of this letter.

1. For each recommendation made by the OIG in the report, describe the corrective action(s), if any, taken by FDA and the dates taken. Please provide documents substantiating the corrective action(s).

2. Please provide a list of the current FDA-State contracts and FDA-State partnership agreements and the date the arrangement started.

3. Per Field Manual Directive 76[2], FDA is required to audit State inspection programs. How many audits has FDA conducted to assess the quality of State inspection programs since 2000? Please provide copies of the audit reports.

4. Are State inspectors required to receive FDA training before they can conduct FDA-contract or partnership agreement inspections? If not, why not?

5. When an FDA audit finds a State inspector inadequate, are these inspectors disqualified from doing contract inspections? If so, when, why and how many have been disqualified? Please provide documents substantiating the disqualifications.

6. Committee staff was told that FDA compiles a list of food firms for the State to inspect under FDA contract, selecting firms using a risk-based approach and based on firms who have not been inspected from which the state chooses which firms to inspect. What factors does FDA consider in selecting firms for this list? Are factors such as the firm's inspection history or prior involvement in food-borne illness outbreaks considered? If not, why not? Can FDA demand that the State inspect a particular firm or only offer a list?

7. On February 3, 2009, FDA posted solicitation number 1053553 requesting applications for a Senior Consultant in Oversight Activities for the Office of Regulatory Affairs. FDA

[2] http://www.fda.gov/ora/inspect_ref/fmd/fmd76-AppendixH.htm

stated that the Consultant will work with key leaders of the Office of Regulatory Affairs and Division of Federal-State Relations to achieve significant progress in various aspects of State program oversight in response to the 2000 OIG report. Prior to the 2009 notice, who completed these tasks and why was this solicitation posted on February 3, 2009? Who is completing these tasks now? Why is FDA contracting out this work that seems to be a core operational function of FDA?

8. Under FDAAA, would a company like Peanut Corporation of America be considered a "responsible party"?

9. Under FDAAA, would food contaminated with salmonella qualify as a "reportable food"?

10. What is the status of FDA's effort to create the Reportable Food Registry System? When can we expect it to be operational? Please provide documents that substantiate FDA actually implementing the Reportable Food Registry System.

11. Do you think this kind of reporting mechanism, already enacted within FDAAA, would help prevent a salmonella outbreak like the one involving Peanut Corporation of America?

We would respectfully request, if the Department withholds any documents or information in response to this letter, that a Vaughan Index or log of the withheld items be attached to the response. The index should list the applicable question number, a description of the withheld item (including date of the item), the nature of the privilege or legal basis for the withholding, and a legal citation for the withholding claim.

Your consideration and response is greatly appreciated. If your staff has any questions, please contact Mr. Alan Slobodin or Ms. Krista Carpenter Rosenthall of the Committee Minority staff at (202) 225-3641.

Sincerely,

Joe Barton
Ranking Member

Greg Walden
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable Henry Waxman, Chairman
The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations