DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

MAY 6 2009

Dear Mr. Barton:

Thank you for your letter of March 11, 2009, cosigned by Ranking Member Gregg Walden, Subcommittee on Oversight and Investigations, regarding two issues related to the food safety responsibilities of the Food and Drug Administration (FDA or the Agency).

Specifically, your letter concerned 1) the oversight of state contracts for food inspections, and 2) the implementation of the Reportable Food Registry provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA). With respect to the first issue, your letter referenced a report by the Office of Inspector General (OIG) of the Department of Health and Human Services entitled "FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability," released in June 2000.

We have restated your questions and requests for documents below, in bold type, followed by our responses.

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).**

- *Recommendation 1 -- FDA Should Work with States to Achieve Basic Equivalency in Food Safety Standards and Laws, and in Inspection Programs and Practices.*

In 2003, FDA established a committee of regulatory officials from FDA and several state agencies responsible for the regulation and inspection of food facilities. This committee drafted the Manufactured Food Regulatory Program Standards (MFRPS). This approach encouraged a climate of collaboration between FDA and the states and leveraged the resources of these entities. The MFRPS, comprised of 100 pages of text, worksheets, and report forms, is enclosed at Tab A. In 2008, five states piloted the implementation of the MFRPS and a program audit of the pilot states was conducted.

The MFRPS is being used to improve FDA's oversight of the food contract inspection program with state agencies. The standards are based on performance (i.e. how inspections are conducted) rather than inspection outcomes. Consequently, they provide

a more comprehensive examination of a state's inspection program as well as a program for continuous improvement.

While MFRPS is the primary mechanism FDA is using to meet this recommendation, there are several other mechanisms FDA uses to ensure strong communication, continuous education of individuals, and continuous improvements of state programs. FDA shares compliance program information with our state partners and asks them, whenever possible, to adopt similar or equivalent measures for inspections and analyses. FDA has many state partnership agreements focusing on a range of relationship-building activities, joint work, coordination of programs, and increased training opportunities. Also, training opportunities, when possible, are done jointly to increase communication and information sharing. All of the coordination and cooperation, official and unofficial, helps to build the cohesion needed to create a well-integrated food safety system.

- *Recommendation 2 -- FDA Should Devote High Priority to Improving its On-Site Audit Mechanism for Evaluating the Effectiveness of State Inspections.*

The MFRPS Standard No. 4, Inspection Audit Program (the Audit Program) is a standardized quality assurance program available to FDA and states for evaluating the food contract inspections. The Audit Program was developed jointly by FDA and the states to audit the food contract inspections and it has been in use since Fiscal Year (FY) 2008. The audit program established (1) procedures for conducting audits of contract inspections, (2) a percent-based performance standard, (3) a required frequency of audits, (4) auditor training requirements, and (5) standardized records (an audit form, and quarterly and annual summary report forms of audit findings) to document the audits.

Although FDA audits the state inspection programs with which we contract, the recent *Salmonella* outbreak from contaminated peanuts and peanut products from the Peanut Corporation of America has highlighted limitations in our current approach and has prompted internal discussions on potential enhancements to the audit program.

- *Recommendation 3 -- FDA Should Require that States Routinely Provide FDA with Standardized Information on the Inspections They Conduct.*

For FDA's state contract inspections, state inspectors are required to input complete inspection information in the Electronic State Access to Field Accomplishments and Compliance Tracking System (eSAF). Those inspections are reviewed by both the state supervisor and FDA District contract monitor. Enclosed at Tab B is a screen shot of the data elements required. FDA provides training and helpdesk support for eSAF to state contract inspectors.

- *Recommendation 4 -- FDA Should Draw on Multiple External Sources of Information in Assessing State Inspection Performance.*

FDA is open to receiving information from external sources, but is not actively collecting external source information to assess state contract inspection performance. However, Standard No. 7 of the MFRPS, "Industry and Community Relations," requires states to

interact with industry and consumers to foster communications and facilitate feedback directly into their programs.

- *Recommendation 5 -- FDA Should Provide Substantive and Timely Feedback to States on Their Inspection Performance.*

FDA and the states audit contract inspections following the procedures in FDA's Field Management Directive No. 76, a copy of which is enclosed at Tab C. Each contract year, seven percent of the food contract inspections are set as an auditing goal. In rare instances, the audit rate may be adjusted when the state has limited and experienced inspectors who don't require repeated oversight. The FDA District Office and the state meet to plan the audits and again to discuss the audit findings. When there are opportunities FDA also conducts joint inspections with the states. These can be for training purposes or to accomplish the inspection of an establishment in which both FDA and the state have jurisdiction. Throughout the calendar year, the FDA District Office and the state work together to provide training to state inspectors who conduct the food contract inspections.

As another level of oversight, FDA reviews and must approve each state inspection report before it can be entered in the FDA system. This process, depending on the situation, can include discussions with state partners to provide feedback, ask questions, or determine next steps for collaborative actions.

- *Recommendation 6 -- FDA Should Enhance Its Internal Capacities to Conduct Effective Oversight.*

To enhance FDA's internal capacities for oversight, FDA has increased the number of staff dedicated to the oversight and operation of state programs. In FY 2008, 25 staff positions were dedicated to state program oversight and emergency response coordination. These positions, at both the District and Regional level, were established to give each office a dedicated resource for this work.

FDA has developed a structured formal audit training course, and we conduct joint inspections with states to broaden the knowledge base of inspection protocols and perform FDA-run audits of state inspectors to ensure inspector competence in both inspection and audit functions. A copy of the state food contract auditing training manual is enclosed at Tab D.

FDA District Offices are accountable for conducting effective oversight by tracking and reporting on District program tasks. Districts must review and accept state reports before they are uploaded into FACTS (Field Accomplishments and Tracking System). To help ensure timely review of state reports, a list of outstanding District reviews is pulled each quarter by Headquarters and provided to District and Regional management for resolution. Districts are also required to submit annual audit reports, which are compiled into one comprehensive annual audit report, and is shared with all levels of management.

To enhance FDA's knowledge of food firms operating in interstate commerce, FDA District Offices regularly provide states that have commissioned officers with state inventory lists for review, comment, and edit. States also have the ability in eSAF to update firm data for FDA review, and the contracts require at minimum an annual work planning session to exchange and discuss the inventory.

As part of this recommendation, the OIG report also encouraged FDA to seek broader enforcement authorities. The President has established a working group on food safety and asked that it make recommendations on updating our food safety laws, fostering coordination throughout the government, and enhancing enforcement. FDA is an integral part of the working group's efforts.

- *Recommendation 7 -- FDA Should Increase Public Disclosure of Its Oversight of State Food Firm Inspections.*

Contract audit reports have been, and will in the future, be posted on FDA's Office of Regulatory Affairs, Division of Federal State Relations Web page as resources and legal protections for confidential information permit. During 2007 and 2008, FDA changed its Web management system and began a Web content upgrade. Contract audit reports for the last two contract cycles will be posted by May 15, 2009.

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

These lists are enclosed at Tabs E and F, respectively.

3. **Per Field Manual Directive 76, 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 audit reports.**

A partial response to this request is enclosed at Tab G. We have provided copies of the annual audit summaries from FY 2000, FY 2002, FY 2004, Calendar Year (CY) 2006-2007 and CY 2007-2008. The table below provides the total number of audits performed for the years 2000 through 2008.

FDA Food Contract Inspection Audit Summary for 2000-2008

CY 07-08	358
CY 06-07	442
FY 05	355
FY 04	386
FY 03	421
FY 02	326
FY 01	47
FY 00	52
Total	2,387

FY = Fiscal Year, CY = Contract Year

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

For Hazard Analysis and Critical Control Point (HACCP) inspections for juice and seafood, and for Low-Acid Canned Foods (LACF) inspections, state inspectors do have minimum training requirements, as described below. State inspectors cannot perform contract work in these program areas without having successfully completed the training.

Current Food Contract Statement of Work (SOW) Language for Training Requirements:

- Juice HACCP inspections shall be performed only by state inspectors who have been properly trained and have completed Juice HACCP Alliance Training (or comparable training), FDA Juice HACCP Regulatory Training, required readings and the performance of a HACCP-based inspection.

- Acidified and Low-Acid Canned Foods inspections are to be performed by state inspectors who have successfully completed the FDA Basic LACF Course and Acidified Food Course, and are familiar with LACF and acidified-food regulations.

- Seafood HACCP inspections shall only be performed by state inspectors who have successfully completed the AFDO Seafood HACCP Training Course (3-day Alliance) (or Cornell's online courses + 1 day of classroom) and FDA's "Conducting Seafood Inspections" (FD249) course for regulators, including passing the course assessments and examinations.

In all contract programs, FDA works only with those states with established and experienced programs that have strong working relationships and a history of collaboration with their coordinating FDA District Office. Even though most state inspectors are not required to receive a prescribed FDA training program before conducting contract inspections, FDA is confident in the strength of the state programs with which we contract. Once contracts are established, FDA works continuously with those state partners to improve the quality of inspections. Contract programs are audited annually to identify opportunities for improvement and to assess training needs. A percentage of slots are allocated to state attendees in all FDA-sponsored training, and some special training opportunities are planned primarily for our state partners. FDA funds state attendance at these training opportunities under their Food Safety Contracts.

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.

FDA does not disqualify state inspectors. In June 2000, Field Management Directive No. 76 was revised to incorporate OIG recommendations for improvements to state contract oversight. An FDA audit may find a state inspector "needs improvement," which would

trigger District action as defined in the State Contract Statement of Work, which provided in relevant part:

> G. (5.) Contract Inspection Audit Performance Evaluation: The District shall coordinate with the state to take appropriate action when the Audit Program identifies deficiencies in the performance of contract inspections. The following conditions indicate a need for action on the part of the District: (1) an audit of an establishment contract inspection is rated "needs improvement"; (2) a single performance factor is rated "needs improvement" in multiple audits, (4 or more); (3) the overall rating for the contract performance period is below 80 percent.
>
> An unacceptable audit will not cause a contract to be altered or unpaid nor will payment for the contract inspection be withheld. The state will be evaluated on its overall work performance during the contract year, not the outcome of one contract audit. A single audit may give an indication of a problem but may not prove sufficient to determine its scope. If this occurs, it may indicate an area in the state's inspection program that may be improved.

When our audits have found a state inspector "needs improvement," the District initiates remedial action and monitors progress. Field Management Directive No. 76 provides deficiency resolution guidance. In contract performance year 2007-2008, there were eight occurrences when our audits found a state inspector "needs improvement," triggering a District action.

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?**

In developing FDA's targeting for food inspections each fiscal year, the Agency considers factors that include previous recalls, outbreaks associated with a particular food or firm, adverse event reports, and compliance history. These and other factors result in a risk ranking, which drives the prioritization of which firms are inspected.

FDA does not demand that our state partners inspect any particular firms. Instead, a collaborative work-planning exercise is conducted every year to ensure that FDA and our state partners are using all of their available resources in the most targeted, efficient, and effective way possible to protect public health. A draft list is offered by FDA, and the state partner generally offers comment and updates to the list prior to the work-planning session.

The goals of each session are to:

- Coordinate an inspection schedule that will avoid duplication of inspections by FDA and

state personnel;

- Develop a consensus of the priority in the selection of firms to inspect;
- Establish and exchange primary contact information. Along with program management, it is recommended that senior management from the state and District are also part of the process;
- Confirm understanding of key contract deliverables and schedules;
- Discuss training needs, sharing of resources, and other collaborative efforts;
- Discuss and coordinate audit requirements.

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 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?

In 2008, a former Government Accountability Office auditor, under contract with the Division of Human Resource Development, assisted ORA's senior federal-state programs specialist to conduct audits of the five pilot states implementing the MFRPS. FDA is seeking temporary additional assistance from a contracted source until additional staff can be hired. Prior to 2008 this function did not exist.

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

FDAAA, P.L. 110-85, amended the FD&C Act by creating a new section 417, Reportable Food Registry. Under section 417(a)(1) the term "responsible party," with respect to an article of food, means a person who submits a food facilities registration under section 415(a) for a facility that is required to register under 415(a), at which such article of food is manufactured, processed, packed, or held. A company that performs food manufacturing operations similar to those of the Peanut Corporation of America (PCA) would meet the definition of a responsible party under section 417(a).

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

Under section 417(a)(2), the term "reportable food" means an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. An article of food contaminated with *Salmonella* would meet the definition of 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.

FDAAA created new section 417(b) of the FD&C Act, which requires FDA to establish an electronic portal by which instances of reportable food may be submitted to FDA by responsible parties or public health officials. FDAAA specified this should occur within one year after enactment. Accordingly, the statutory deadline for the Registry was September 27, 2008. After evaluation and consideration of the steps necessary for implementation, on May 27, 2008, FDA announced in the *Federal Register* (73 FR 30405) that we would be setting forth a new projected implementation date of Spring 2009 for section 417 of the FD&C Act.

We delayed full implementation to allow integration of the Registry with the Agency's MedWatch^{Plus} system, an agency-wide system which was already under development, in collaboration with the National Institutes of Health (NIH), to receive electronic reports of adverse events and other reports associated with any FDA-regulated product. After carefully examining alternative electronic methods for implementing the Registry, Agency officials concluded that a single, consolidated system for gathering reports on all regulated products (including foods) would be more useful, efficient, cost effective, and user friendly than separate systems for different product types.

However, in view of the time needed to fully implement MedWatch^{Plus}, we are taking steps to create an interim Reportable Food Registry system by the end of FY 2009. This will provide the necessary electronic portal while we await full implementation of the MedWatch^{Plus} reporting system.

Barring unforeseen events, system development for the Registry under MedWatch^{Plus} should be completed within 2009. NIH and FDA have plans to commence testing immediately thereafter. FDA estimates that the testing phase will last approximately one month. FDA anticipates fully implementing the Registry at the conclusion of successful testing.

FDA intends to begin enforcing the reporting requirements after the Registry becomes operational, and after providing appropriate notice to interested parties. Meanwhile, as stated in the May 27, 2008, *Federal Register* notice referred to above (73 FR 30405), FDA continues to encourage people to report instances of adulterated food through existing mechanisms, such as notifying the relevant FDA District Office, until the Registry is fully implemented.

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?**

Existing requirements under the FD&C Act prohibit the introduction of adulterated food into interstate commerce and require processing firms to follow current Good Manufacturing Practices. We do not know whether, if the electronic portal had been operational in the fall of 2008, PCA would have submitted a required report. Although

FDA has not yet established the required electronic portal, and thus is not enforcing the reporting requirement until the portal is operational, a firm can voluntarily report adulterated food to FDA through existing mechanisms, and FDA has encouraged firms to do so. For example, the Agency became aware of the positive *Salmonella* finding in the current recall of pistachios because the Kraft food company did report their findings to FDA.

Implementing this provision is a priority, and we are working diligently to develop the electronic system. FDA believes that the electronic reporting requirement will be another tool to enhance the Agency's ability to respond quickly to protect consumers from contaminated food.

Thank you for your interest in these matters. If you have further questions or concerns, please let us know. The same letter has been sent to Ranking Member Walden without enclosures.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures