DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

SEP 10 2014

Dear Mr. Chairman:

Thank you for providing the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the February 5, 2014, hearing before the Subcommittee on Health, Committee on Energy and Commerce, entitled "Examining the Implementation of the Food Safety Modernization Act." This letter provides responses for the record to questions posed by Committee Members, which we received on February 24, 2014. We apologize for the delay in responding.

If you have further questions, please let us know.

Sincerely,

Thomas A. Kraus
Associate Commissioner
for Legislation

cc: The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

"Examining the Implementation of the Food Safety Modernization Act"
Hearing before the Subcommittee on Health
Wednesday, February 5, 2014

Attachment 1—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. **The foreign supplier verification proposed rule is focused on the ingredient risk. We believe that industry should also be looking at supplier risk. Does FDA agree that industry should look at both ingredient and supplier risk when making decisions on how to allocate supplier verification resources?**

We agree that importers should consider supplier risks in determining appropriate supplier verification activities. The proposed rule on Foreign Supplier Verification Programs (FSVPs) acknowledges the importance of supplier risks in the requirement to conduct a compliance status review and in the requirement to consider supplier practices as part of the analysis of hazards. We are considering comments that we have received regarding the ways importers consider supplier risks as part of the risk analyses they perform to help them determine appropriate verification activities. We will take these comments into consideration when we address risk-evaluation issues.

2. **The auditing and recordkeeping requirements in the foreign supplier verification proposed rule is correctly focused on the source of the problem in foreign food plants. But FDA has no authority over foreign food plants, and therefore, will rely on holding food importers responsible. How will FDA verify that only safe food is being imported? How will FDA plan to expand import testing in a cost-effective and timely manner?**

FDA will continue to conduct inspections of foreign food facilities to assess their compliance with applicable regulations, including the preventive controls regulations, once those regulations are finalized and are implemented. The FSVP requirements provide additional assurance that imported food is produced in a manner consistent with U.S. food safety requirements. After the FSVP regulations become effective, FDA will begin inspecting importers in addition to our scheduled inspection of foreign food facilities, as part of our efforts to ensure that imported food is safe and meets U.S. standards. Importer inspections will become a component of the risk-based approach to food-safety-related inspections that the Agency is developing in accordance with section 201 of FSMA (section 421 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). However, our capacity to fully implement importer oversight will depend on the resources the Agency has to devote to such efforts. The President's fiscal year (FY) 2015 budget proposed an import user fee that would help FDA meet its import safety obligations under FSMA.

3. **FSMA specifically recommends that the FDA take advantage of the capacity and expertise of certified contract testing laboratories to effectively and efficiently expand import testing. What are the FDA's plans for third-party testing domestically?**

Establishment of the FSMA laboratory accreditation program and model standards through rulemaking to implement FSMA section 202 is important to the Agency. FDA's priority presently is finalizing the seven foundational preventive-controls rules to meet court-ordered deadlines. The timing of the release of the proposed laboratory accreditation rule is still under discussion by the Agency. When the proposed laboratory accreditation rule is released, there will be a public review and comment period as has been provided for other proposed FSMA regulations.

4. **In your testimony, you stated that "FSMA will only be as effective as its on-the-ground implementation." To date, what has FDA done to develop and implement a comprehensive training program for its inspection workforce to ensure FSMA is enforced effectively, uniformly and fairly at both the federal and state level? What are the agency's plans and timeline for inspector training moving forward?**

FDA recognizes the need to establish training programs for Federal and state regulators who will oversee compliance with the new FSMA regulations, when finalized, to ensure consistency in the performance and quality of inspections regardless of the regulatory entity that performs such inspections. To implement FSMA, FDA will need to work closely with state agencies and other partners to oversee compliance with the new requirements. FDA has funded the creation of three private-public university-based alliances—the Produce Safety Alliance (PSA), the Food Safety Preventive Controls Alliance (FSPCA), and the Sprouts Safety Alliance (SSA). These alliances are responsible for providing standardized curricula and establishing mechanisms to train industry and regulators on the requirements of the Produce Safety and Preventive Controls (PC) rules for human and animal food. This will help promote widespread industry compliance with the rules and provide for consistent regulatory inspections by state and Federal officials. More information about the alliances is available on the Internet at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm293423.htm.*

Further, we expect to collaborate with state regulatory partners under the Partnership for Food Protection (PFP) umbrella, which includes representatives from the Association of Food and Drug Officials (AFDO) and the National Association of State Departments of Agriculture (NASDA), to develop training and tools targeted for use by regulators when performing inspections and other types of oversight activities to ensure industry compliance with the new prevention-oriented standards.

Finally, FDA's Office of Regulatory Affairs University (ORAU) offers an extensive course catalog of instruction, both traditional in-classroom and distance-learning formats. We envision collaborating with our state regulatory partners to develop and deliver FSMA-related training targeted specifically for regulators by using the alliances'

standardized curricula and ORAU regulator training. We also envision that Federal and state regulators will be trained together using qualified trainers to ultimately establish a cadre of investigators who will conduct inspections to assess compliance with FSMA rules on the farm and in food facilities. We expect the alliances and others to begin conducting training before the compliance dates of the final regulations.

5. **Under the proposed rule for preventative controls, food facilities need to have "qualified individuals" write and implement their food safety plans. How is FDA planning to train its investigators so they know how to evaluate the merits of a facility's food safety plan from a risk based standpoint? Will FDA investigators have the same training as qualified individuals?**

We intend to train food safety staff throughout the Agency and the states, including subject matter experts, investigators, and compliance officers across FDA's Foods Program, and state food safety personnel who conduct inspections on behalf of FDA. FDA plans to develop and provide guidance and technical assistance for food safety staff including regulatory partners to develop an adequate technical understanding of the prevention-oriented regulations and how to conduct prevention-based inspections. FDA also intends to have technical experts available at the time of inspection to respond to questions from Federal and state field investigators about food safety plans.

6. **It is essential that FSMA regulations are enforced consistently from one region to another, and by both federal and state officials. What is FDA doing to ensure this happens?**

As mentioned previously, FDA recognizes the need to establish training programs for Federal and state regulators who will oversee compliance with the new FSMA regulations, when finalized, to ensure consistency in the performance and quality of inspections regardless of the regulatory entity that performs such inspections. To implement FSMA, FDA will need to work closely with state agencies and other partners to oversee compliance with the new requirements. FDA has funded the creation of three private-public university-based alliances – the Produce Safety Alliance (PSA), the Food Safety Preventive Controls Alliance (FSPCA), and the Sprouts Safety Alliance (SSA). These alliances are responsible for providing standardized curricula and establishing mechanisms to train industry and regulators on the requirements of the Produce Safety and Preventive Controls (PC) rules for human and animal food. This will help promote widespread industry compliance with the rules and provide for consistent regulatory inspections by state and Federal officials. More information about the alliances is available on the Internet at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm293423.htm*.

Further, we expect to collaborate with state regulatory partners under the Partnership for Food Protection (PFP) umbrella, which includes representatives from the Association of Food and Drug Officials (AFDO) and the National Association of State Departments of Agriculture (NASDA), to develop training and tools targeted for use by regulators when performing inspections and other types of oversight activities to ensure industry

compliance with the new prevention-oriented standards.

Finally, we envision collaborating with our state regulatory partners to develop and deliver FSMA-related training targeted specifically for regulators by using the alliances' standardized curricula and FDA regulator training offered by our Office of Regulatory Affairs (ORA). We also envision that Federal and state regulators will be trained together using qualified trainers to ultimately establish a cadre of investigators who will conduct inspections to assess compliance with FSMA rules on the farm and in food facilities. We expect the Alliances and others to begin conducting training before the compliance dates of the final regulations.

7. **FSMA does not provide FDA with authority to mandate submission of facility profiles or electronic/remote access to records. While the preventive controls proposed rule does not explicitly require submission of facility profiles or electronic/remote access to records, it does request comment on whether FDA should require these in the final regulation. Is FDA still considering requiring these in the final rule and if so, under what authority?**

We have received numerous comments expressing concern about the submission of facility profiles and electronic/remote access to records. We are evaluating these comments and considering whether there are alternative approaches to obtaining information in advance of an inspection that would improve the efficiency of on-site inspections or perhaps obviate the need for an on-site inspection in certain circumstances. We note that section 418(h) of the FD&C Act provides, in relevant part, that the "...written plan, together with the documentation described in subsection (g) [Recordkeeping], shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request." Section 418(h) does not provide that the written request must be made during an inspection.

On June 26, 2013, the FDA Office of Planning's Risk Communication Staff (RCS) conducted a usability test and a focus group with industry stakeholders on the topic of voluntarily submitting food/feed facility profile information. In addition to the end user testing, RCS also conducted a focus group with the same industry stakeholders to assess the ability of individual facilities to gather the information requested, the time needed, and the cost to the companies for filling out the profile, the major barriers for industry participation, and expected benefits, and to identify alternative sources for the government in obtaining similar information. We are currently evaluating the results from these focus groups along with the comments to the proposed preventive controls rule.

8. **In the preamble to the preventive controls proposed rule, the FDA "tentatively concludes" that it is appropriate to apply Part 11 to FSMA electronically maintained records. Then, FDA asks for comment on whether there are circumstances that warrant not applying Part 11 requirements. FDA did not apply Part 11 requirements during the Bioterrorism Act rulemaking process because it would have required companies to significantly redesign and replace existing systems. Please explain why the FDA has taken a different position here in its "tentative conclusion," and whether the FDA intends to move forward with requiring compliance with Part 11 for FSMA records under all of the proposed rules?**

We have received comments expressing concern about the need to comply with Part 11 for electronic records. We are still reviewing and evaluating these comments and considering whether there are alternative approaches that reduce the burden on industry, while ensuring the integrity of electronic records and protecting public health.

9. **The preventive controls proposed rule requires that records be kept for at least two years. Is this requirement prospective—and therefore would only apply to records created after the effective date of the final rule?**

Yes, it is a prospective requirement. The records retention requirements would become effective on the applicable compliance date. In our proposed rule we indicated that it is reasonable to allow for one year after the date of publication of the final rule for businesses other than small and very small businesses to come into compliance with the new requirements established under FSMA. We further indicated that it is reasonable to allow for two years after the date of publication of the final rule for small businesses and three years after the date of publication of the final rule for very small businesses to come into compliance with the new requirements established under FSMA.

The Honorable G.K. Butterfield

1. **The FDA and food companies can agree that the timely sharing of information is important. However, we have all been reading about the danger of computer hackers and the theft of business and trade secrets as well as personal data.**

    a. **As the Agency considers the exchange of food safety records electronically, should we be concerned about the protection of confidential business information and trade secrets?**

    With regard to the protection of data, FDA adheres to the Federal Information Security Management Act (FISMA) to ensure that the appropriate levels of information system security controls are in place for the sensitivity of any given information.

b. Can you guarantee that the FDA can secure its own data systems and prevent criminals—foreign and domestic—from stealing trade secrets?

FDA continually updates its information technology security systems to ensure the safety and security of the information and data entrusted to the Agency.

c. Could a data breach result in counterfeit products?

We have no evidence that a situation such as this has occurred. As mentioned above, FDA adheres to FISMA to ensure that the appropriate levels of information system security controls are in place for the sensitivity of any given information.

2. **I represent a district that still has pockets of persistent poverty. Many of my constituents in eastern North Carolina struggle from paycheck to paycheck and some have been unemployed for some time. This question is about new rules required by FSMA. I favor regulation when and where it is necessary to protect the public's health and wellbeing. But it's important to remember that regulations come with a cost. Often those costs are passed onto the consumer in the form of higher prices.**

   Considering the amount of work the Agency has done, the work that needs to be accomplished and the work required to consider technical public comment, can the Agency assure this committee that the final rules won't unnecessarily impact consumers like some in my district who can least afford it?

Food safety is a fundamental public health concern and a topic on which the public has high expectations. Unfortunately, one in six Americans suffers from a foodborne illness each year, with the Centers for Disease Control and Prevention (CDC) estimating that 128,000 Americans are hospitalized and 3,000 die annually from foodborne pathogens. Prevention of foodborne illness through a modernized food safety system is the goal of FSMA and the foundational rules proposed by the Agency. The cost/benefit analyses that have accompanied the FSMA rules issued thus far demonstrate significant public health benefits compared to costs. In general, these rules establish best industry practices, and many companies are already in compliance with many of the provisions. To assist industry in complying with the rules in an efficient manner, FDA is also allowing extended time for small and very small businesses to come into compliance. In addition, the Agency has formed Alliances to provide technical assistance and outreach to help industry understand and comply with the regulations. FDA is committed to protecting public health and ensuring food safety by promulgating rules that address the risk to consumers, without placing an undue burden on industry.

3. **Commissioner Hamburg distributed a memo on February 3, 2014. That memo outlined changes and modernization of the FDA. One of the biggest changes is moving the FDA to commodity-based and vertically-integrated regulatory programs.**

   a. What was the impetus for the changes?

   The growing challenges posed by a myriad of new responsibilities acquired through recent legislation, the pace of scientific innovation, and globalization were the impetus for change. In response, on September 6, 2013, Commissioner Hamburg charged the Program Alignment Group (PAG), consisting of senior FDA leaders representing all Directorates, Centers, and ORA, with identifying and developing plans to modify Agency functions and processes in order to best achieve mission-critical Agency objectives. In order for FDA to avoid duplication of function and effort and enhance FDA's ability to succeed in the future, the Commissioner felt it imperative that there be greater clarity and transparency about relative roles and responsibilities of the Directorates, the Centers, and ORA, as well as greater operational and program alignment among these organizations.

   b. Do you think that the shift to commodity-based regulatory programs will improve FDA review and response times, particularly for drug and device applications?

   While each Center has sole control over its application review processes and program alignment changes will not directly impact this activity, any overall changes to streamline Agency processes and create more efficient work flow can contribute to improved review and response times for drug and device applications.

   c. Has the FDA set a deadline for when this transition should be complete?

   The Commissioner directed the Directorates, Centers, and ORA to establish Action Plans for each program that will define with greater specificity the operational changes and decisions needed, as well as the processes for their implementation. The Action Plans are due to the Commissioner by October 1. Successful implementation of these changes will take time, commitment, continued investment and evaluation, and will likely occur over the next several years. Concurrently, ORA and the Centers will streamline management and review levels, where feasible, in order to enable FDA to take timely and appropriate action, avoid duplication, improve efficiency and enhance accountability.

The Honorable Marsha Blackburn

1. **I was one of 33 House members who wrote you last fall asking for an administrative fix to a language problem in the Food and Drug Administration Amendments Act (FDAAA) of 2007 affecting animal food ingredient approvals. It has to do with your agency's interpretation of language related to a statutory requirement you set regarding pet food ingredient "standards." Your response to our letter was that you are working on it, but you hadn't quite figured out what to do. What is the status of the FDAAA fix? When can we—and the industry—reasonably expect you to fix the FDAAA problem?**

To comply with the requirements of FDAAA section 1002, FDA intends to initiate rulemaking to establish definitions for animal food ingredients which are either generally recognized as safe (GRAS) or approved food additives for use in animal food. We anticipate that the regulation would apply to all animal food ingredients rather than only to pet food because we do not believe it would be practicable to separate pet food ingredients from other animal food ingredients.

The Honorable Peter Welch

1. **We understand from farmers that the cost of implementation of these rules may put them out of business. Are you certain your economic costs for compliance estimates are accurate?**

The estimates are based on the best data available to FDA at the time of publication of the proposed rules. We understand that, due to the limited amount of data, and because the estimates reflect average costs over broad size categories, the estimates may not perfectly reflect reality for every individual farm or facility. Wherever possible, we attempted to capture the variability across size and category and the uncertainty inherent in this type of estimation. We are already aware of public comments that will likely lead us to change the estimations for the final analysis.

2. **What role will the states play in implementing FSMA? Is there an opportunity to begin the implementation process now, in advance of the finalization of the rules?**

The states have a very important role in implementing FSMA, and FDA has already begun working on implementation with the states. FDA established several workgroups under the leadership of the FSMA Operations Team to plan the implementation of the final FSMA rules. Each workgroup includes representatives from the key FDA Foods Program components and one or more state representatives. The workgroups are already developing strategies for outreach, training, technical assistance, data collection, and inspections and compliance/enforcement. In order to operationalize FSMA, FDA will need to leverage the resources and efforts of others by working in partnership to create an integrated global food safety network that includes other government agencies (Federal, state, local, and foreign). To that end, FDA has already begun to work with its regulatory partners through the

Partnership for Food Protection to discuss data sharing needs with our regulatory partners to guide inspection work planning. States and other food safety counterparts will be vital partners with FDA to leverage resources to conduct inspections, particularly in the produce arena.

3. **Do you plan to construct an adjudication or conflict resolution process to address the inevitable conflicts between federal regulators, state regulators, and/or the regulated community? If so, will you describe in detail—or at least give a preliminary outline of—what that process would look like?**

ORA has analyzed the need and is initiating the process to establish an Ombudsman position and associated processes, whereby issues or establishment concerns raised in these inspectional communications may be escalated by the establishment or by FDA in a manner consistent with how disputes are processed by other FDA Centers and offices. As part of the FSMA implementation effort, FDA has acknowledged industry's request to consider dispute resolution processes that provide for confidentiality as well as for enhanced consistency across all regions and commodities and an improved global approach in light of the increased formal foreign presence. The possible ORA Ombudsman would address these goals as well as offer a process for resolving issues that arise outside of an inspection.

4. **FSMA was designed to ensure a level playing field between domestic and imported foods. Can you assure Congress that domestic and imported foods will be treated equally?**

FSMA envisions a preventive controls framework to modernize food safety and help ensure the safety of domestic and imported foods. To establish this framework, FDA has proposed seven foundational rules. Rules such as the preventive controls for human food and animal food rules and the produce safety rule would apply to both domestic and imported foods. To provide additional oversight of imported foods, FSMA also mandates the implementation of Foreign Supplier Verification Programs (FSVPs) by food importers. Specifically, FSMA requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not, among other things, adulterated and that it was produced in a manner consistent with FDA's preventive controls and produce safety requirements, where applicable. In addition, FDA has issued a proposed rule on accreditation of third party auditors, a program that, when established, will provide a way to obtain certifications for foreign facilities and food under specified programs. The goal of the suite of FSMA proposed rulemakings is to ensure a level playing field for domestic and imported foods. It should be noted that to ensure adequate oversight and fully implement FSMA, the Agency will need additional resources as proposed in the FY 2015 President's Budget.

5. **We have heard that you have said we will need to educate before we regulate. How do you plan to implement this goal? What is your time line?**

FDA has funded three Alliances to develop training to help educate industry on how to

comply with the requirements of the preventive controls for human food and the produce safety rule. Each of the Alliances has a website on which they have posted informational materials about the Alliance and its activities.

The Food Safety Preventive Controls Alliance (FSPCA), developed in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH), is a broad-based public/private Alliance consisting of key industry, academic, and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training, and outreach program to assist companies producing human and animal food in complying with the preventive controls regulations. The FSPCA will also be a repository for up-to-date scientific and technical information on hazards and preventive controls for foods. The core curriculum will be finalized shortly after the publication of final preventive controls rules for human and animal food. The Alliance and others will conduct training that will begin during the period that precedes the compliance dates.

The Produce Safety Alliance (PSA) is led by Cornell University, and involves FDA, the U.S. Department of Agriculture (USDA), state food and agriculture departments, and two national industry trade associations. The PSA will produce a standard on-farm training manual and curriculum and plans to offer courses to deliver the training. The PSA is developing a training protocol with state and Federal regulators to help ensure uniformity in inspections. It will also be a repository for up-to-date scientific and technical information, including a compendium of produce hazards. The training will be finalized shortly after the publication of the final rule on produce safety. The Alliance and others will conduct training that will begin during the period that precedes the compliance dates.

The Sprout Safety Alliance (SSA), developed in cooperation with IIT IFSH, is a partnership of Federal/state regulators, academia, and industry experts who are developing a core curriculum, training and outreach programs for stakeholders in the sprout production community to enhance the industry's understanding and implementation of best practices for improving sprout safety, and requirements for sprout producers in the produce safety rule. Content development will be complete in 2014 and will be followed by review and refinement and additional pilot training sessions with industry. The training will be finalized shortly after the publication of the final rule on produce safety. The Alliance and others will conduct training that will begin during the period that precedes the compliance dates.

6. Will you please explain how the agency will fix the "farm" definition so that it includes many activities that are regularly part of farming but that, as proposed, triggered the "facility" definition?

We have received many comments related to activities conducted on a farm that are considered part of farming by farmers, yet trigger the requirement for a farm to register with FDA as a facility. Many comments expressed concern that activities such as packing or holding produce from a farm they do not own would subject them to requirements of the proposed preventive controls rules. Some of these issues predate the

proposed FSMA regulations. We are still reviewing comments on this topic. We are planning to publish revised language on key provisions of the produce safety and preventive controls for human food proposed rules affecting small and large farmers, including provisions affecting mixed-use facilities.

The Honorable Michael C. Burgess

1. **FDA's budget appropriations have grown from $1 billion to over $2.5 billion in the last seven years. Despite last year's sequester, FDA received from Congress an increase of $96 million over the amount provided in FY 2013 and $3 million above the agency's budget request. Of this $900 million was targeted to the food safety work of the Center for Food Safety and Applied Nutrition (CFSAN).**

   The Administration's proposed FY 2014 budget for FDA included a proposal to impose a food facility registration and inspection fee to fund agency activities related to FSMA. While maintaining the safety of the U.S. food supply is the highest priority for both Congress and the FDA, I am concerned about how the Agency is using the funds that have already been allocated for food safety. Will you provide documentation and accounting for the $900 million that was targeted to the CFSAN?

The $900 million you reference was for the Center for Food Safety and Applied Nutrition (CFSAN) and related field activities in ORA for FY 2014. Congress has provided additions to FDA's base budget for food safety in the amount of $138 million from FY 2011 through FY 2014. Those funds were used to replace staff who were lost during earlier budget reductions as well as to begin the process of implementing FSMA. A compilation of some of the most important uses to which those additional funds were allocated is outlined below.

Funding History

When FSMA was enacted, the FDA foods program was just rebounding from a decline in resources and expertise. In 2003, FDA's headquarters food center, CFSAN, had 950 scientists and other food-oriented staff. Various budget reductions in the 2000s had reduced the staffing level at CFSAN by 20 percent (to 750 people).

In 2010, food safety rose to the forefront of Congressional attention with enactment of FSMA and changed how food in the United States would be regulated. The new Act was passed in response to a cascade of food safety problems in the 2000s that sickened millions of Americans, reduced consumer confidence in the safety of the food supply, and cost farmers and the food industry untold dollars in lost sales, recalled products, and legal liability. Congress responded with additional funding for the FDA food safety program and over the next four years provided FDA with over $138 million in base funding. It also provided a one-time increase in FY 2013 of $37 million to support FSMA implementation.

With these new resources, FDA has strengthened its food safety program in a variety of important ways:

Began the development of new prevention standards – FSMA directs a massive paradigm shift for food safety, from reacting to food contaminations that have already occurred to focusing on preventing such problems before they affect consumers. With the new funding provided, FDA has been able to design, develop, and propose for public comment the seven foundational regulations that will govern this new paradigm. FDA has held numerous public meetings to ensure thorough involvement by stakeholders in the creation of these rules and to ensure a transparent rulemaking process. Just to illustrate the extent to which FDA has gone to ensure transparency in the evolution of these rules, the following example is offered. In support of the intentional adulteration proposed rule entitled "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration," FDA has conducted three FSMA public meetings strategically located across the domestic U.S., 16 rule overview/listening sessions to both national and international stakeholders, and two listening sessions requested by stakeholders with specific topics of concern. A FSMA Fact Sheet specific to the intentional adulteration proposed rule was posted on FDA's website as well as a "Frequently Asked Questions" document to inform and assist stakeholders.

Met public and Congressional expectations for increased domestic food inspections – A key direction by Congress in FSMA is that every domestic facility deemed to be "high risk" must be inspected at least once in the five year period following the date of enactment of FSMA, and at least once every three years thereafter. With the new resources, FDA developed and released in March 2012 information on how it would apply the High-Risk definition to food facilities resulting in an increased inspection rate. Using these criteria, FDA met that target in FY 2013 and is now inspecting every high-risk domestic food facility once every three years.

Increased oversight of imported foods – As with domestic food inspections, FSMA directs FDA to increase efforts to help ensure the safety of food imports, which arrive at U.S. ports in over 12 million shipments each year. With the increased funding provided by Congress in FY 2011-2014, FDA has:

- Exceeded its target of import inspections by more than 10 percent (to almost 200,000 examinations by 2013);
- Increased inspections of foreign food facilities from about 350 in 2010 to 1,400 by FY 2013;
- Completed seven comprehensive assessments of foreign regulatory systems to determine if they provide the same safety protections as FDA and, with New Zealand, FDA has negotiated the first systems-recognition arrangement;
- Expanded FDA's foreign offices in some of the largest food-producing countries of the world, including China and Mexico; and
- Created the first regional training center, in Southeast Asia, aimed at building aquaculture producers' regulatory capacity and to address widespread problems

with imported seafood from Asia.

Developed state programs – Continued its efforts to assist the states through grants, contracts, and cooperative agreements to build their capacity as partners in the U.S. food safety system and be active partners in the prevention focus of FSMA and major contributors to the management of foodborne outbreak responses.

- Provided funding for 40 states to help them meet the Manufactured Foods Regulatory Standards; and
- Provided funding for 31 states to upgrade their public health laboratories.

Created three "Alliances" to help affected industries adopt new prevention standards – The new funding enabled FDA to magnify its investment by embracing a strategy of creating alliances that provide education, training, and technical assistance for industry and government officials. The Preventive Controls Alliance, the Produce Safety Alliance, and the Sprout Safety Alliance will tremendously help producers, especially small and medium-sized businesses, comply with the new prevention rules once they are completed.

Began a program of "risk analytics" – FSMA directs FDA to adopt risk-based regulations and compliance strategies, and FDA has used its new funding to initiate that effort, which will, over time, enhance the Agency's ability to focus on the highest risk foods and food facilities as well as better prioritize and utilize its own resources.

Conducted the Product Tracing Pilot Project – As required by FSMA, FDA has designed and conducted pilot efforts to determine how tracing of food can be carried out most effectively and efficiently. Included in this are examinations of the data that need to be collected by industry and government, ways to connect data to various points in the supply chain, and the rapidity with which government can receive data on contaminated food.

The examples above comprise some of FDA's most significant accomplishments as a result of increased funding over the past four years, but the Agency also made many other important achievements of smaller scope, such as:

- Updated, expanded, and improved the facilities registration system, which now includes over 193,000 domestic and foreign food facilities;
- Completed a final regulation on administrative detention of contaminated food, which provides a means through which FDA can hold adulterated or misbranded food and prevent it from reaching the marketplace, thus further enhancing FDA's ability to ensure the safety of food for the U.S. consumer;
- Developed a plan to help foreign governments build their capacity to better oversee food that might be exported to the United States;
- Established the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), an integrated Federal-state laboratory initiative to improve identifying and analyzing chemical and microbiological contamination of animal feed;
- Researched pathways by which foods become contaminated and how to prevent such contamination; for example, FDA developed a new rapid method for

detecting Salmonella and a new testing protocol for paralytic shellfish toxins;
- Executed a pilot project to utilize handheld analytical tools at ports of entry;
- Published a draft guidance for industry on Salmonella testing;
- Updated guidance for industry on eliminating seafood hazards in fish and fishery products; and
- Increased the Centers' compliance staffs to assist in the review of the cases resulting from the increased inspections.

2. **FSMA directs FDA to write new regulations for facilities that manufacture, process, pack, or hold human food. Facilities are required to maintain a written food safety plan and comply with the Preventive Controls rule, which includes specific food allergen controls.**

a. How will FDA execute these preventive controls for allergens?

FSMA requires a facility to identify and evaluate known or reasonably foreseeable hazards and lists allergens as one of the hazards facilities would need to consider. In the proposed preventive controls rule for human food, FDA proposed to require the implementation of preventive controls for hazards that are reasonably likely to occur and included food allergens as chemical hazards to be considered by facilities. We proposed including food allergen controls as preventive controls for facilities that handle major food allergens. We also proposed to require that food allergen controls include procedures, practices, and processes employed to ensure protection from cross-contact and for labeling of finished food to ensure allergens were declared on the label. In addition, we proposed to clarify in several provisions of our Current Good Manufacturing Practice requirements that protection against allergen cross-contact (inadvertent incorporation of an allergen into food) is required. FDA has been requiring facilities to address food allergens for a number of years and will continue to assess the control of food allergens during inspections.

b. Will there be thresholds or standard levels?

In December of 2012, FDA opened a docket to gather data and information related to the possibility of conducting a risk assessment related to food allergen thresholds. We have completed a detailed analysis of the comments submitted to this docket. We are also actively assessing the publicly available data in the published scientific literature on levels of sensitivity in the allergic population. Based on these inputs, we will use a risk assessment-based approach to determine if the data support establishing practical thresholds for any or all of the major food allergens. We will make a draft version of any risk assessment available for public comment before the document and results are finalized. We are aware of the public concern about the consequences of establishing such thresholds and will consider those concerns in making any final determinations.

3. **In the FSMA proposed rules, the FDA has proposed requiring submission of facility profiles with hazards and controls information as well as providing FDA with remote access to company manufacturing and related records. It is clear that the statute allows the FDA to access company record during the course of an on-site authorized inspection.**

    a. **Will you describe what statutory authority the FDA has in FSMA to require companies to provide FDA with remote access to company manufacturing and related records?**

    The proposed preventive controls rules require that records be made available upon oral or written request. It does not explicitly require a facility to send records to the Agency rather than making the records available for review at a facility's place of business. FDA requested comment on whether the proposed rule should be modified to explicitly address this circumstance. We note that section 418(h) of the Federal Food, Drug, and Cosmetic Act provides, in relevant part, that the "...written plan, together with the documentation described in subsection (g) [Recordkeeping], shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request." Section 418(h) does not provide that the written request must be made during an inspection.

    b. **What additional information does FDA feel it needs to obtain through remote access to records that it could not obtain during an on-site inspection?**

    The information that would potentially be submitted is the same as what we would obtain during an inspection. As we noted in the preamble to the preventive controls rule, information in a food safety plan is not reviewed by FDA investigators until they are physically present at a facility and have begun an inspection. Having information in advance of an inspection could aid in the efficient oversight of preventive controls by allowing FDA to better target inspectional activities to facilities that produce foods that have an increased potential for contamination (particularly with biological hazards) and to improve on-site inspections by focusing attention on hazards and preventive controls for which the facility appears to have deficiencies. We indicated that facilities would benefit from our advance preparation through interaction with better-prepared investigators and potentially reduced inspection time. Further, such advance record access could obviate the need for an on-site inspection in certain circumstances.

    c. **I am concerned that this additional regulatory burden and time-consuming process does not provide a commensurate benefit to overall food safety. How do you propose companies prioritize these additional activities over the usual activities that directly enhance food safety?**

    In our proposed preventive controls rules, we proposed that the records for part

117 be made available to an authorized representative of the Secretary of HHS upon oral or written request. We did not propose to require facilities to submit records electronically, but asked whether we should do so. We have received numerous comments expressing concern about the submission of records electronically. We are evaluating these comments before making a decision and will consider whether such requirement will impose a burden on industry that is not commensurate with food safety.

The Honorable John Shimkus

1. **Is it true that finished product testing may not be identified as necessary in a facility's food safety plan based on the relevance for the facility, food, and information from other verification activities but under the proposed Preventative Controls rule those products would be subject to mandatory finished product testing?**

The proposed preventive controls for the human and animal food rules would require that a facility verify that its preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. We did not include requirements for finished product testing. We did, however, acknowledge that product testing programs, when implemented appropriately in particular facilities, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. In appendices to the proposed rules, we provided our current thinking on the role of and need for product testing as well as some of the factors a facility should consider in establishing a product testing program. We agree that finished product testing may not be identified as necessary in a facility's food safety plan, depending on the food, the activities of the facility, and the nature of the controls. Our discussions in the proposed rules noted that finished product testing plays a very important role as a verification measure in ensuring the safety of food, *when implemented appropriately in particular facilities*. (Emphasis added.) We are evaluating the many comments on this issue.

2. **During your testimony, you noted that "certain kinds of testing programs ...can be important" in food safety systems, while stating that it is "well-understood that those testing programs have to be based on particular risk considerations." The Committee agrees that testing should be risk- based and that a "one size fits all" approach will not work. Although the FDA did not provide proposed testing language on which industry could comment, would you agree that prescribing specific testing for all possible variables is not practicable?**

Yes, we agree that testing for all hazards in all foods is neither practical nor necessary. As noted above, we believe that testing can be an important tool in a modern food safety system, particularly as a verification procedure under specific circumstances.

3. **In your opening statement, you said the Agency "intends to publish and seek comment on revised rule language on key provisions of the Preventive Controls rule... on which our thinking has evolved." I believe it is important for the FDA to seek additional comment from stakeholders on specific regulatory language that was left out of the initial proposal. Will this revised proposed rule allow for an academic discussion and response to detailed testing, supplier verification, and economic adulteration rules?**

In December 2013, FDA announced that it intends to publish revised proposed rule language in summer 2014 on key provisions of the produce safety and preventive controls for human food proposed rules affecting small and large farmers. These provisions include water-quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities, and procedures for withdrawing the qualified exemption for certain farms.

Though we did not include specific requirements for environmental monitoring, finished product testing, or supplier verification programs in the proposed preventive controls rule, we did acknowledge that such programs, when implemented appropriately in particular facilities, could be used to verify the effectiveness of preventive controls and ensure the safety of incoming ingredients. We provided our current thinking on the role of and need for these types of programs in appendices to the proposed rules. We received many comments on these issues, including comments that requested an opportunity to comment on draft codified language in advance of a final rule. We are considering these comments and options to allow comment on these issues while maintaining our commitment to move swiftly to final rules.

With regard to provisions on economic adulteration, in FDA's proposed rule on intentional adulteration related to acts of terrorism, the Agency stated that before we decide to finalize provisions on economically motivated adulteration, we plan to provide new language and an analysis of costs associated with these provisions, and to seek comment. The Agency remains committed to allowing this opportunity for comment.

4. **FDA inspectors and investigators will need to be well educated in how to properly audit food safety systems. Historically, investigators have primarily inspected food facilities for physical evidence of hazards. Under the proactive nature of FSMA, FDA personnel will need to undergo a paradigm shift. They will need to be effective in understanding and evaluating the effectiveness of a facility's food safety system and they will need to evaluate through records review and physical inspection, whether the facility is complying with that system. Please provide a timeline for the Agency's implementation of a comprehensive training program for FDA inspectors, including state and local partners.**

FDA recognizes the need to establish training programs for Federal and state regulators who will oversee compliance with the new FSMA regulations, when finalized, to ensure consistency in the performance and quality of inspections regardless of the regulatory entity that performs such inspections. To implement FSMA, FDA will need to work closely with

state agencies and other partners to oversee compliance with the new requirements. FDA has funded the creation of three private-public university-based alliances – the Produce Safety Alliance (PSA), the Food Safety Preventive Controls Alliance (FSPCA), and the Sprout Safety Alliance (SSA). These alliances are responsible for providing standardized curricula and establishing mechanisms to train industry and regulators on the requirements of the Produce Safety and Preventive Controls (PC) rules for human and animal food. This will help promote widespread industry compliance with the rules and provide for consistent regulatory inspections by state and Federal officials. More information about the alliances is available on the Internet at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm293423.htm.*

Further, we expect to collaborate with state regulatory partners under the Partnership for Food Protection (PFP) umbrella, which includes representatives from the Association of Food and Drug Officials (AFDO) and the National Association of State Departments of Agriculture (NASDA), to develop training and tools targeted for use by regulators when performing inspections and other types of oversight activities to ensure industry compliance with the new prevention-oriented standards.

Finally, FDA's Office of Regulatory Affairs University (ORAU) offers an extensive course catalog of instruction, both traditional in-classroom and distance-learning formats. We envision collaborating with our state regulatory partners to develop and deliver FSMA-related training targeted specifically for regulators by using the alliances' standardized curricula and ORAU regulator training. We also envision that Federal and state regulators will be trained together using qualified trainers to ultimately establish a cadre of investigators who will conduct inspections to assess compliance with FSMA rules on the farm and in food facilities. We expect the alliances and others to begin conducting training before the compliance dates of the final regulations.

5. **The Committee is concerned that the final rule may establish costly testing requirements that focus resources away from the most critical food safety activities. How will you ensure the final rule should provide that the necessity, location, and frequency of pathogen testing in the processing environment and on equipment, including product contact surfaces, is based upon the risk of the product, process, and hygienic status of the production environment, as well as risk information provided from other verification activities?**

In our proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," we did not include specific requirements for environmental monitoring but we acknowledged that such programs, when implemented appropriately in particular facilities, could be used to verify the effectiveness of preventive controls when contamination of food with an environmental pathogen is reasonably likely to occur. We provided our current thinking on the role of and need for environmental monitoring and some of the factors a facility should consider in establishing such a program in appendices to the proposed rules. Environmental monitoring programs should be based on the risk associated with the product and process, as well as the nature of the controls applied in a facility. We are evaluating the many

comments on this issue.

6. **During the hearing, you noted that the Agency is working with industry to "figure out how to exchange information," stating that there is "no lack of sensitivity" to the issue of protecting confidential business information. Viewing facility records is most meaningful when it is done within the context of an on-site inspection. Does the Agency plan to require access to information outside the context of an inspection? If electronic records access is necessary, what security measures does the Agency plan to put in place to prevent unauthorized release of confidential business information?**

We have received numerous comments expressing concern about remote access to records and the need to protect confidential business information. We are evaluating these comments and considering whether there are alternative approaches to obtaining information in advance of an inspection that would improve the efficiency of on-site inspections or perhaps obviate the need for an on-site inspection in certain circumstances. FDA currently collects information during inspections that companies consider to be confidential business information. We take our obligation to protect confidential business information seriously; FDA has Freedom of Information personnel throughout the Agency responsible for handling requests for information and for adherence to laws and procedures regarding the maintenance of confidentiality of non-public information. In addition, FDA has in place all of the appropriate encryption and firewall tools necessary to safeguard the confidential business information and trade secrets entrusted to the Agency.

7. **FSMA limits FDA's ability to mandate auditor reporting to Reportable Food Registry conditions and narrow situations where third-party auditors must be accredited under the FDA Third-Party Auditor Accreditation proposed rule. Will other audits, including consultative audits, be subject to reporting requirements to FDA? If so, under what circumstances?**

Section 307 of FSMA (21 U.S.C. 384d) establishes requirements for: (1) audit reports; and (2) notification to FDA when an auditor "discovers a condition that could cause or contribute to a serious risk to the public health." With respect to audit reports, FSMA section 307(c)(3) requires submission of reports of regulatory audits (conducted for purposes of food or facility certification to FDA) but not reports of consultative audits that would be conducted under FDA's proposed accredited third-party auditor program. FSMA section 307(c)(3) states that such consultative audit reports would be available to FDA only under section 414 of the FD&C Act (21 U.S.C. 350c), which gives us access to facility records if we have a reasonable belief that an article of food, and any other article of food that we reasonably believe is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA).

With respect to "notification" of a condition that "could cause or contribute to a serious risk to the public health" under FSMA section 307(c)(4), we note that the statute does not define "serious risk to the public health" nor does it give examples of such conditions.

Rather, FSMA section 307(c)(4)(A) (Risks to Public Health) describes notifiable conditions as ones that "could" cause or contribute to a serious risk to public health, which suggests to us that the scope of this provision is broader than SAHCODHA circumstances. As explained above, FSMA section 307(c)(3) on audit reports specifically cross-references section 414 of the FD&C Act (21 U.S.C. 350c), but Congress did not use the SAHCODHA standard in describing the types of conditions that could cause or contribute to a serious risk to the public health and that must be reported to FDA under FSMA section 307(c)(4)(A). While we believe Congress intended the standard for notification under FSMA section 307(c)(4)(A) to be a different standard than SAHCODHA, in the proposed rule we invited comment from the public on how to interpret this standard.

The Honorable Leonard Lance

1. **The Committee is aware of and encourages the FDA's work with the cosmetics industry to develop a new regulatory framework to insure safety of personal care products while allowing innovation in product development. Will any proposed new regulatory requirements involve new revenue sources to the Agency?**

The President's FY 2015 budget requests new legislative authority to require domestic and foreign cosmetics manufacturers to register with FDA and pay an annual registration fee. The product, ingredient, and facility information submitted with registration would expand FDA's information about the industry and better enable the Agency to develop necessary guidance and safety standards. With these additional funding resources, FDA would be able to conduct priority activities that meet public health and industry goals.

FDA worked hard with the cosmetics industry last year to produce an agreement with industry on a detailed framework for legislation that established a regulatory scheme to protect consumers from risks associated with cosmetics. That framework included the concept of user fees. Unfortunately, the cosmetics industry has reconsidered the earlier agreement and we received a new proposal from them that would weaken FDA's current ability to take action to protect consumers from dangerous cosmetics. Industry's new proposal is unclear on the issue of new revenue sources. However, as noted above, the President's FY 2015 budget requests a cosmetic safety user fee.

2. **In my judgment, a key element of proposed new regulations, and an important part of a new regulatory framework, would be national uniform requirements. Does FDA support having national safety standards for cosmetics?**

The detailed framework that FDA and industry agreed on last summer included the concept of national uniformity on certain aspects of cosmetic regulation. States would have been preempted from taking action against cosmetic ingredients that FDA had found safe and would have been prohibited from establishing different requirements for registration, cosmetic listing, adverse event reporting, and good manufacturing practices (quality controls) from those of FDA. These limitations on State authority made sense in the context of significantly enhanced authorities for FDA to strengthen

the Agency's ability to protect consumers from dangerous cosmetics. Unfortunately, the proposal we received from the cosmetics industry in early 2014 would weaken FDA's current ability to take action against unsafe cosmetics. Through sweeping preemption provisions that, to our knowledge, are unprecedented in Federal legislation, this new industry proposal would also almost completely eliminate states' authority to protect their citizens from unsafe cosmetic products and ingredients, including thousands of ingredients FDA has not reviewed and has no resources to review. It would also remove basic state enforcement powers, such as inspection and recall authority. We believe that these sweeping preemption provisions could endanger public health by preventing states from taking action on safety issues that FDA may not be able to address.

3. **For years, the Agency has been asked to establish safety levels of ingredients, such as for lead in lipstick. A lack of action in this area results in consumer confusion and regulatory uncertainty for manufacturers. Will the Agency provide the Committee with a timeline for completion of safety level determinations under the proposed new regulations?**

The framework for new cosmetics legislation that FDA and industry agreed on last summer and the proposal FDA has received from industry in early 2014 differ dramatically in this area. The industry's proposal would require FDA to undertake a very resource-intensive and burdensome process requiring two separate rulemakings before FDA could establish limiting levels on either an ingredient or a contaminant (such as lead in lipstick). It is difficult to estimate how long this process might take, but we believe it would be substantially longer than the process outlined in the framework agreement.

The Honorable H. Morgan Griffith

1. **The Food Safety Modernization Act uses the term "reasonably foreseeable," but there are concerns that FDA may use the term "reasonably likely to occur" (RLTO) to define a threshold for determining preventive controls. The proposed RLTO standard lends itself to regulatory rigidity and perhaps absurdity. During the hearing, you stated that there is "a way to solve this and manage this" concern so that those facilities with advanced food safety systems do not have to change their already effective practices. How does FDA plan to address this concern, and when can the Committee expect a successful resolution?**

In the proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," we proposed that the application of preventive controls would be required in cases where facilities determine that hazards are reasonably likely to occur. We have received many comments related to the use of the term "reasonably likely to occur." Comments expressed concern that if we use this term as the basis for determining the need for preventive controls, then either all preventive controls will need critical control points (CCPs) or people will be confused by the term being different in this rule from the seafood and juice Hazard Analysis and Critical

Control Points (HACCP) rules. Comments have also expressed concern that this approach would require existing food safety systems to be revised. We are still reviewing comments on this matter.

The Honorable Gus Bilirakis

1. **Currently, over 200 Food and Drug Administration (FDA) regulations incorporate food ingredient standards the United States Pharmacopeia (USP) publishes in the Food Chemicals Codex (FCC). FDA from time to time updates these references, and the Agency has also worked closely with USP on important issues including adulteration of food ingredients (e.g., glycerin). In the hearing, FDA stated that a national standard of identity is useful, but FDA was limited due to resources. Would FDA be willing to work specifically with USP and stakeholders on the issue of economically-motivated adulteration of honey, to help protect its integrity and see if an appropriate national quality standard could be developed and placed in regulation?**

FDA believes that such collaboration may be helpful to us in identifying ingredients that may be sources of economically motivated adulteration in honey and will strongly consider working with USP in this area. Regarding the establishment of a standard of identity for honey, FDA has concluded that the establishment of a standard of identity for honey would not aid the Agency in its enforcement efforts or help ensure industry compliance. The Agency currently has authority under the FD&C Act to take enforcement action against adulterated or misbranded food products, including honey. In fact, FDA has acted to prevent adulterated honey from being distributed in the United States. A standard of identity is not a prerequisite for enforcement actions against food products that are adulterated or misbranded. On April 11, 2014, FDA issued draft guidance on the proper labeling of honey and honey products that advises firms on the proper labeling of honey and honey products to help ensure that honey and honey products are not adulterated or misbranded under sections 402 and 403 of the FD&C Act.

Attachment 2—Member Requests for the Record Raised During the Hearing

The Honorable John D. Dingell

1. **Please submit a survey of what you need in the way of money to properly implement the Food Safety Modernization Act.**

FDA cannot achieve our objective of a safer food supply without a significant increase in resources. As you know, the FDA Food Safety Modernization Act (FSMA) has instructed FDA to overhaul its food safety program, with major new directions, such as:

- Shifting food safety from an old, antiquated system of chasing after problems once they occur to a new focus on prevention
- Better integrating Federal efforts with state and local food safety systems
- Implementing an entirely new import oversight program that relies on importers having more responsibility regarding the foods they bring into the United States
- Increasing both domestic and foreign inspections, especially in facilities producing foods at high risk of contamination
- Modernizing and streamlining the food importing process so as to enhance trade in safe food.

Some of these efforts are well underway. For example, resource increases provided by Congress in earlier years have permitted FDA to meet the Congressional mandate to inspect domestic high-risk food firms more frequently and to greatly increase inspections of foreign facilities.

As reflected in FDA's FSMA Section 110 report last year (*http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm351868.htm*), CBO estimated that the Agency would need an estimated $400 - $450 million in funds added to its FY 2012 base by FY 2017 to implement FSMA. FDA has received approximately $138 million in increases towards FSMA implementation thus far. The FY 2015 President's Budget proposes an additional $253 million to support FSMA implementation.

The urgency of receiving adequate funding is that FDA is under court-ordered deadlines to issue key final rules in late 2015 and early 2016, which means FDA must be equipped to begin sound inspection and other oversight activities to ensure smooth and effective implementation in late 2016 and 2017. Without immediate investment in the advance preparation that is essential for sound implementation of the FSMA rules, implementation will be disrupted and delayed to the detriment of public health, consumers, and the food industry.

Below is a detailed summary of how FDA would use the additional funding to implement FSMA.

Domestic

Center Technical Staffing and Guidance - FSMA directs FDA to undertake its most complex and challenging effort ever to produce the rules and guidelines under which the food industry will ensure safe food and feed production and FDA investigators will inspect. Those new standards must have a strong basis in science, be the product of the best technical expertise available, and be the result of continuous discussion with stakeholders. Additional funding would be used to recruit knowledgeable experts at FDA who can ensure that the new prevention standards and guidelines are based on the best science and intimate knowledge of industry practices. These experts are also essential to support FDA's compliance force in properly overseeing implementation of the new standards. FDA would also support collaboration with industry, academia, and state extension services to ensure that their concerns are heard, that their advice is solicited and utilized, and that the rules are the most cost-effective solutions achievable. Implementing these activities is urgent because the rule and guidance development are underway, and final rules must be submitted to the *Federal Register* for publication on a court-ordered timeline.

Education/Technical Assistance for Industry - The shift toward preventing food contamination directed by FSMA creates a need among many farmers and processors – and especially small producers – for technical assistance to facilitate their implementation of the new standards. For example, approximately 36,000 fruit and vegetable producers could be subject to the proposed produce safety rule, and approximately 40,000 food (including animal feed) facilities could be subject to the proposed preventive controls rules. Many of these firms are expected to seek training, advice, and technical assistance to fully understand and comply with the new requirements. Further, many additional farms and facilities that would be exempt, not covered, or subject to modified requirements are expected to seek assistance. FDA believes that it should expend substantial financial resources to further the food safety objective by providing guidance and working with Federal, state, and local partners assisting industry in coming into compliance. In addition to providing guidance, FDA would provide financial support to state agencies and public-private-academic collaborative entities, such as the Produce Safety Alliance and the Preventive Controls Alliance. Without these activities, industry will not get the help it needs to successfully implement the new requirements, and the movement toward safer food production will be markedly delayed.

Inspection Modernization and Training - FDA inspectors are currently trained to inspect food manufacturers using a compliance model focused on finding evidence of hazards. The new food safety paradigm will be focused on preventing hazards through a system-based approach and on ensuring consistency among all inspections. This new paradigm involves a major reorientation and retraining of almost 1,700 inspectors, compliance officers, and other staff involved in food safety activities in fundamentally different approaches to food safety inspection and compliance. To accomplish this in time, training in the new prevention and systems approach must begin in 2015, with further technical training continuing into 2016 and beyond after the FSMA rules are finalized. FDA has also committed to move toward more targeted, risk-based, and efficient inspection models, which will require better data

about facilities, new IT systems to identify and track risk, and methods for assessing and tracking inspection efficiency and inspector competency. Those systems also need to be in place at the time inspections begin in 2016. Thus, FDA would not need more inspectors, but rather the means to make its current inspectors efficient and effective under the new inspection and compliance approach.

National Integrated Food Safety System - The states are projected to conduct over half of the domestic facility inspections required by FSMA. Building state capacity to coordinate effectively with FDA is a central tenet of FSMA and is needed to ensure that states are prepared to conduct these inspections using the same standards and methodologies as FDA inspectors. States will need inspector training, greater information sharing capacity with FDA and other states, state laboratory coordination, and inspector certification programs. Like FDA's own retraining effort, those processes, which will be carried out mostly via FDA grants to 40 or more states, must begin in 2015 if the states are to be prepared when industry becomes obligated to comply with the new regulations starting in 2016.

Risk Analytics and Evaluation - One key element of FSMA is the vision of future regulatory action being focused on the degree of risk posed by a given food. So FDA is developing new tools that will provide the information needed to focus decisions and resources on areas of greatest risk to public (human and animal) health. This includes new tools for ranking risks, prioritizing program activities based on opportunities to reduce risk, and linking risk-based priorities more clearly with budget formulation and execution. For example, these new tools might better inform FDA about which foods are most vulnerable to which bacterial contaminants or where FDA should invest its research efforts to most effectively identify how to reduce contamination of food. As a result, this will improve FDA's productivity in all areas, including research and standard setting, inspections, and technical assistance to industry. In addition, the FY 2015 budget requested $977,000 in antimicrobial resistance funding to support data collection and evaluation needed to monitor and assess the impact of FDA's initiative to limit the use of antimicrobial drugs in food animal production.

Imports

FSVP Implementation - The Foreign Supplier Verification Program created by FSMA will transform import safety screening by requiring importers to develop supplier verification plans to help ensure greater food safety before food or feed is sent to the United States and examined at the border. This shift will have wide effect for both FDA and food importers, given that there were approximately 88,000 consignees receiving food shipments last year. To be successful, FSVP will require a substantial regulatory development process, staffing and training within FDA to enforce the regulation, and extensive training and technical assistance for importers. Without the means to make FSVP implementation successful, FDA could fall short of meeting FSMA's goals.

Overseas Presence and Partnerships - One of FDA's best opportunities for return on investment is in helping foreign governments better ensure the safety of food and feed before it is even shipped to the United States. FDA has been implementing that concept in three ways: placing staff in foreign offices, increasing the number of foreign inspections, and

developing partnerships with its counterparts overseas. Some of those efforts are focused more on technical assistance, such as helping other nations improve their regulatory systems and upgrade their public health laboratory methods and training. Others are more sophisticated, such as working with more developed countries on "systems recognition," a process by which FDA will determine whether another country's food and feed safety system provides protections comparable to those in the United States and, thus, that food from that country will be of a lesser concern when it is exported to the United States (allowing FDA and industry to focus their import screening efforts on areas of higher risk). The first such analysis was completed with New Zealand in 2012. One with Canada is currently being negotiated, and others may be initiated in the future.

Private and Public Audit Enhancement - FSMA encourages the use of "auditors" to help food and feed importers successfully meet their requirements for better protecting food. Some of those auditors will be certified by FDA as part of a FSMA-mandated system for giving expedited entry for importers who meet the highest standards. All are part of a growing global system of food protection that is focused on helping producers and importers meet modern food and feed safety standards by the United States and other countries. A modest investment by FDA in working with industry to improve the training and performance of those auditors will pay dividends many times over in safer food and feed.

Port of Entry Streamlining - Food importers are increasingly communicating that FDA's screenings have posed challenges for them. Much of that is due to the exponential increase in food and feed imports in recent years, to almost 12 million shipments this year, while the number of border inspectors has remained static. Importers seek improvements to FDA procedures, such as more staff on duty during the busiest periods, a "help desk" to resolve delays, and better FDA information systems to identify the riskiest imports for better targeting. FDA is willing to provide those services, as they will not only assist importers but also enhance the Agency's ability to detect and deter contaminated food and feed being offered for importation into the United States.

2. Please submit a detailed response describing what resources you need to meet the hiring targets set by FSMA and how many full-time equivalent employees FDA needs and plans to hire.

As described in more detail in the previous response, FDA estimates that receipt of funds in the amounts requested in the FY 2015 President's Budget would significantly close the gap toward a goal of an additional $400 million to $450 million in funds added to its FY 2012 base by FY 2017. The President's FY 2015 budget estimates that 390 FTEs would be hired with the appropriated dollars and user fee funds. These hires would be a significant step in performing the work needed to create the import oversight system, provide technical assistance to industry and FDA inspectors in real time, and train federal and state inspectors. Additional full-time equivalents may be needed in future years to fully implement FSMA, but the FTEs anticipated in the President's budget would be a significant resource for FSMA implementation in the near future.

The Honorable Tim Murphy

1. **A couple years ago, the Centers for Disease Control said there was a reduced or different risk in foreign imported products versus the United States. Does that difference still exist? Is there a difference in seafood, meats, fruits, and vegetables? Any categories in terms of which are at higher risk, or does it vary?**

CDC has indicated in recent publications that outbreaks overall decreased in 2009-2010, but noted that preliminary information indicated an increase in outbreaks associated with certain imported foods (seafood and spices) for the same time period. However, CDC also noted that importation of foods was increasing over the same time frame. FDA's draft spice risk profile also noted evidence of increased contamination with certain pathogens in spices compared to other imported foods. However, CDC has also indicated that none of the reporting is over a long enough time period to establish a trend.

Overall, foodborne illness continues to be a significant problem in the United States. Unfortunately, one in six Americans suffers from a foodborne illness each year, with CDC estimating that 128,000 Americans are hospitalized and 3,000 die annually from foodborne pathogens. Prevention of foodborne illness through a modernized food safety system is the goal of FDA, particularly through implementation of FSMA, which contains provisions to address risk from both domestic and imported foods.