FDA FOOD SAFETY MODERNIZATION ACT

BARBARA CASSENS INTERVIEW ON FSMA INSPECTION AND COMPLIANCE PROVISIONS

Following are questions and answers on the topics covered in Barbara Cassens' interview on FSMA inspection and compliance provisions.

GENERAL

FSMA HAS SEVERAL PROVISIONS ON INSPECTIONS AND COMPLIANCE. WHAT WILL BE NEW?

For the first time, FDA has been given an inspection mandate. The legislation requires inspections to be based on risk, and the frequency of inspections to increase. It calls for all high-risk domestic food facilities to be inspected within five years of the bill's signing and then at least once every three years after that. Further, all other domestic food facilities are to be inspected within seven years of the bill's signing and then at least once every five years thereafter.

WHAT ABOUT INSPECTIONS OF FOREIGN FACILITIES?

Within one year of the bill's signing, FDA is to increase inspections of foreign facilities, and then increase that number every year for five years.

MANDATORY RECALL

UNDER FSMA, FDA NOW HAS AUTHORITY TO ORDER A MANDATORY RECALL. HOW WILL THAT WORK?

FDA anticipates that mandatory recall authority will be used in rare instances. Companies will be provided with an opportunity for an informal hearing before an order to require recall is made.

WOULD A VOLUNTARY RECALL PRECLUDE AN FDA MANDATED RECALL UNDER FSMA §206/FDCA §423?

Under FDCA §423(a), FDA is required to first give a responsible party the opportunity to cease distribution and conduct a voluntary recall of an article of food. If the responsible party refuses to or does not voluntarily cease distribution or recall such food within the time and in the manner prescribed by FDA, FDA may proceed under the mandatory recall authority as set forth in FDCA §423.

WHAT IS THE STANDARD AND PROCESS FOR A MANDATORY RECALL?

FDA's mandatory recall authority became effective when President Obama signed the FSMA into law on January 4, 2011. Section 206 of FSMA sets forth the standard for mandatory recall and procedures FDA will follow when it exercises its mandatory recall authority.

SUSPENSION OF REGISTRATION/ADMINISTRATIVE DETENTION

WHAT ARE OTHER KEY PROVISIONS RELATING TO COMPLIANCE?

The legislation provides FDA authority to suspend a facility's registration under certain circumstances, which would prevent that facility from introducing any food into commerce in the U.S., including importing or exporting food into the U.S. It also provides more flexibility for FDA in using its administrative detention authority to keep potentially adulterated or misbranded products from entering the marketplace.

WHAT IS FDA'S AUTHORITY TO SUSPEND THE REGISTRATION OF A FOOD FACILITY?

Section 415(b) of the Federal Food Drug and Cosmetic Act, as amended by the Food Safety Modernization Act Title 1, Section 102, for the first time explicitly provides FDA the authority to suspend by order the registration of a facility registered under section 415 in certain circumstances involving food manufactured, processed, packed, received or held by a registered facility that has a reasonable probability of causing serious adverse health consequences or death to humans or animals. FDA did not previously have a process for suspending the registration of a food facility in such circumstances.

WHEN MAY FDA SUSPEND THE REGISTRATION OF A FACILITY REGISTERED UNDER SECTION 415 OF THE FEDERAL FOOD DRUG AND COSMETIC ACT?

If FDA determines that food manufactured, processed, packed, received, or held by a facility has reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that :

- Created, caused or was otherwise responsible for such reasonable probability; OR
- Knew of or had reason to know of such reasonable probability AND packed, received or held such food.

WHEN ARE REGISTERED FACILITIES SUBJECT TO THE SUSPENSION OF REGISTRATION PROVISIONS?

Registered facilities became subject to the suspension of registration provisions in section 415(b) of the Federal Food Drug and Cosmetic Act on July 3, 2011; 180 days after the date of enactment of the Food Safety Modernization Act (January 4, 2011).

WHAT IS THE EFFECT OF SUCH A SUSPENSION?

If the registration of a facility is suspended, no person shall import or export food into the United States, offer to import or export food into the United States, or otherwise introduce food into interstate or intrastate commerce in the United States from such facility. This important authority will further help the FDA assure the safety and security of our nation's food supply.

WHO MAY ISSUE AN ORDER TO SUSPEND A FACILITY'S REGISTRATION?

The authority to issue an order to suspend a registration or to vacate an order of suspension may not be delegated by the Secretary of Health and Human Services to any officer or employee other than the FDA Commissioner.

Is there an opportunity for a hearing on suspension?

FDA will provide the registrant with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 business days after the issuance of a suspension of registration order, unless an alternate time period is agreed upon by FDA and registrant. The registrant will have opportunity for an informal hearing on actions required for reinstatement of registration and why the registration that is subject to suspension should be reinstated. FDA may reinstate a registration if it determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

What happens if it is determined that suspension remains warranted after the opportunity for the informal hearing?

FDA will require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by FDA.

How may a suspension of registration order be vacated?

Upon a determination that adequate grounds do not exist to continue the suspension actions required by an order of suspension of registration, or that such actions should be modified, FDA may vacate the order and reinstate the registration of the facility subject to the order, or modify the order, as appropriate.

Is FDA going to promulgate regulations on suspension of registration?

Although FDA's authority to suspend registration under section 415(b) of the Federal Food Drug and Cosmetic Act became effective on July 3, 2011, FDA is required by section 415(b) to promulgate regulations to implement the suspension of registration provisions. Such regulations may more fully document components of the suspension of registration provisions. Registered facilities are subject to the suspension of registration provisions regardless of the status of regulations to implement section 415(b).

For administrative detention, what is the process to detain food and what if the food is perishable and can spoil?

FSMA enhances FDA's administrative detention authority by authorizing FDA to administratively detain articles of food that FDA has a reason to believe may be adulterated or misbranded. FDA intends to revise its administrative detention regulations and other relevant documents to reflect this new standard.

FEES

Will there be a fee associated with FDA inspections?

FSMA authorizes FDA to assess and collect fees related to certain domestic food facility, foreign food facility, and importer reinspections. There is no fee for an initial FDA inspection. The fee for reinspection is to cover reinspection-related costs when an initial inspection has identified certain food safety problems.

WILL THERE BE ANY FEES CONNECTED TO THE NEW RECALL AUTHORITY FDA NOW HAS?

FDA has authority to assess and collect fees for food recall activities associated with a recall order when a domestic food facility or importer does not comply with such order.

WHO IS AFFECTED BY THESE FEES?

Only those parties in the food and feed industry whose non-compliance results in the following activities:

- Facility reinspections – follow up inspections conducted by FDA subsequent to a previous inspection that found a violation materially related to food safety requirements. The reinspection must be conducted specifically to determine that compliance has been achieved.
- Recalls – food recall activities performed by FDA that are associated with a recall order with which a responsible party has not complied.
- Importer reinspections – follow up inspections of a food offered for import conducted by FDA subsequent to a previous inspection that found a problem materially related to food safety requirements. The reinspection must be conducted specifically to determine that compliance has been achieved.

WHAT ARE THE FY 2012 FEES?

The rates are as follows: $224 an hour if no foreign travel is required and $335 an hour if foreign travel is required.

SMALL BUSINESS

CAN SMALL BUSINESSES HAVE THEIR FEES WAIVED?

The FY2012 fee schedule does not contain any reduced fee rate for small business. However, FDA recognizes that for some small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, and there may be unique circumstances in which some relief would be appropriate. Thus, during FY2012, FDA will consider waiving in limited cases some or all of an invoiced fee based on a severe economic hardship, the nature and extent of the underlying violation, and other relevant factors.

HOW IS FDA ADDRESSING THE IMPACT OF THESE FEES IN FUTURE YEARS ON SMALL BUSINESSES?

A separate *Federal Register* Notice is being issued that requests comments on the burden of the fees on small business. The notice is being published at the same time as the FY2012 fee schedule. The notice requests public input to help the agency understand what factors it should consider in developing guidelines in consideration of the burden of fees on such businesses in future years.

WHEN DO THE FY2012 FEES GO INTO EFFECT?

The fees are effective October 1, 2011 through September 30, 2012