FDA FSMA Progress Report: May – July 2011

The FDA intends to provide regular updates to inform the public and Congress on its progress in implementing the FDA Food Safety Modernization Act (FSMA). This summary does not reference all actions taken by FDA.

July 2011

Six-Month Milestone in the Implementation of FSMA

July 3 marks the six-month anniversary of the signing of the FSMA. On this date, FDA met two additional milestones required under the new law.

Joint Anti-smuggling strategy

FDA issued on July 3, a joint anti-smuggling strategy developed with the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS). The anti-smuggling strategy will help to identify and prevent smuggled foods from entering the United States and posing a threat to national security and consumer safety. The FDA will work with U.S. Customs and Border Protection (CBP) to review historical data and better identify products, firms, and countries of origin to establish food smuggling targeting criteria. The FDA and CBP also will share information on import shipments and conduct joint examinations, when appropriate, to identify shipments that may contain smuggled food. When possible, the agencies will work together to publicize food smuggling enforcement actions to deter others from attempting similar acts.

Anti-smuggling strategy fact sheet
http://www.fda.gov/downloads/ForIndustry/ImportProgram/UCM261739.pdf

Draft guidance for dietary supplement industry

FDA issued on July 3, draft guidance for the dietary supplement industry on assuring the safety of new dietary ingredients. The draft guidance clarifies agency expectations on new dietary ingredients for industry and is an important preventive control to ensure that consumers are not exposed to unnecessary public health risks from new ingredients with unknown safety profiles. Dietary supplement manufacturers are required to notify the FDA in advance when they intend to add a new dietary ingredient to their products, except in certain situations when the ingredient has been part of the food supply and has not been chemically altered for use in supplements. The notifications must identify the new dietary ingredient and be accompanied by evidence on its safety. The draft guidance is intended to inform and assist manufacturers, distributors, and others in deciding when a premarket safety notification for a dietary supplement containing a new dietary ingredient is necessary and in preparing premarket safety notifications.

New Dietary Ingredient Guidance

http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm257563.html

Authority to suspend the registration of food facilities

On July 3, the agency's authority to suspend the registration of food facilities to prevent the import and export into the United States, or other intrastate or interstate distribution of food became effective. The FDA expects individuals responsible for registered food facilities to take steps to produce safe products. If those efforts fail, the facility should file a food report with FDA, voluntarily recall the affected product, and take action to keep products from reaching consumers. FDA may suspend the registration of a facility in certain circumstances involving food that has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

Building Food Safety Capacity through Training

On July 1, FDA and United States Department of Agriculture (USDA), National Institute of Food and Agriculture (NIFA), entered into an agreement to collaborate on the establishment of a competitive grant

program for food safety training, and other projects, as part of a Memorandum of Understanding with USDA's Research, Education and Economics Agencies.

MOU for New Training Grants
http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm261929.html

Administrative detention of foods

This rule, issued in May, allows the FDA to administratively detain food products that it has reason to believe are adulterated or misbranded for up to 30 days, if needed, and went into effect on July 3. Under this rule, these products will not be sold or distributed while the agency determines whether an enforcement action such as seizure or federal injunction against distribution of the product, is warranted.

Administrative Detention

http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0197-0001

June 2011

Public Meeting on Inspections and Compliance

FDA held on June 6 it third public meeting to hear stakeholders' views on key FSMA provisions. This meeting focused on inspections and compliance. Almost 700 people participated in person or via webcast. The public had an opportunity to provide information and share views that will inform the development of guidance and regulations and/or the implementation of: Enforcement Authorities; Frequency and Targeting of Facility Inspections; Manner of Inspection in a Preventive Controls Environment; and Enhancement of the Reportable Food Registry (RFR).

Comments were due to docket by 7/6/11. FDA-2011-N-0366

FDA Public Meeting on Inspections and Compliance

http://www.fda.gov/Food/FoodSafety/FSMA/ucm255954.html

May 2011

Interim Final Rule on Prior Notice of Imported Food

On May 5, FDA issued an interim final rule requiring that a person submitting prior notice of imported food, including food for animals, to report the name of any country to which the article has been refused entry. The new information can help FDA make better informed decisions in managing potential risks of imported food into the United States.

Interim Final Rule on Prior Notice

http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0179-0001

Interim Final Rule on Criteria for Administrative Detention

On May 5, FDA issued an interim final rule on criteria used to order administrative detention of food for human or animal consumption. The rule changes the criteria for ordering administrative detention of human or animal food. Under the new criteria, FDA can order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. This will further help FDA prevent potentially harmful food from reaching U.S. consumers.

Interim Final Rule on Administrative Detention

http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0197-0001

Preventive Controls for Registered Human Food and Animal Food/Feed Facilities

On May 23, FDA announced the opening of a docket to obtain information about preventive controls and other practices used by facilities to identify and address hazards associated with specific types of food/feed and specific processes. FDA established this docket to provide an opportunity for interested parties to provide information and share views that will inform the development of guidance on preventive controls for food and feed facilities that manufacture, process, pack, or hold human food or animal food/feed (including pet food. Comments are due August 22, 2011

Docket on Preventive Controls

http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0238-0001