FSMA Kayıt İşlemine İlişkin Bilgi Notu

Registration

Information available related to Registration under the FDA Food Safety Modernization Act (FSMA).

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New Registration Mandates under the FDA Food Safety Modernization Act

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, enables FDA to better protect public health by strengthening the food safety system. It recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge.

Building a new food safety system based on prevention will take time, and FDA is creating a process for getting this work done. Congress has established specific implementation dates in the legislation. The funding the Agency gets each year, which affects staffing and vital operations, will affect how quickly FDA can put this legislation into effect. FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

FSMA, which amends the Federal Food, Drug, and Cosmetics Act, Section 415, requires domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the U.S. to register with the Food and Drug Administration. The amendments are focused on improving the agency's ability to respond quickly and efficiently.

Frequently Asked Questions on Registration and Registration Renewal

IC.3.1 When does a facility need to start biennial re-registration if it is required to register with FDA under FDCA §415?

FSMA amended FDCA §415 to provide that facilities required to register will have to re-register every 2 years, during the period beginning on October 1 and ending on December 31 in even numbered years. This will first occur in October-December 2012.

IC.3.2 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.

IC.3.3 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.

IC.3.4 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
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IC.3.5 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).

IC.3.6 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.

IC.3.7 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.

IC.3.8 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.

IC.3.9 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.

IC.3.10 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.

IC.3.11 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).

IC.3.12 Does the Food Safety Modernization Act require a food facility to submit additional information to FDA in order for the facility to receive a food facility registration number?

Yes. Section 102 of FSMA amends section 415(a)(2) of the Federal Food, Drug, and Cosmetic Act by requiring food facilities to submit registrations to FDA containing additional information. Specifically, registrations are required to contain the e-mail address for the contact person of the facility, or for a foreign facility, the email address of the United States agent for the facility, and an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Additionally, if determined necessary by FDA, registrations are required to contain information regarding other applicable food categories, as determined appropriate by FDA, for foods manufactured/processed, packed, or held at registering facilities.

IC.3.13 Will food facilities already registered with FDA under section 415 of the FD&C Act be required to renew their registrations during the October 1 – December 2012 registration renewal period?

Yes. All facilities that are required to register must renew their registrations during the period beginning on October 1 and ending on December 31 of each even-numbered year. The first registration renewal cycle will be held from October 1 to December 31, 2012. Registrants are required to submit registrations

to FDA containing the new information added by section 102 of FSMA. As new requirements and guidance go into effect related to facility registration renewal, FDA will post the information on this FSMA website. For more information on Food Facility Registration, please visit the FDA's Food Facility Registration page.

IC.3.14 What form do I use to renew a food facility registration?

Registrants must use Form 3537 to register, update, or renew a registration. Form 3537 is being updated to meet registration renewal needs. The next registration renewal cycle begins October 1, 2012. Facilities may register online via the Internet at www.fda.gov/furls, which operates during business hours from 7:00 am to 11:00 pm U.S. Eastern Standard Time. **NEW**

- Registration by Paper (Mail or FAX) or CD-ROM
- Step by Step Instructions

IC.3.15 Am I required to renew a food facility registration online?

No. Registrants can renew food facility registrations online or submit the paper Form 3537 by mail or fax. A business with multiple facilities may also register on a CD-ROM by mail. FDA encourages online registration as the least costly, quickest, and most efficient means for food facility registration. With online registration, a food facility must enter all of the required information before the system will accept the submission. After all required information has been entered, a registrant will receive confirmation of registration and a registration number. Paper registration is a more costly and less efficient process to supply FDA with registration information and to provide food facilities with their registration numbers. Further, paper registration may have a higher number of errors or omissions on the form, which may require additional time to complete the registration process.

IC.3.16 Why wait until October 1, 2012 to start the registration renewal process?

The FDA Food Safety Modernization Act (FSMA) mandates that all food facilities that are required to register must renew their registrations every other year during the period beginning on October 1st and ending on December 31st of each even-numbered year. The first registration renewal cycle will occur from October 1 to December 31, 2012.

IC.3.17 What changes were made to the "Guidance for Industry: Necessity of the Use of Food Product Categories in Registration of Food Facilities"? NEW

FDA updated this guidance document (see the new draft verion Draft Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories) to specify additional food categories to be included as mandatory fields in the food facility registration form, as provided by section 102 of the FDA Food Safety Modernization Act (FSMA). The updated guidance notes that the list of additional food categories includes food categories that are currently included on the food facility registration form as optional fields, including food categories for animal consumption. This guidance also describes certain FSMA amendments to section 415(a) of the Federal Food, Drug, and Cosmetic Act, which provide that, when determined necessary by FDA "through guidance," a registrant must submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in 21 CFR 170.3 or any other food categories, as determined appropriate by FDA,

including by guidance) of any food manufactured, processed, packed, or held at such facility. This guidance was renamed "Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registration and Updates to Food Categories."

IC.3.18 Why did FDA make changes to "Guidance for Industry: Necessity of the Use of Food Product Categories in Registration of Food Facilities"? NEW

FDA believes that information about the food categories of foods manufactured, processed, packed or held at food facilities is a key element to allow for rapid communications between FDA and facilities directly impacted by actual or potential bioterrorist attacks, other food-related emergencies, or food safety incidents. Information about the categories of food a facility handles currently assists FDA in conducting investigations and surveillance operations in response to food-related emergencies. These categories also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected. The proposed additional food categories enhance the agency's ability to respond quickly and accurately to an actual or potential bioterrorist incident or other food-related emergency. See the updated guidance, Draft Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories, for more information.

Full Text of the Law Relating to Inspection and Compliance

- SEC 102. Registration of Food Facilities.

Guidance and Rules

- *Draft Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories*
  FDA updated this guidance document to propose additional food categories to be included in the food facility registration form as mandatory fields, including food categories that are currently included on the food facility registration form as optional fields.
- Upcoming Guidance for Industry on Food Facility Registration
  Three other updated food facility registration guidance documents will be released later this year to further clarify the process.