

Fact Sheet: The FDA Food Safety Modernization Act (FSMA) and Registration of Food Facilities

September 26, 2012

The FDA Food Safety Modernization Act and Changes to Registration of Food Facility Registration

The FDA Food Safety Modernization Act (FSMA), enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 350d] to require in relevant part that facilities engaged in manufacturing, processing, packing, or holding food for human or animal consumption in the United States submit additional registration information to the Food and Drug Administration (FDA).

FSMA amended section 415(a)(2) of the FD&C Act to require a food facility registrant to provide the following additional information to FDA in the facility's registration:

- The e-mail address for the contact person of the facility or, in the case of a foreign facility, the e-mail address of the U.S. agent for the facility;
- An assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act; and
- As determined necessary and appropriate by FDA, additional food category information for food manufactured, processed, packed, or held at such facility.

Registration and Biennial Registration Renewal Process

Food facilities subject to section 415 of the FD&C Act were required to register with the FDA before December 12, 2003 (21 C.F.R. § 1.230). A food facility that begins to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003 must register before the facility begins such operations (21 C.F.R. § 1.230). If a change occurs to a facility's previously submitted required registration information, such facility must update its registration to reflect the change within 60 calendar days of the changes, except for a change of the owner (21 C.F.R. § 1.234(a)). If a facility has a new owner, the former owner must cancel the facility's registration within 60 calendar days of the change and the new owner must re-register the facility (21 CFR 1.234(b)).

The failure to register your facility, update required elements, or cancel a registration in accordance with the regulations at 21 CFR Part 1, Subpart H is a prohibited act under the FD&C Act (see 21 C.F.R. § 1.241). The federal government can bring a civil action against a person who commits a prohibited act, or it can bring a criminal action in federal court to prosecute a person who is responsible for the commission of a prohibited act, or

both (see e.g., 21 C.F.R. § 1.241). If a foreign food facility is required to register with FDA, but fails to do so, food from that facility that is being imported or offered for import into the U.S. is subject to refusal under section 801(1)(1) of the FD&C Act.

FSMA amended section 415(a)(3) of the FD&C Act to require that food facilities that are required to register under section 415 must renew their registrations by submitting renewal registrations to FDA during the period beginning on October 1 and ending on December 31 of each even-numbered year. The first registration renewal cycle will occur from October 1 to December 31, 2012. Registrants are required to submit renewal registrations to FDA containing the registration information described in section 415(a)(2) of the FD&C Act, including the new information described above.

Registrants can register or update registration information at any time using the online food facility registration module or paper Form 3537. Registrants renewing registrations during the October 1 – December 31 time period can use the food facility registration module or paper Form 3537. FDA will accept registration submissions, including initial registrations, updates of registration information, and biennial registration renewals via online entry, mail, fax, or CD-ROM for multiple submissions. FDA encourages online registration as a quick and efficient means for food facility registration. There is no fee to register, update, or renew the registration of a food facility.

Suspension of Registration

Section 415(b) of the FD&C Act, as amended by FSMA, also provides FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a 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:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

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 (section 415(b)(4) of the FD&C Act).

FDA will provide a registrant subject to an order of suspension of registration 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 order, unless an alternate time period is agreed upon by FDA and the registrant (section 415(b)(2) of the FD&C Act). 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 (section 415(b)(2) of the FD&C Act). If FDA determines that the

suspension remains necessary, FDA will require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by FDA (section 415(b)(3)(A) of the FD&C Act). Upon a determination that adequate grounds do not exist to continue the suspension actions required by a suspension order, or that such actions should be modified, FDA will vacate the order and reinstate the registration of the facility subject to the order, or modify the order, as appropriate (section 415(b)(3)(B) of the FD&C Act).