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Regulatory Alert: FDA Releases Proposed Food Facility Registration Rule

Significant Changes to Registration Process in the Works

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On April 9, 2015, FDA published a proposed rule in the Federal Register (the "Proposed Rule") to amend and update its existing regulation on registration of food facilities. The Proposed Rule would implement provisions of FSMA that require food facility reregistration and changes to the definition of retail food establishments. The Proposed Rule makes additional changes not required by FSMA among other things. Please contact Erik Lieberman at erl1@liebermanpllc.com or 202.830.0300 if you have questions or would like additional information.

Background

Under the current regulations, U.S. and foreign facilities that process, pack or hold food for consumption in the U.S. are required to register with FDA and keep their registrations up-to-date. FSMA imposed new requirements that are currently in effect (e.g. biennial reregistration) but not yet codified in the Code of Federal Regulations. The Proposed Rule codifies these requirements. In addition it expands the definition of retail food establishments to clarify that certain on-farm establishments are exempt. The Proposed Rule also requires that all food facility registrations be submitted electronically among other things.

Key Proposed Changes

Change in the Definition of Retail Food Establishment: The definition of retail food establishment has been expanded to explicitly address on-farm establishments and what types of sales are considered to be sales "directly to consumers."

Codification of Reregistration Requirement: The Proposed Rule codifies the food facility reregistration requirement currently in effect. In Proposed § 1.232, facilities are required to submit registration renewals every other year, during the period beginning on October 1, and ending on December 31 of each even-numbered year.

Mandatory Electronic Filing: The Proposed Rule requires registrations and renewals to be filed electronically beginning on January 4, 2016, unless a facility has been granted a waiver by FDA.

Additional Data Elements

The Proposed Rule requires the input of additional data elements to those currently required to complete food facility registration. These additional elements include:

1. The D-U-N-S number of the facility.
2. The type of activity conducted on each category of food processed, packed or held at the facility.

3. A statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug and Cosmetic Act.
4. The email address of the owner, operator or agent-in-charge of the facility.
5. The email address for the contact person of a domestic facility, and an email address for the U.S. agent of a foreign facility. Email addresses must also be provided for the emergency contact for both U.S. and foreign facilities (the emergency contact may be the same person as the "contact person" for a domestic facility, or the U.S. agent of a foreign facility).

Updating Information: The Proposed Rule reduces the time facilities are given to update facility registration information from 60 to 30 days.

New FDA Verification Procedures

1. **D-U-N-S Numbers:** Food facility registration numbers will no longer be provided immediately upon the submission of a registration form. Instead, the Proposed Rule states that FDA will verify the accuracy of the D-U-N-S number for a facility and the facility's address information against the information linked to the D-U-N-S number. Similarly, if a registration is updated and the D-U-N-S number changes as part of the update, FDA will not provide confirmation of the update until the accuracy of the D-U-N-S number for the facility and facility's address is verified.
2. **Verification of Owners, Operators or Agents in Charge:** After submission of an initial registration, renewal, update, or cancellation by a person who is not an owner, operator, or agent in charge of a facility, FDA will email the owner, operator or agent in charge and not confirm the registration, renewal, update, or cancellation until the owner, operator or agent in charge confirms the action with FDA.
3. **Verification of Food Facility Agents:** After a foreign facility submits its registration or renewal, FDA will email the person identified as the U.S. agent for the facility to verify that they have agreed to serve as the agent. FDA will not confirm registration until the U.S. agent submits verification to FDA.

Change in the Definition of U.S. Agent: Under existing regulations, all foreign facilities must have a U.S. agent to serve as a point of contact for FDA. The Proposed Rule changes the definition of U.S. agent to add language which explicitly states that the U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration. FSMA imposed a new liability (which FDA characterizes as an "additional role") on U.S. agents. Section 107 of the FSMA provides FDA with authority to assess and collect fees from U.S. agents for each foreign facility subject to reinspection to cover reinspection-related costs. FDA states in the Proposed Rule that providing registration information on facilities to U.S. agents will further enable them to "serve their intended role."

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