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# Regulatory Alert: FDA Publishes Final FSMA Food Facility Registration Rule

***Significant Changes to Food Facility Registration Process***

**July 18, 2016**

On July 14, 2016, the U.S. Food and Drug Administration (FDA) published in the Federal Register the final rule on Amendments to Registration of Food Facilities (Final Rule). The Final Rule was issued to implement section 102 of the Food Safety Modernization Act (FSMA) (21 USC § 350d) and makes significant changes to the food facility registration process. The Final Rule formalizes food facility registration renewal requirements, requires additional information to be submitted during registration including a unique facility identifier such as a D-U-N-S[1] number, provides for several additional verification steps before registrations, renewals or updates are accepted by FDA and creates a U.S. agent voluntary identification system among other things. This Regulatory Alert sums up the key points of the regulation.

## Key Points

### What facilities are impacted under the Final Rule?

Pursuant to section 415 of the Federal Food, Drug and Cosmetic Act (FDCA) (enacted as part of the Bioterrorism Act of 2002), all U.S. and foreign facilities that process, pack and hold human and animal food for consumption in the U.S. are required to register with FDA. The Final Rule makes changes to the registration process.

### When is compliance required?

The Final Rule is effective on September 12, 2016, meaning all food facilities will be impacted as they renew this year. The renewal period is October 1-December 31. The requirement for a unique facility identifier goes into effect on October 1, 2020, as well as the requirement to file electronically

### How has the definition of retail food establishment changed?

FSMA required FDA to amend the definition of retail food establishment to include farm-operated businesses that as their primary function sell products directly to consumers at

[1] Dun & Bradstreet Data Universal Numbering System

farmers' markets, roadside stands, through community-supported agriculture programs, and through other direct-to-consumer sales platforms including door-to-door sales, mail, catalog, and Internet orders, including online farmers markets and online grocery delivery, religious or other organization bazaars, and state and local fairs.

**How has the definition of U.S. agent changed?**

FDA provides that the U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration. While FDA acknowledged that the U.S agent for purposes of food facility registration is not the same person as the U.S. agent for purposes of compliance with the Foreign Supplier Verification Program Rule, the agency rejected suggestions to codify this distinction in the text of the Final Rule.

**What are the renewal requirements?**

Food facility renewal/reregistration requirements went into effect in 2014 and now have been codified in the regulation. Facilities must renew in every even-numbered year from October 1, 2014 to December 31, 2014 onward. The email address of the individual who authorized submission of the registration renewal is required if the individual submitting the registration renewal is not the owner, operator, or agent in charge of the facility. For these types of registrations, the name, address, and telephone number of the individual who authorized submission must be provided.

For each electronic registration renewal, the registration must include the name of the individual submitting the renewal

**Is there an abbreviated renewal process if no changes need to be made to reregistration?**

Yes. The registrant merely needs to confirm that no changes have been made to the registration information since the last submission. The submitter's name, and for abbreviated renewals not submitted by the owner, operator or agent in charge of the facility, the email address of the individual who authorized the submission of the renewal, must also be provided. FDA will not confirm the abbreviated renewal until the owner, operator or agent in charge confirms that they authorized the submission.

**Are electronic registrations required?**

Yes, beginning January 4, 2020, electronic registrations are required. FDA can grant waivers to the electronic registration requirement.

**Will facilities need to have a form of unique identifier to register?**

Yes. Beginning January 4, 2020, all registrants will have to provide a unique facility identifier (UFI) in order to register or renew registration. FDA has stated it expects to recognize D-U-N-S numbers as an acceptable UFI.

**Will FDA verify facility information submitted with the D-U-N-S database, or another database?**

Yes. Before accepting a registration, renewal or update, FDA will verify the UFI and address information submitted against the D-U-N-S database, or another database the agency recognizes as being acceptable. If FDA is unable to verify the UFI or the address of the facility, it will immediately notify the food facility. The facility will have the opportunity to fix the discrepancy.

**How will FDA verify that registrations are authorized?**

FDA will not confirm a registration or renewal or provide a registration number until an individual at the owner, operator or agent in charge of the facility confirms that they authorized the submission. Furthermore, FDA will not provide confirmation of a registration update or cancellation until the individual confirms that they authorized the submission.

**Will FDA verify that U.S. agents consented to representing a foreign facility?**

Yes, FDA will not confirm a registration, renewal, registration update, or provide a registration number until the person identified as the U.S. agent for the foreign facility confirms that they have agreed to serve as the U.S. agent. FDA will issue guidance on this subject. It is likely FDA will email the U.S. agent to receive the verification.

**What if incorrect information was previously submitted in a registration or update to FDA?**

The registrant must immediately update the information.

**What new information is required to be provided to FDA?**

- The email address of the U.S. agent (this went into effect immediately upon enactment of FSMA)
- The email address of the U.S. contact for domestic facilities
- The email address of the owner, operator or agent in charge of the facility
- A UFI, such as a D-U-N-S number

- Specific food product categories (previously optional)
- Activity type for food product categories (previously optional)

**For what new reasons will FDA cancel registrations?**

- If FDA independently verifies that a facility is not required to register
- If information about the facility's address was not update in a timely manner
- If the registration was submitted by an unauthorized person
- Failure to renew a registration

FDA will send a confirmation of cancellation using contact information submitted by the facility in the registration database.

**What is the U.S. Agent Voluntary Identification System?**

The U.S. Agent Voluntary Identification System (VIS) will allow U.S. agents to independently identify the facilities for which they have agreed to serve. VIS would allow U.S. agents to directly provide FDA with the agent's contact information and the names of the facilities in which they have agreed to serve. VIS will provide U.S. agents with an identification number which agents may provide to foreign facilities that the U.S. agent agrees to represent. FDA intends for the system to notify the U.S. agent if a registration for the facility in which it serves is cancelled. Further information on VIS will be provided in a future guidance document.

Please contact Erik Lieberman at erl1@liebermanPLLC.com or 202.830.0300 if you have questions or would like additional information.