

November 07, 2018

It's Time to Renew Your Food Facility Registration with FDA

As a reminder, the U.S. Food and Drug Administration (FDA) requires all domestic and foreign food facilities that manufacture, process, pack, or store food for U.S. consumption to renew their FDA registrations between October 1 and December 31 of each even-numbered year.

Renewals can be submitted electronically through the FDA Industry Systems website by 11:59 PM on December 31, 2018. Alternatively, FDA will allow food facilities to renew through mail or fax by using FDA Form 3537 for this year only as electronic submissions are required for future renewal years.

If a registration is not renewed on time, FDA considers the registration expired and will remove it from the account. Food facilities that market food for consumption in the U.S. without a valid registration may be subject to civil or criminal penalties. Food facilities should be aware that renewing a registration is different than updating a registration, and even facilities that registered or updated a registration with FDA as recently as September 2018 are required to renew.

Updated FDA Regulations on Food Facility Registration

In July 2016, FDA issued several amendments to federal regulations governing the registration of food facilities. Several of the 2016 amendments were mandated by the Food Safety Modernization Act (FSMA), and merely codify certain provisions of FSMA that were self-implementing and effective upon enactment of FSMA. Specifically, the new regulations reflect that food facility registrants are required to:

- Provide an email address for the facility-responsible owner, operator, or U.S. Agent (for a foreign facility);
- Renew food facility registration every two years (October 1 to December 31 of even years, as discussed above); and

Related Industries

Food & Beverage
Related Practices

FDA Regulatory
Regulatory

- Attest that the FDA will be permitted to inspect the facility at the times and in the manner specified by the Federal Food, Drug, and Cosmetic Act.

Additionally, during the renewal process, facilities located outside of the U.S. must also designate a U.S. agent for FDA communications. For these foreign facilities, the renewal will not be considered complete until the listed U.S. agent accepts this designation.

The July 2016 amendments also added a number of new requirements aimed at improving the accuracy of the food facility registration database for all facilities both foreign and domestic. Per these new provisions, food facility registrants will now be required to:

- Identify the type of activities conducted at the facility for each food product category (effective July 14, 2016);
- Submit registration, registration renewal, update, and cancellation electronically to FDA (effective January 4, 2020); and
- Utilize a Unique Facility Identifier (UFI) to assist FDA in identifying specific food facilities and verify certain registration information for those facilities (effective October 1, 2020).

If a food facility is unable to renew its registration electronically, the facility can request a waiver from FDA by explaining why it is not reasonable to submit the registration, registration renewal, update, or cancellation to electronically. Additionally, a food facility unable to provide an email address of the owner, operator, or U.S. Agent in charge of the facility, must explain to FDA why this requirement is not reasonable.

Importantly, FDA also amended its definition of “retail food establishments” in a way that expands the number of establishments meeting the definition. This is significant because businesses that satisfy the FDA definition as retail food establishments are not subject to food facility registration requirements. The amendment clarified that “retail food establishments” may claim activities such as:

- The sale of food products or food directly to consumers by such establishment at a roadside stand or farmers’ market where such stand or market is located other than where the food was manufactured or processed;
- The sale and distribution of such food through a community supported agriculture program; and
- The sale and distribution of such food at any other such direct sales platform.

Of course, all food establishments, including retail food establishments, are required to continue meet their food safety obligation regardless of the need to register with FDA.

FDA Guidance for Industry

In August of 2018, FDA issued several updated guidance documents pertaining to food facility registration. FDA issued one document, Questions and Answers Regarding Food Facility Registration (Seventh Edition), as guidance on issues relating to the July 2016 amendments and the significance of

these revisions for other FDA regulatory programs, including the preventive control rules for human and animal foods.

FDA also issued draft guidance, *Supplemental Questions and Answers Regarding Food Facility Registration*, to address ongoing confusion regarding registration requirements in situations where multiple entities share physical space in a food facility or warehouse, such as where one entity owns a building and lessees manufacture, process, pack, or hold food in the building. Accordingly, FDA drafted several questions and answers to clarify what entity should register the facility in these situations. This guidance will eventually be incorporated into a fourth edition of the more comprehensive *Questions and Answers Regarding Food Facility Registration* guidance.

To learn more about Biennial Registration Renewal and other FDA food facility requirements, please contact your Michael Best attorney.