



WHAT DO FOOD FACILITIES NEED TO KNOW ABOUT THIS YEAR'S BIENNIAL REGISTRATION RENEWAL PERIOD?

Food facilities that are required to register with the U.S. Food and Drug Administration must renew their registration this year between October 1 and December 31. This fact sheet provides information about this biennial food facility registration renewal period.

■ Why are food facilities required to register with the FDA?

Food facility registration helps FDA determine the location and source of potential bioterrorism or foodborne illness outbreak incidents, and also helps the agency quickly notify facilities that may be affected. Food facility registration requirements were initially brought about by The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA.

The FDA Food Safety Modernization Act (FSMA) then amended the FD&C Act to require domestic and foreign facilities to submit certain additional new information to FDA and to renew registrations every other year. In 2016, FDA issued a **final rule** updating FDA's registration regulation, including to reflect the FSMA amendments.

■ What food facilities must register with the FDA?

If you are the owner, operator, or agent in charge of either a domestic or foreign facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States, you are required to register with the FDA, unless an exemption applies.

■ What facilities are exempt from the registration requirement?

Establishments that meet the definition of a primary production farm, secondary activities farm, retail food establishment, restaurant, or nonprofit food establishment are not required to register (These definitions can be found in [21 CFR 1.227](#)).

In addition, certain other entities are not required to register, including: certain fishing vessels; foreign facilities if the food from the facility undergoes further manufacturing/processing by another facility outside the United States; and facilities that are regulated exclusively throughout the entire facility by the U.S. Department of Agriculture under certain statutes (For more information on who does not need to register see [21 CFR 1.226](#)).

However, mixed-type facilities must register. These are facilities that conduct activities that are both exempt and covered by the registration requirement. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the "farm" definition that require the establishment to be registered.

Please note that FDA **intends** to initiate a rulemaking that could change the definition of "farm." Such a rulemaking could change the status of an entity from a facility required to register to a farm. We do not anticipate that the rulemaking would result in an entity that is currently a "farm"

becoming a “facility.” While FDA intends to initiate this rulemaking, the rulemaking has not yet taken place, and establishments that are domestic and foreign facilities are required to register, and to renew their registrations biennially.

■ **When must facilities initially register?**

If you are required to register you must do so before your facility begins manufacturing/processing, packing or holding operations.

■ **When are food facilities required to renew their registration?**

Food facilities are required to renew their registration every other year, during the period beginning on October 1 and ending on December 31 of each even-number year. This year’s renewal period begins October 1, 2018 and ends December 31, 2018.

■ **What happens if facilities don’t renew their registration?**

FDA will consider a registration for a food facility to be expired if the registration is not renewed as required. FDA will consider a food facility with an expired registration as having failed to meet their registration requirements, and failure to register a food facility is a prohibited act under the FD&C Act. FDA will cancel a registration if the facility’s registration has expired because the facility has failed to renew its registration as required.

■ **Is there a fee that must be paid?**

No. There is no fee for registration or renewal.

■ **How can food facilities go about renewing their registration?**

Owners and operators of facilities can renew their registration through their [FDA Industry Systems](#) account, or by requesting and submitting Form FDA 3537 via mail or fax. This is the last renewal period that we are accepting paper submissions. As of January 4, 2020 all submissions must be electronic unless the facility has received a waiver. Forms can be requested and submitted in the following ways:

Fax: 301-436-2804

Mail:

U.S. Food and Drug Administration
Food Facility Registration (HFS-681)
5001 Campus Drive
College Park, MD 20740

Email: FurlIs@fda.gov

Telephone: 1-800-216-7331 or 240-247-8804

When contacting the FDA by phone, please anticipate long hold times during the renewal period. Likewise, please anticipate a delay in the time it takes FDA to respond to e-mails due to the significant increase in call and email volume that FDA receives during the registration renewal period. In response to previous customer feedback, we have included the addition of a callback feature on our lines and have implemented an announcement of the estimated hold time.

■ Is there a way to save time during the renewal process?

The FDA provides an abbreviated registration renewal process for facilities that do not have information changes since the preceding registration, registration renewal, or update. This process requires the registrant to confirm that no changes have been made since the registrant's last registration submission and certify that information submitted is truthful and accurate. The abbreviated renewal is available on both paper and electronic submissions and must include the name of the individual submitting the abbreviated renewal, and the individual's signature (for the paper option).

■ Are there any resources available to help facilities with this process?

Yes. The FDA has a number of resources available to help facilities register and renew their registration. Recently, FDA released two guidance documents to help food facilities meet their registration requirements. The first is a [seventh edition](#) of a guidance to help the owners and operators of food facilities better understand the registration requirements and reflects updates made to the registration provisions in the FD&C Act that were made following the passage of FSMA. The second is a [supplemental draft guidance](#) to the seventh edition which includes questions and answers that clarify our thinking about the registration requirements when multiple entities are sharing physical space.

The following materials are also available:

- [Registration of Food Facilities](#)
- [Food Facility Registration User Guide: Biennial Renewal](#)
- [Biennial Renewal of Food Facility Registration: Information for Startups and Small Entities](#)

■ Does the registration include an assurance that FDA can inspect the facility?

Yes. Registration for both domestic and foreign food facilities includes an assurance that the FDA can inspect at the times and in the manner authorized by the FD&C Act.

■ Can FDA suspend a facility's registration?

FDA can suspend a registration if the agency determines that food manufactured, processed, packed, received, or held by the facility has a reasonable probability of causing severe adverse health consequences or death to humans or animals and that facility either created, caused, or was otherwise responsible for the reasonable probability or knew of (or had reason to know of) the reasonable probability and packed, received, or held such food.