



F15/17: USA FDA Registration as a Food Facility

Food Products

27/03/2017

1 FDA Food Facility Registration

1.1 Registration as a Food Facility

The FDA established regulations requiring that foreign food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States need to register as a food facility. Food Facility registration has been in place for a number of years to, in particular, implement provisions of the United States Bioterrorism Act 2002.

Facilities that are required to register with the FDA must register prior to commencement of manufacturing, processing, packing or holding food for consumption in the United States. The FDA supplies confirmation, and a confirmation number, of prior notice once all information has been submitted. This confirmation does not mean that the FDA have approved the shipment, or that the shipment may proceed without any further FDA action.

Information, including detailed guidance and instructions on Food Facility Registration can be found [Draft Guidance for Industry: Questions and Answers Regarding Food Facility Registration \(Seventh Edition\) - Revised](#) and on the [FDA's Food Facility Registration website](#) or contact FDA's Unified Registration and Listing System (FURLS), call the help desk at +1-800-216-7331 or +1-301-575-0156 or email furls@fda.gov. The phones are only staffed 0730 to 2300 ET.

Refer also to the MPI document [F41/16: FYI USA Food Safety Modernisation Act Rules: Information and Guidance](#) issued 6 October 2016.

1.2 Biennial Renewal

Food facilities are required to renew their registrations every other year (i.e. biennially). Section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 350d] requires food facilities that are required to register with FDA to renew such registrations during the period beginning on October 1 and ending on December 31 of each even-numbered year.

The 2016 Food Facility Registration Biennial Renewal period began 12:00 AM on 1 October 2016 and ended 11:59 PM on 31 December 2016 US time. If a registration was not renewed by 11:59 PM on 31 December 2016, the registration would have expired and been removed from the registrant's account.

1.2.1 Food Facility Registration Forms

Although the “Amendments to Registration of Food Facilities final rule (81 Fed. Reg. 45912)” issued on 14 July 2016, introduced the need for new data elements to be provided by food facilities during the registration process, the FDA have not as yet updated the registration form to implement this.

For initial registration, renewal, and updating, FDA is continuing to use the version of the food facility registration form, Form FDA 3537 (available in fill-in [PDF](#) for printing). FDA plans to implement a revised version of the form in the near future.

For cancellation of food facility use FDA Form No. 3537a: (available in fill-in [PDF](#) for printing).

1.3 Problems encountered with renewal

MPI has had numerous reports from industry that have highlighted some common problems encountered when renewing registrations.

1.3.1 “INVALID” status

When attempting to renew a registration, some companies are getting an “INVALID” status for their food facility registration, with an error message indicating that “the registration is invalid and updates are not allowed”. The companies have advised MPI that their renewal was submitted during the renewal period, compliant with the FDA requirements.

MPI has been advised that foreign food facilities must also have a United States agent. The United States agent must reside or maintain a place of business in the United States and be physically present in the United States.

The United States agent needs to confirm the food facility’s registration in the system within 30 days, otherwise the registration is cancelled.

To remedy the situation companies:

- (1) Need to re-register; and
- (2) The US agent needs to confirm the listing. The system then issues a facility registration number.

US agents may contact FDA’s help desk with questions about foreign facilities that they represent. In addition, a US agent may contact FDA’s help desk on behalf of the foreign facility.

1.3.2 Facilities that have missed the biennial renewal period

The FDA has also advised that companies that miss the biennial renewal period will have their registrations removed from the system. If this occurs, the company will need to create a new registration instead of renewing. Their FURLS account ID and password should remain the same.

1.4 Updating a registration

“Updating” a registration is a different function from “renewing” a registration. A registration should be “updated” when necessary, such as when there is a change to any of the establishment details provided.

During the biennial renewal period, the “Update Facility Registration” button listed on the Food Facility Registration main menu (FFRM) is hidden until the registration has been renewed.

1.5 New Zealand consultants

There are a number of consultancy businesses in New Zealand who offer services in helping businesses get through market access regulatory processes. Industry representative bodies often keep consultant company details.

Contact for further information

Ministry for Primary Industries (MPI)
Policy and Trade Branch
Market Access Directorate
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