Registration of Food Facilities and Other Submissions

Registration of Food Facilities and Other Submissions

Online Registration of Food Facilities

CFSAN Online Submission Module (COSM)

Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF)

Infant Formula Registration & Submissions

New Dietary Ingredient (NDI) Notification Electronic Submissions

Qualified Facility Attestation

Shell Egg Producer Registration

Structure/Function Claim Notification for Dietary Supplements Electronic Submissions

FDA Industry Systems

Login / Create Account

FDA Industry Systems Account Management

Online Registration of Food Facilities Guides and Tutorials

Content current as of:
06/22/2022

Regulated Product(s)
Dietary Supplements
Food & Beverages

The **Public Health Security and Bioterrorism Preparedness and Response Act of 2002** (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that:

- Food facilities register with FDA, and
- FDA be given advance notice on shipments of imported food.

These regulations became effective on **December 12, 2003.**

The **FDA Food Safety Modernization Act (FSMA)**, enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Section 415 of the FD&C Act, as amended by FSMA, also requires food facilities required to register with FDA to renew such registrations every other year, and provides FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

Food Facility Registration Statistics

Status of FDA Industry Systems

OMB Approval Number: **0910-0502**
OMB Expiration Date: **08/31/2022**
See OMB Burden Statement.

Actions on Food Facility Registration

FDA Actions on the FSMA

- Guidance for Industry: Enforcement Policy for Providing an Acceptable Unique Facility Identifier (UFI) for the 2020 Food Facility Registration Biennial Renewal Period
- Guidance for Industry: U.S. Agent Voluntary Identification System (VIS) for Food Facility Registration
- Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)
- Draft Guidance for Industry: Supplemental Questions and Answers Regarding Food Facility Registration
- Guidance for Industry: What You Need to Know About Registration of Food Facilities: Small Entity Compliance Guide
- Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories
- Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities
- FSMA Proposed Rule: Amendments to Registration of Food Facilities
- Compliance Policy Guide - Sec. 100.250 Food Facility Registration (Human and Animal Food)

FDA Actions on the Bioterrorism Act of 2002 Legislation

- Compliance Policy Guide Guidance for FDA Staff: Registration of Food Facilities
- Final Rule: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Topic Specific Systems and Submissions

- CFSAN Online Submission Module (COSM)
- Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF)
- Infant Formula Registration & Submissions
- New Dietary Ingredient (NDI) Notification Electronic Submissions
- Qualified Facility Attestation
- Shell Egg Producer Registration
- Structure/Function Claim Notification for Dietary Supplements Electronic Submissions