**FDA’s Food Facility Registration Regulation At-a-Glance**

**WHAT It Is:** Domestic and foreign facilities that manufacture, process, pack, or hold food, as defined in 21 C.F.R. 1.227, for human or animal consumption in the U.S. must register with FDA effective December 12, 2003.

**WHY It’s Required:** To help FDA to determine the location and source of a potential or actual bioterrorism incident or an outbreak of food-borne illness, and permit the Agency to notify quickly facilities that may be affected.

**WHICH Facilities Must Register:** Domestic and foreign food manufacturers/processors, packers, and storage operations that handle foods for consumption in the U.S. as defined in 21 CFR 1.227.

**Examples of WHICH Foods Require Facility Registration:**

* Dietary supplements and dietary ingredients
* Infant formula
* Beverages (including alcoholic beverages and bottled water)
* Fruits and vegetables
* Fish and seafood
* Dairy products and eggs
* Raw agricultural commodities for use as food or components of food
* Canned and frozen foods
* Bakery goods, snack food, and candy (including chewing gum)
* Live food animals
* Food for animals (e.g., pet food, pet treats and chews, animal feed)

**WHEN Facilities Must Register:** Effective December 12, 2003.

**WHO May Register:** The owner, operator, or agent in charge of a facility, or an individual authorized by one of them, may register that facility.

Foreign facilities must designate a U.S. agent, who lives or maintains a place of business in the U.S. and is physically present in the U.S., for purposes of registration. The U.S. agent may be authorized to register the facility.

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| HOW to Register | |
| Online | Go to <http://www.access.fda.gov/> (24 hours a day, 7 days a week). |
| By Mail or Fax | 1. Request Form 3537 from FDA (1-877-332-3882).  2. Mail or fax completed form to:          U.S. Food and Drug Administration  HFS-681  Fishers Lane  Rockville, MD 20857  U.S.A.  Fax: 301-436-2804 |
| On CD-ROM  (For multiple facilities using the same mailing address) | * Download Form 3537 at [http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073728.htm](https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073728.htm) * Create separate electronic files for each facility. * Submit files on CD-ROM (ISO 9660 CD-R or CD-RW format). * Include a signed certification statement. * Mail to the above address. |
| Get HELP: (business days, 7:00 AM to 11:00 PM U.S. EST) | |
| By phone | WITHIN THE U.S.: Call 1-800-216-7331 or 301-575-0156  OUTSIDE THE U.S.: Call 301-575-0156 |
| By fax | Fax questions to 301-436-2804 |
| By email | Email questions to [furls@fda.gov](mailto:furls@fda.gov) |

**WHAT Information is Required:**

* Facility name, address, phone number and emergency contact phone number
* Parent company name, address and phone number (if applicable)
* Name, address and phone number of the owner, operator or agent in charge
* Email address for the contact person of the facility or, in case of a foreign facility, the U.S. agent for the facility
* All trade names the facility uses
* Applicable food product categories, as listed on the registration form
* Name, address, phone number and emergency contact phone number of a foreign facility’s U.S. agent
* Assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act
* Certification that the information submitted is true and accurate and that the person submitting it is authorized to do so