

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA. Facilities must re-register every even-numbered year.

Who must register?

- Domestic and foreign manufacturers or processors
- Domestic and foreign packers
- Domestic and foreign storage operations

How much does it cost?

Registering with FDA is free, as are registration updates.

What information is required to register?

- 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
- All trade names the facility uses
- Applicable food product categories as listed on the registration form
- Name, address and phone number of a foreign facility's U.S. agent, and phone number of the facility's emergency contact, if it is someone other than the U.S. agent
- Certification that the information submitted is true and accurate and that the person submitting it is authorized to do so.

How do I register a facility?

Form 3537 must be used to register or to update a registration. The form is available online and in paper form. If you have multiple facilities, you may also register on CD-ROM. The CD-ROM must have ISO 9660 (CD-R or CD-RW) data format. More information is available at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>

Can I register online?

You can register online at www.access.fda.gov/. This website offers online assistance and operates 24 hours a day, seven days a week. The Online Registration Help Desk is available on business days from 7 a.m. to 11 p.m. Eastern Standard Time.

You can submit questions to the help desk at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>

How do I submit a paper registration form?

You can fax or mail Form 3537. To request the form:

Mail: US Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville, MD 20857

Phone: (800) 216-7331