



▶ FDA Registration Primer

A Part of AFI's Tuesdays at Two

Who Must Register

- ▶ If you are the owner, operator or agent in charge of either a domestic or foreign facility engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the U.S., you must register with FDA, unless exempt.
- ▶ If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce.
- ▶ A foreign facility must name someone in the U.S. to serve as their registration agent.

Exemptions*

- ▶ Farms
- ▶ Retail Establishments
- ▶ Restaurants
- ▶ Non-Profit Food Establishments
- ▶ Fishing Vessels
- ▶ Facilities Regulated by USDA
- ▶ Facilities that Export Food to the U.S. Solely for Export from a Bonded Warehouse

When Must One Initially Register a Facility?

- ▶ If you are required to register with FDA, you must register before your facility begins manufacturing/processing, packing or holding operations.

What Information is Required at Registration?

- Facility name, address, phone number, and emergency contact phone number.
- Preferred mailing address, if different from that of the facility.
- Parent company name, address, and phone number (if the facility is a subsidiary of the parent company).
- All trade names the facility uses.
- Name, address, and phone number of the owner, operator or agent in charge.
- Email address of the owner, operator or agent in charge.
- Applicable food product categories of any food manufactured/processed, packed or held at the facility, as identified on Form FDA 3537.**
- The type(s) of activity at the facility for each food product category.

Required Information, continued

- ▶ A statement in which the owner, operator or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act.
- ▶ A statement in which the owner, operator or agent in charge certifies the information submitted is accurate.
- ▶ If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies the information submitted is true and accurate, certifies that he/she is authorized to submit the registration and identifies by name, address and telephone number, the individual who authorized submission of the registration. In addition, the registration must identify the individual who authorized submission of the registration by email address.
- ▶ The facility's Unique Facility Identifier (DUNS Number).
- ▶ The email address for the contact person of the facility.
- ▶ An emergency contact phone number and email address if different from the email address for the contact person.
- ▶ For a foreign facility, the registration must also include: The name, full address, phone number and email address of the foreign facility's U.S. agent.

When Must Registrations be Renewed?

- ▶ Within 60 days of a change at the facility OR;
- ▶ During the period beginning Oct. 1 and ending Dec. 31 of each even-numbered year.
- ▶ 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 to have failed to register. The failure to register a food facility is a prohibited act.

More on Duns Numbers

Beginning Oct. 1, the facility's Unique Facility Identifier recognized as acceptable by FDA will be required to be submitted with the registration information.

- ▶ The DUNS number is the preferred UFI recognized as acceptable to FDA for food facility registration. The DUNS number is assigned and managed by Dun & Bradstreet and is available free of charge. Information on how to obtain a DUNS number will be available on the FDA Web site.
- ▶ <https://fdadunslookup.com/Login.aspx>

Users will need to create an account. Once an account is created, users will be able to access an instruction guide. **Duns numbers are location-specific - unique facility identifier.**

What is an Agent?

- ▶ The U.S. agent acts as a communications link between FDA and a foreign facility for both routine and emergency communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact.
- ▶ A foreign facility may change its U.S. agent at any time. Updates to required information, including the U.S. agent designation by foreign facilities, must be made within 60 calendar days.

Agent Considerations

- ▶ Knowledge, Reliability.
- ▶ Should an Importer Serve as the U.S. Agent for its Supplier?
- ▶ Should a Foreign Supplier Have a Customer as its U.S. Agent?
- ▶ Liabilities
- ▶ Aggressive Marketing Tactics by Some
- ▶ U.S. Agent vs. FSVP Agent

AFI as a Registration Agent

SERVICES

AFI	OTHERS
✓ Agent Services	✓ Agent Services
✓ Ongoing Information on Food Safety Modernization Act	Ongoing Information on Food Safety Modernization Act
✓ Ongoing Information on U.S. Regulations	Ongoing Information on U.S. Regulations
✓ Help With Questions on U.S. Laws	Help With Questions on U.S. Laws
✓ Assistance With Problem Entries	Assistance With Problem Entries
✓ Free Listing in U.S. Food Industry Annual Report	Free Listing in U.S. Food Industry Annual Report
✓ Pipeline to Top U.S. Food Importers	Pipeline to Top U.S. Food Importers

BEST OPTION?
There's No Comparison!