



---

# Registration of Food Facilities

October 2003

---

## FDA Industry Systems

# Food Facility Registration Questions and Answers

### General Questions about Registration

1. [Do I need to register?](#)
2. [How long will it take to register a facility?](#)
3. [How long will it take FDA to process registrations received by mail or FAX?](#)
4. [How much does it cost to register a facility?](#)
5. [What is the deadline for registration?](#)
6. [What happens if I don't register?](#)
7. [What registration options are available?](#)
8. [What determines whether I can access a registration electronically?](#)
9. [What is a U.S. Agent?](#)
10. [What does it mean to cancel a registration?](#)
11. [Will I be notified when my registration is modified?](#)
12. [I sold my facility. May I transfer my registration to the new owner?](#)

### Technical Questions about Electronic Registration

1. [What if my country doesn't use Zip codes \(postal codes\)?](#)
2. [What do I do if I receive an error message that says: "Country Code must be a 3 digit number"?](#)
3. [How can I review the information I submitted?](#)
4. [If I received more than one registration number for a single facility, how do I delete the additional number?](#)
5. [What is the difference between an Account ID and a Registration Number?](#)

### See Also:

- [Glossary of Terms \(Overview\)](#)
  - [Summary of Fields in Food Facility Registration](#)
  - [Account Management Questions and Answers](#)
- 

1. **Do I need to register?**

If your facility manufactures, processes, packs, or holds food for human or animal consumption in the United States, you must register the facility with FDA by December 12, 2003. The only exemptions are:

- A foreign facility is exempt from registering if food from the facility undergoes further processing (including packaging) by another facility outside the United States. The first facility is **not** exempted from registration if the processing or packaging activities of the subsequent facility are limited to affixing a label to a package or other *de minimis* activity. The facility that conducts the *de minimis* activity also must register.
- The following domestic and foreign facilities also do not need to register:
  - **Private residences of individuals**, even though food may be manufactured/processed, packed, or held there.
  - **Non-bottled water drinking water collection and distribution establishments and structures**, such as municipal water systems.
  - **Transport vehicles that hold food only in the usual course of their business as carriers**.
  - **Farms**, i.e., facilities in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling of produce are considered part of harvesting. The term "farm" also includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership, and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. A farm-operated roadside stand that sells food directly to consumers as its primary function would be exempt from registration as a retail food establishment.
  - **Restaurants**, i.e., facilities that prepare and sell food directly to consumers for immediate consumption, including pet shelters, kennels, and veterinary facilities that provide food directly to animals. Facilities that provide food to interstate conveyances, such as commercial aircraft, or central kitchens that do not prepare and serve food directly to consumers are not restaurants for purposes of the rule.
  - **Retail food establishments**, such as groceries, delis, and roadside stands, that sell food directly to consumers as their *primary function*, meaning that annual sales directly to consumers are of greater dollar value than annual sales to other buyers. An establishment that manufactures/processes, packs, or holds food and whose primary function is to sell food directly to consumers, including food that the establishment manufactures/processes, from that establishment is a retail food establishment and is not required to register.
  - **Nonprofit food establishments**, which are charitable entities that meet the terms of § 501(c)(3) of the Internal Revenue Code and that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the U.S. Central food banks, soup kitchens, and nonprofit food delivery services are examples of nonprofit food establishments.
  - **Fishing vessels** that harvest and transport fish. Such vessels may engage in practices such as heading, eviscerating, or freezing fish solely to prepare the fish for holding on board the vessel and remain exempt.
  - **Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture**, that is, facilities handling only meat, poultry or egg products.

## 2. How long will it take to register a facility?

FDA estimates that it will take one or two hours of a manager's time to read and understand the regulations. Foreign facilities' workers would need one hour to read and understand the registration requirements if they have access to the Internet and can read and write in English. An additional five (5) hours would be needed if they do not have Internet access, and an additional five (5) hours would be needed if they do not read or understand English.

Once the necessary information is gathered, filling out a registration form would take a total of one hour -- 45 minutes of an administrative worker's time and 15 minutes of a owner, operator, or agent-in-charge's time to verify that the registration information is correct before submitting the form to FDA. Foreign facilities' workers would need one hour to fill out the form if they have access to the Internet and can read and write in English. An additional one (1) hour would be needed if they do not have Internet access and an additional one (1) hour would be needed if they do not read or understand English.

Once the information is entered into the registration system a registration number and PIN are generated. If you choose to register electronically via the Internet you will get this information immediately. If you choose to enter by mail or FAX, FDA will enter complete and legible mailed and faxed registration submissions into its registration system as soon as practicable, in the order FDA receives them. FDA will then mail to the address or FAX to the FAX number on the registration form a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the agency (i.e., by mail or fax.).

### **3. How long will it take FDA to process registrations received by mail or FAX?**

The paper processing facility will be able to process over 1,800 Form 3537 submissions each day during the regulatory peak processing period of October 12, 2003, through December 12, 2003 (45-business day period). This will result in a total of 80,000 submissions processed in a 45-day period. All Form 3537 submissions will be processed in the order they are received and will be turned-around within a 24-hour period, if the registration form is error free. Submitters should expect to receive their registration number within five to seven days after processing depending on postal mailing delays if the number of submissions does not exceed the processing capacity.

If the registration submissions should exceed the daily 1,800 Form 3537 processing capacity, a backlog will develop. We expect that if backlogs occur, they are most likely near the end of the initial 45-day registration period. If our estimates are correct, we would expect a backlog of two to three weeks. However, if the number of submissions and rejections being resubmitted exceed our estimates, the backlogs will be longer. So with mailing time, backlog, and processing times, the delay toward the end of the initial registration period could be three to six weeks or longer if the number of submissions exceeds our estimates.

FDA strongly encourages [electronic registration](#) for the benefit of both FDA and the registrant.

### **4. How much does it cost to register a facility?**

There is no fee associated with registration. Also see [FDA Notice Regarding Firms Offering Registration Services](#).

## 5. **What is the deadline for registration?**

The owner, operator, or agent in charge of a facility that manufactures/processes, packs or holds food for consumption in the U.S. must register the facility no later than December 12, 2003. Facilities that begin to manufacture/process, pack, or hold food for consumption in the U.S. on or after December 12, 2003, must register before they begin such activities.

## 6. **What happens if I don't register?**

Failure to register is a prohibited act under the Federal Food, Drug and Cosmetic Act. You may be subject to civil or criminal sanctions. If an unregistered foreign facility attempts to import food into the United States, the food will be held at the port of entry unless FDA or U.S. Customs directs otherwise. In that case, you will be responsible for moving it and any costs associated with the move and subsequent storage.

## 7. **What registration options are available?**

You can register electronically via the Internet, which is the fastest method. You can register via mail by submitting paper forms or a CD-ROM containing multiple submissions. You can also register via FAX. FDA strongly encourages electronic registration [via the Internet](#), which will be quicker and more convenient for facilities and FDA than registration by mail or FAX.

## 8. **What determines whether I can access a registration electronically?**

You may only access registrations "linked" to your account. There are several ways to link your account to a facility registration:

- When you register a facility, your account is automatically linked to that registration.
- If your account is a Subaccount type, when you register a new facility the system will ask you whether you want the Account associated with your Subaccount to also have access to the registration. If you answer "yes," the Account will also be "linked" to the registration.
- When your facility is registered, the system shows you the Registration Number and a PIN (Personal Identification Number). If you want a trusted person, such as your U.S. agent or agent in charge, to be able to access the registration, provide them the Registration Number and PIN. The trusted person can then access the registration using the Link Registration to your Account option from the FFRM Main Menu. When someone accesses a registration using the Registration Number and PIN, a link is created between that person's account and the registration.
- Account owners can assign or unassign registrations to their Subaccounts. Assigning a registration to a Subaccount creates a link between the registration and the Subaccount so the Subaccount is able to view, update, or even cancel the registration. If you unassign a registration from a Subaccount, you remove that link.

## 9. **What is a U.S. Agent?**

U.S. agent means a person residing or maintaining a place of business in the U.S. whom a foreign facility designates as its U.S. agent for purposes of the registration regulation. The

U.S. agent acts as a communications link between FDA and the foreign facility. FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent equivalent to providing the information or documents to the foreign facility. Having a single U.S. agent for the purposes of registration does **not** preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the U.S. need not be conducted through the U.S. agent designated for registration purposes.

A U.S. agent cannot be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's U.S. agent is not physically present.

**10. What does it mean to cancel a registration?**

If a registration is canceled, it means the facility is no longer registered. If the facility needs to be re-registered, a completely new registration will need to be created.

A facility canceling its registration must do so within 60 calendar days of the reason for cancellation (e.g., facility ceases operations, ceases providing food for consumption in the U.S., or the facility is sold to a new owner).

FDA will cancel a registration if the agency independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. If FDA cancels a facility's registration, FDA will mail a notification of the cancellation to the facility at the address provided in the facility's registration.

**11. Will I be notified when my registration is modified?**

FDA will send various notifications, based on who makes modifications to the registration. For example, if a foreign facility has a change in U.S. Agents, the contact for that facility may be notified and asked to confirm receipt of this notification. Also, FDA may periodically mail notifications to account holders to verify that information submitted in the registration is accurate. FDA also may send out notifications to account holders when various kinds of changes are made to their facility registrations. For example, if a foreign facility has a change in U.S. Agents, the contact for that facility may be notified and asked to confirm receipt of this notification.

If FDA sends an account holder or other person a notification with return receipt pending that person must respond within 60 days or the registration is invalidated.

The notifications will be sent by e-mail if an e-mail address was provided on the registration. Otherwise, notifications will be sent by U.S. Postal mail to the address provided on the registration.

**12. I sold my facility. May I transfer my registration to the new owner?**

A change in the owner of a facility requires a new registration. If the facility comes under new ownership the former owner must cancel the old registration within 60 calendar days of the change. The new owner must submit a new registration for the facility and should supply the previous owner's name and registration number if known.

## Technical Questions about Electronic Registration

### 1. What if my country doesn't use Zip codes (postal codes)?

If your area does not use Zip codes (postal codes) or if there is no information available for any other specific block in a mandatory section, enter the words "Not Available," "N/A," or "None" in that block unless specified otherwise.

### 2. What do I do if I receive an error message that says: "Country Code must be a 3 digit number"?

The system requires that the country code be a three digit number. Add leading zeros to your country code to make it a three digit number. For example, if your country code is 1, enter 001 in the box for Country Code.

### 3. How can I review the information I submitted?

When you submit your initial registration a copy of the information you submitted will be sent to you by postal mail or by e-mail if you provided an e-mail address. Keep this information for your records. You may also view all registration information online by using the [Search Facility Registrations](#) function on the online Food Facilities Registration Module. Choose submit without entering any search criteria to find all registrations linked to your account. Choose the hyperlinked registration number to review the information for a registration.

### 4. If I received more than one registration number for a single facility, how do I delete the additional number?

First, carefully review the information you have submitted using the [Search Facility Registrations](#) function on the online Food Facilities Registration Module. Choose submit without entering any search criteria to find all registrations linked to your account. Choose the hyperlinked registration number to review the information for a registration. If you are certain that you have two registration numbers for a single facility, select the radio button to the left of one of the registration numbers and choose "Change Registration Status" to cancel the duplicate registration. Cancellation is permanent.

### 5. What is the difference between an Account ID and a Registration Number?

An Account ID is specific to *you*, as a person. You use it, along with your password, to gain access to all of the FDA Industry Systems. An Account ID is sometimes also known as a "User ID" or "Username". Its sole purpose is to keep your information safe from modification by unauthorized individuals. If you wish, you can also create [Subaccounts](#) for other people to help you with your Registrations and other FDA Industry Systems, but that is completely optional. Most people will not need to do this.

A Food Facility Registration Number is specific to a particular food facility. One person, with one Account ID, can register as many Food Facilities as he or she needs to. Each facility should have exactly one registration number and PIN. Together, these allow you to give permission to other people (with other Account IDs) to manage your registrations.

url

[CFSAN Home](#) | [CFSAN Search/Subject Index](#) | [CFSAN Disclaimers & Privacy Policy](#) | [CFSAN Accessibility/Help](#)  
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

FDA Industry Systems Website Staff  
November 6, 2003