



USAID
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NEEP Nigeria Expanded
Exports Program

GUIDE TO REGISTERING FOOD FACILITIES WITH THE U.S. FOOD AND DRUG ADMINISTRATION



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Introduction

This guide was produced by the Nigeria Expanded Exports Program (NEEP), funded by USAID. The guide was developed in response to exporters' requests for information about registering a foreign facility with the U.S. Food and Drug Agency (FDA), which regulates U.S. food imports.

Food products may be imported to the United States only if the foreign facility in which the products were manufactured is registered with the FDA. Although companies can register their facilities on the FDA's website, many find the process challenging.

To overcome these challenges, this guide

1. Provides step-by-step assistance in registering on the FDA website,
2. Clarifies the role of a U.S. Agent, and
3. Identifies U.S. companies that manage the registration process for a fee.

Registration Essentials

Much of the information presented here is from the website of the U.S. FDA:

www.fda.gov

Who Must Register?

Owners and operators of facilities that manufacture, process, pack, or hold food intended for human or animal consumption in the United States are required to register. Registration is required only once for each food facility.

Which Facilities Must Register?

If your facility is in one of following food industry sectors, you must register it with the FDA:

- Manufacturers or processors
- Packers
- Storage operations

If...	Then...
A foreign facility manufactures processes, packs, or stores food	The facility is required to register.
A foreign facility that manufactures, processes, packs, or stores food sends it to another foreign facility for further manufacturing, processing, or packaging before the food is exported to the United States	Only the second foreign facility is required to register.
The second foreign facility performs only a minimal activity, such as putting on a label	Both facilities must register.
Any foreign facility packs or holds food after the last foreign manufacturer / processor of the food	The foreign packer or holder must register.

Food Included in the Regulation

The following goods are defined as “food” for purposes of complying with the facility registration regulation. If your facility handles any of these goods, you must register it:

- Dietary supplements and dietary ingredients, infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell 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
- Animal feeds and pet food

Facilities That Do **Not** Have to Register

- **Private residences of individuals**—except if the facility is on the premises of a private residence and is used for selling or exporting food for consumption in the United States
- **Non-bottled 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**—Facilities devoted to growing and harvesting crops, raising animals—including seafood—or both, but NOT involved in the manufacturing, processing, packing, or storing of food
- **Restaurants and retail food establishments**—facilities that prepare and sell food directly to consumers for immediate consumption and as a primary function, including pet shelters, kennels, and veterinary facilities that provide food directly to animals
- **Nonprofit food establishments**—charitable entities that prepare or serve food directly to consumers or otherwise provide food or meals for consumption by humans or animals in the United States.
- **Fishing vessels** that harvest and transport fish
- **Facilities handling only meat, poultry, or egg products**, which have separate requirements and fall under the regulatory authority of the U.S. Department of Agriculture (USDA).

How Often a Facility Must Register

Registration is required only once for each food facility. The registration must be updated if information about the facility changes.

Who May Register

The owner, operator, or a person authorized to do so by the owner/operator, may register the facility. Foreign facilities must designate a U.S. Agent, who lives or maintains a place of business in the United States and is physically present in the United States for purposes of registration. The U.S. Agent, further defined below, may be authorized to register the facility.

Failure to Register

If registration is not completed or updated as required, food imports from that facility may be refused entry and held at the port of entry unless otherwise directed by the FDA or U.S. Customs and Border Protection.

How Do You Register?

There are two ways to register:

1. Directly through the FDA Industry Systems website:
www.access.fda.gov/oa
2. Indirectly through a third party (private) company in the United States.

The FDA does not require use of a third party, nor is any company officially responsible for FDA registration. Some U.S. businesses spread false information about registration requirements, suggesting that the FDA requires facilities to use a U.S. company for registration or that registration must be updated annually.

Registration Fees

The FDA charges no fee for initial registration or updates. Third-party companies that register on behalf of foreign facilities charge fees for their services. The FDA is not affiliated with these companies nor does it regulate them.

U.S. Agent for Foreign Facilities

Foreign facilities are required to designate a U.S. Agent to be a point of contact between the FDA and the facility. There are only two qualifications for a U.S. Agent:

1. The agent must reside in or maintain a place of business in the United States.
2. The agent must be physically present in the United States.

A U.S. Agent can be any “person”—defined as an individual, partnership, corporation, or association—that meets the qualifications and is listed as a specific point of contact in the facility’s registration. Foreign facilities may use an existing contact in the United States as a U.S. Agent(s).

The U.S. Agent could be a business connection, such as a buyer, importer, or broker, or if the facility does not yet have business contacts in the United States, a friend, relative or any other personal or business relation who resides in the United States. Having one U.S. Agent for registration purposes does not prohibit a foreign facility from having multiple agents for other purposes (e.g., sales).

Role of U.S. Agent: Point of Contact

The U.S. Agent serves as the point of contact between the FDA and the facility on routine and emergency matters unless the facility designates a separate emergency contact in its registration. Unless otherwise designated, the U.S. Agent must be accessible to the FDA 24 hours a day, 7 days a week. If an emergency contact is specified, the FDA will still use the U.S. Agent for routine communications. Routine communications includes requests for information about the facility, scheduling of inspections, or relaying of information in response to a potential bioterrorism threat or other public health emergency.

U.S. Agent Liability

The FDA will not hold the U.S. Agent responsible for violations of the law committed by the foreign facility unless the agent knowingly submits false information to the FDA. Liability issues between the facility and its U.S. Agent must be resolved between them, probably through the terms of their contractual relationship, if one exists.

Third-party Firms Offering Registration Services

Third-party firms offer services to assist domestic or foreign facilities with registration. These companies are not affiliated with the FDA, nor has the FDA contracted with any of them to register facilities.

Companies that can be hired to register facilities and/or serve as U.S. Agents are listed at the end of this guide. The list includes many of the larger of such companies but is not comprehensive.

Fees listed are for registration of one facility. Fees for registering more than one facility vary by company but are usually less per facility than for registering just one facility. Some companies will cancel or change a registration for free, while others charge a fee, usually less than \$100.

After facilities have been registered, most companies will continue to serve as U.S. Agent for an annual fee. Some additional services may be covered by fees for U.S. Agent or registration services and some will be covered separately. Examples of such services include legal, labeling, or sales-related activities. These services may not be necessary for every facility. Each company's website provides detailed information on fees, costs for registering more than one facility, and fees for additional services.

When you have registered your facility—directly or through a third party that also serves as your U.S. Agent—and you have sold food products in the United States, you should be able to request that one of your new U.S.-based business contacts be your U.S. Agent beyond the first year. This will require only a simple update of the registration information.

Online Registration

Registering a food facility online with the FDA is relatively easy. The FDA estimates that reading and understanding the regulations takes 1 to 2 hours. A staff member should be able to fill out the registration form in less than 2 hours, and the owner, operator, or agent should be able to certify the registration in about 15 minutes. These estimates assume that all parties have reliable access to the Internet and can read and write English.

Required Information for Registration

Mandatory data fields are marked with an asterisk (*). The following information is mandatory:

- Name, physical address, and phone number of the facility
- Parent company's name, physical 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
- Type of food product manufactured, processed, packed, or stored at the facility
- Name and contact information of the person submitting the certification statement
- Name of foreign facility's U.S. Agent and the agent's address, and phone number
- Emergency contact information, including an emergency phone number

Optional Information for Registration

You do not have to fill out every data field in each section. If a “*” is not in a data field or if the field/section is designated “optional,” you do not have to provide information. The following fields are optional:

- Facility fax number and e-mail address
- Preferred mailing address, if different from that of the facility
- Fax number and email address of the owner, operator, or agent in charge of the facility
- Fax number and email address of the parent company (if applicable)
- For a foreign facility: the fax number and e-mail address of the U.S. Agent
- Type of activity conducted at the facility (i.e., processing, packing, etc.)
- Food for animal consumption products (associated with the facility) under section 11b
- Type of storage (for holding facilities)
- Whether the facility manufactures/processes, packs, or holds most or all of the product categories

- Approximate dates of operation (if the facility's business is seasonal)

Online registration begins at www.access.fda.gov/oa. The first step is to create a user account. You will then provide information in 13 sections. Each section is described briefly here, and screenshots of the most important steps in online registration are provided.

Create Account

1. Type www.access.fda.gov/oa into your web browser (or click on the live link). When the page opens, hit **Create New Account** under the new users heading (left side).

NEW USERS	LOGIN
<p data-bbox="169 584 496 608">Create New Account</p> <p data-bbox="169 635 496 659">See Instructions</p> <p data-bbox="169 686 496 710">See Tutorials</p> <p data-bbox="169 737 496 761">Help Desk</p>	<p data-bbox="565 571 893 587"><i>Existing account holders, enter your account ID and password.</i></p> <p data-bbox="576 592 742 608">Account ID: <input type="text"/></p> <p data-bbox="576 635 871 651">Password: <input type="password"/> Forgot your password?</p> <p data-bbox="565 671 930 703"><small>Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.</small></p> <p data-bbox="703 699 785 715"><input type="radio"/> I understand</p> <p data-bbox="725 735 770 751"><input type="button" value="Login"/></p>

Note: For online assistance click the **See Instructions**, **See Tutorials**, or **Help Desk** buttons.

2. On the next page click on **Food Facility Registration** under the sections titled *FDA Unified Registration Listing Systems* and *Please select registration system* (see screenshot below). Then click **Continue**.

CREATE AN ACCOUNT

Select the systems you will need to access: [» Get Help ?](#)

FDA Unified Registration Listing Systems

Food Facility Registration Device Registration And Listing

Please select registration system

Food Facility Registration

Low Acid Canned Food

Drug Facility Registration

Shell Egg Producer Registration

Other FDA Systems

Prior Notice

Continue **Cancel**

1. Enter your account information, including a preferred password, on the following page and click **Continue**.
2. Review the information you entered for this account. If the information is correct, select **Submit**. If it is not correct, select **Modify** to return to the edit screen and make changes.

Note: The message, *Warning: This address could not be validated*, means that the system was unable to verify the address you entered. Re-check the address entered. If it is correct, disregard the notice and submit the application. The application will be processed normally.

3. If your account creation was successful, the following message will be displayed: *You have successfully created an Account. Your account ID is....*and a button to Login to the FDA Industry Systems home page.
4. Log in to FDA Industry Systems using your account ID and newly created password.

Register a Food Facility

When you are logged into FDA Industry Systems choose “Food Facility Registration.”

The screenshot shows a user interface for account management. On the left is a vertical menu titled "Account Management" with options: Edit Account Profile, Change My Password, Update System Access, Create a Subaccount, Deactivate a Subaccount, and Reactivate a Subaccount. The main content area has a header "Welcome" and "You are logged in as fda27603". Below this is a welcome message: "Welcome to the FDA Industry Systems. You are logged in to your account for company PN Test". A red text block follows: "You may choose an option on the left to manage your account or select an FDA system below. To obtain access to available FDA systems, choose the Update System Access option to add the FDA system to your account." Underneath is the section "FDA Unified Registration Listing Systems" with buttons for "Food Facility Registration", "Low Acid Canned Food", "Device Registration & Listing", and "Drug Facility Registration". At the bottom is the section "Other FDA Systems" with a button for "Prior Notice".

To register a food facility, click on **Register a Food Facility** from the Main Menu. After you have registered a facility you may also use this menu to update a registration, cancel a registration, link a registration to your account, search for one of your registrations, manage registrations among your accounts, or confirm receipt of mailed notifications.

The screenshot shows the "FFRM MAIN MENU" with a list of buttons on the left: Register a Food Facility, Update Facility Registration, Cancel/Change Registration Status, Link Registration to your Account, Search Facility Registrations, Manage Registrations Among Accounts, and Confirm Notification Receipt. On the right, there is a "Form Approval: OMB No. 0910-0502" section with an expiration date of 10/31/2006 and a note: "An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number." Below this is a "Please Note:" section with a red warning: "The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning."

At the top of every page in the Food Facility Registration Module, a status bar tracks your progress. **Get Help** provides page-specific help.



At the top and bottom of each screen are three navigation buttons:

1. **Back to Step XX**—Go back one screen and continue entering registration information. Information entered on the current screen will not be lost.
2. **Continue**—Go to the next screen and continue entering registration information.
3. **Cancel & Start Again From Section 1**—Return to Section 1. Any information you have entered will be lost.

Section 1. Type of Registration REQUIRED

Indicate the location of the facility you are registering and whether you are submitting a registration as a new owner of a previously registered facility. Choose *Foreign* if the facility is not in the United States.

Type of Registration cannot be changed later in the application process. If you wish to change this selection, you must cancel the application and create a new registration.

Fields Particular to Section 1	
Type of Registration	Specifies whether the facility is domestic or foreign.
New Owner of a Previously Registered Facility	Select Yes if you are submitting a registration as a new owner of a previously registered facility. Select No if you are submitting a registration for a facility never previously registered.
Previous owner's name	If you are a new owner of a previously registered facility, provide the name of the previous owner.

Fields Particular to Section 1

Previous owner's registration number	If you are a new owner of a previously registered facility, provide the previous owner's FDA registration number for this facility, if known. If the new owner does not provide the old registration number, FDA will keep the old registration in its database until it independently affirms that the facility is under new ownership.
--------------------------------------	--

Fields Standard in Sections 2, 3, 4, 7, 12, and 13 (required=*)

* Street Address	The street/physical/geographical location or other mailing address.
*City	City in which the facility or individual is located.
*Country	Select a country from the pull-down menu.
*State/Province/Territory	The state, province, or territory in which the facility is located. Select from the pull-down menu or select "Not applicable."
*Zip Code (Postal Code)	The postal code of the facility or individual.

Note: FDA's electronic system is designed to request zip code information only for facilities in the United States, and the postal code only for countries that have postal codes, based on the country selected above.

*Phone Number: Country Code	The three-digit country code of the telephone number for the facility or individual.
*Phone Number: Area/City Code	The city code (for foreign addresses) of the telephone number for the facility or individual.
*Phone Number	Telephone number of the facility or individual.
Phone Number: Extension	The telephone extension, if any, dialed after the telephone number, of the facility or individual.
Fax Number: Country Code	The three-digit country code of the number of the fax machine for the facility or individual.
Fax Number: Area/City Code	The city code of the number for the fax machine of the facility or individual.
Fax Number: Fax Number	The telephone number of the fax machine of the facility or individual.
E-mail Address	An e-mail address for the facility or individual.

Section 2. Facility Name/Address Information **REQUIRED**

Enter the name, address, and phone number of the facility being registered (Figure 1). (You may also enter information about a preferred mailing address in Section 3.) Select **Continue** when the information is complete.

The messages “Facility Address is invalid” or “The address submitted has been validated with corrections” means that the system could not verify the address entered. If the address is incorrect, select “Return to Step 2 and make changes” to correct the information. If the changes made by the system are correct, select “Accept validated address and continue.” If you wish to keep your original data, select “Keep your address and continue” and continue with the registration. The registration will be processed normally.

Fields Particular to Section 2

*Facility Name The name of the facility being registered.

Figure 1

SECTION 2 FACILITY NAME / ADDRESS INFORMATION

* - These fields are required

>> AutoFill Address >> Clear

*FACILITY NAME
[Text Input]

*FACILITY STREET ADDRESS, Line1
[Text Input]

FACILITY STREET ADDRESS, Line2
[Text Input]

*CITY
[Text Input]

*COUNTRY
[Dropdown: United States]

*STATE/PROVINCE/TERRITORY
[Dropdown: [Please Select]]

*ZIP CODE (POSTAL CODE)
[Text Input]

Numbers only. No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g.033)	Area/City Code (e.g.101)	Phone Number (e.g.5551111)	Extension (e.g.1111)
*PHONE	[Text Input]	[Text Input]	[Text Input]	[Text Input]

	Country Code (e.g.033)	Area/City Code (e.g.101)	Fax Number (e.g.5551111)
FAX NUMBER	[Text Input]	[Text Input]	[Text Input]

E-MAIL ADDRESS
[Text Input]

Section 3. Preferred Mailing Address **OPTIONAL**

If the preferred mailing address is the same as the facility address, leave this section blank. The facility address and the preferred mailing address do not have to be in the same country. When you have finished with this section, select **Continue** to validate your address(es).

Note on AutoFill: If this is the first facility registration entered by this account holder this session, this option will fill the fields automatically using data in this section from the last registration entered this session.

Fields Particular to Section 3	
Name	The name of the person or company that is to receive mail from FDA regarding this registration.
Address	The mailing address of the company or person named - the address at which you would like to receive notices from FDA about this registration.

Section 4. Parent Company Name/Address Information **REQUIRED, if applicable**

If applicable, enter information about the company that owns the facility being registered (Parent Company). If the facility and the parent company have different names, you must complete this section (Figure 2); if they have the same name, leave this section blank. The facility address and the parent company address do not need to be in the same country.

Fields Particular to Section 4	
If information is the same as another section, check which section	<p>Specifies whether the parent company name/address is identical to previously entered information. If you choose one of these and decide the information is not what you wanted, choose Clear to undo and fill in the correct information manually.</p> <p>Choose Section 2 if the parent company name/address is the same as the facility name/address information entered in Section 2.</p> <p>Choose Section 3 if the parent company name/address is the same as the preferred mailing address information entered in Section 3.</p> <p>Choose Clear if you need to clear Section 4</p>
Name of Parent Company	The name of the company that owns the facility being registered, if different from the Facility Name.

Figure 2

SECTION 4 PARENT COMPANY NAME/ADDRESS INFORMATION

(IF APPLICABLE AND IF DIFFERENT FROM SECTIONS 2 and 3). IF INFORMATION IS THE SAME AS ANOTHER SECTION, CHECK WHICH SECTION:

Section 2 - Facility Address Information or

Section 3 - Preferred Mailing Address Information

**** - These fields are required only if the section applies**

Autofill Address will fill the address fields automatically using data in Section 4 from the last registration entered

****NAME OF PARENT COMPANY**

****STREET ADDRESS OF PARENT COMPANY, Line 1**

STREET ADDRESS OF PARENT COMPANY, Line2

****CITY**

****COUNTRY**

****STATE/PROVINCE/TERRITORY**

****ZIP CODE (POSTAL CODE)**

Numbers only. No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g.033)	Area/City Code (e.g.101)	Phone Number (e.g.5551111)	Extension (e.g.1111)
**PHONE NUMBER	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

	Country Code (e.g.033)	Area/City Code (e.g.101)	Fax Number (e.g.5551111)
FAX NUMBER	<input type="text"/>	<input type="text"/>	<input type="text"/>

E-MAIL ADDRESS

Section 5. Emergency Contact Information

OPTIONAL, but recommended

Enter the name of the individual who should be contacted in case of an emergency. The FDA will use this information to notify the facility in case of an emergency. This individual should be available 24 hours per day, 7 days per week. The FDA will use the specified U.S. Agent as the emergency contact if this section is not completed.

Fields Particular to Section 5	
Individual's Name	The first name and last name (surname) of the person to contact in case of emergency for the facility being registered.
Title	The job title for the emergency contact.
*Emergency Contact Phone: Country Code	For foreign registrations, the three-digit country code for the telephone number of the person or entity that the FDA can call 24 hours per day, 7 days per week, in case of emergency.
*Emergency Contact Phone: Area/City Code	The three-digit area code (for domestic addresses) or city code (for foreign addresses) for the telephone number of the person or entity that FDA can call 24 hours per day, 7 days per week, in case of emergency.
*Emergency Contact Phone: Phone Number	The telephone number of the person or entity that FDA can call 24 hours per day, 7 days per week, in case of emergency.

Section 6. Trade Names REQUIRED, if applicable

Enter alternate trade name information. If this facility conducts any business under a name other than that entered in Section 2, complete this section.

Fields Particular to Section 6	
Alternate Trade Name #1	A trade name other than that listed in Section 2: Facility Name / Address Information. A facility trade name is the name or names under which the facility conducts business, or additional names by which the facility is known.
Alternate Trade Name #2, 3, 4	Additional trade names other than that listed in Section 2: Facility Name / Address Information.

Section 7. United States Agent REQUIRED

Enter information about the U.S. Agent for the facility being registered (Figure 3). Every foreign facility must have a U.S. Agent who acts as the domestic communication representative for that facility. The instructions specify the name of an individual, but, the FDA’s literature indicates that the name of a partnership, corporation, or association may also be inserted here.

Figure 3

SECTION 7 UNITED STATES AGENT

(TO BE COMPLETED BY FACILITIES LOCATED OUTSIDE ANY STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO)

**** - These fields are required only if the section applies**

>> AutoFill Address

>> Clear

Autofill Address will fill the address fields automatically using data in Section 7 from the last registration entered.

****NAME OF U.S. AGENT.**

TITLE

****ADDRESS, Line 1**

ADDRESS, Line2

****CITY**

****STATE**

****ZIP CODE**

COUNTRY: U.S.A.

Numbers only. No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Area/City Code	Phone Number	Extension
***PHONE NUMBER	(e.g.101)	(e.g.5551111)	(e.g.1111)
	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

	Area/City Code	Phone Number
**EMERGENCY CONTACT PHONE	(e.g.101)	(e.g.5551111)
	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

	Area/City Code	Fax Number
	(e.g.101)	(e.g.5551111)
	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

Do not confuse the U.S. Agent with the agent-in-charge. The agent-in-charge is the person designated by the owner or operator of a facility to register on its behalf if the owner/operator chooses not to register directly.

Fields Particular to Section 7	
Name of U.S. Agent	The first name and last name (surname) of the person acting as U. S. Agent for the foreign facility being registered.
Title	The job title of the U.S. Agent.

Section 8. Seasonal Facility Dates of Operation OPTIONAL

Dates of Operation refers to the months during which the facility is open for business. If the facility operates on a seasonal basis, you may choose to complete this section. You might enter, for example, March-September.

Section 9. Type of Activity Conducted at the Facility OPTIONAL

You may choose to select the types of operations that are performed at this facility for the manufacturing, processing, packing, or holding of food. Select as many as appropriate.

Section 10. Type of Storage OPTIONAL

If the facility is solely a warehouse/holding facility, you may choose to complete this section. If the facility is not solely a warehouse/holding facility, skip this section.

Section 11a. Food for Human Consumption REQUIRED

Select as many of the 36 categories as appropriate. At least one category must be selected. If your facility does not manufacture, process, pack, or hold food for human consumption, select box 37: “None of the Above Mandatory Categories.”

Section 11b. Food for Animal Consumption OPTIONAL

Select as many of the 26 categories as appropriate.

Section 12. Owner, Operator, or Agent-in-Charge REQUIRED

If the contact information for the owner, operator, or agent-in-charge is the same as that in another section of the form, choose the circle corresponding to that section; otherwise enter the information as requested (Figure 4).

Fields Particular to Section 12

Name of entity or individual who is the owner, operator, or agent in charge

The name of the person or entity who is the owner, operator, or agent-in-charge of the facility being registered.

If information is the same as another section of the form, check which section specifies whether the owner, operator, or agent-in-charge address is identical to previously entered information. If you choose one of these and decide the information is not what you wanted, you may choose Clear to undo and fill in the correct information manually.

Choose Section 2 if the owner, operator, or agent-in-charge address information is the same as the facility address information entered in Section 2: Facility Name / Address Information. - or -

Choose Section 3 if the owner, operator, or agent-in-charge address information is the same as the preferred mailing address information entered in Section 3: Preferred Mailing Address Information. - or -

Choose Section 4 if the owner, operator, or agent-in-charge address information is the same as the Parent Company address information entered in Section 4: Parent Company Name / Address Information. - or -

For foreign facilities, choose Section 7 if the owner, operator, or agent-in-charge address information is the same as the U.S. Agent address information entered in Section 7: United States Agent. - or -

Choose Clear if you need to clear Section 12

Figure 4

SECTION 12 OWNER, OPERATOR, OR AGENT IN CHARGE INFORMATION

* - **These fields are required**

*NAME OF ENTITY OR INDIVIDUAL WHO IS THE OWNER, OPERATOR, OR AGENT IN CHARGE

PROVIDE THE FOLLOWING INFORMATION, IF DIFFERENT FROM ALL OTHER SECTIONS ON THE FORM. IF INFORMATION IS THE SAME AS ANOTHER SECTION OF THE FORM, CHECK WHICH SECTION:

Section 2 - Facility Address Information

Section 3 - Preferred Mailing Address Information

Section 4 - Parent Company Address Information

*STREET ADDRESS, Line1

STREET ADDRESS, Line2

*CITY

*COUNTRY
[Please Select] ▼

*STATE/PROVINCE/TERRITORY
[Please Select a Province] ▼

*ZIP CODE (POSTAL CODE)

Numbers only. No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code	Area/City Code	Phone Number	Extension
	(e.g.033)	(e.g.101)	(e.g.5551111)	(e.g.1111)
*PHONE	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

	Country Code	Area/City Code	Fax Number
	(e.g.033)	(e.g.101)	(e.g.5551111)
FAX NUMBER	<input type="text"/>	<input type="text"/>	<input type="text"/>

E-MAIL ADDRESS

Section 13. Certification Statement REQUIRED

Enter information about yourself as the submitter of this registration and about the person who authorized submission of this registration, and certify its truth and accuracy (Figure 5). When you have completed this section, you will be able to review your registration and make any necessary changes before submitting it for processing.

The owner, operator, or agent-in-charge of the facility, or an individual authorized by the owner, operator, or agent-in-charge, must submit this form. In submitting the form, the submitter certifies that the information presented is true and accurate and that the facility has authorized the submitter to register on its behalf.

Fields Particular to Section 13	
Check One Box	<p>A. Owner, Operator, or Agent-in-charge (Stop here, form is completed) - or -</p> <p>B. Individual Authorized to Submit the Registration (Fill in address below)</p>
Indicate who authorized you to submit the registration	<p>If you checked box B, identify the person who authorized you to submit this registration. Choose:</p> <p>Owner, Operator, or Agent –in-charge (Stop here, form is completed) - or -</p> <p>Fill in the name of individual who authorized registration on behalf of owner, operator, or agent in charge.</p>

Figure 5

SECTION 13 CERTIFICATION STATEMENT

The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent in charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

PRINT NAME OF THE SUBMITTER

CHECK ONE BOX

A. OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)

B. INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION (FILL IN ADDRESS BELOW)

IF YOU CHECKED BOX B ABOVE, INDICATE WHO AUTHORIZED YOU TO SUBMIT THE REGISTRATION:

OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)

NAME OF INDIVIDUAL WHO AUTHORIZED REGISTRATION ON BEHALF OF OWNER, OPERATOR, OR AGENT IN CHARGE (FILL IN ADDRESS BELOW)

**** - These fields are required only if the section applies**

ADDRESS INFORMATION FOR THE AUTHORIZING INDIVIDUAL:
**AUTHORIZING INDIVIDUAL STREET ADDRESS, Line1

AUTHORIZING INDIVIDUAL STREET ADDRESS, Line2

**CITY

**COUNTRY

[Please Select]

**STATE/PROVINCE/TERRITORY
[Please Select a Province]

**ZIP CODE (POSTAL CODE)

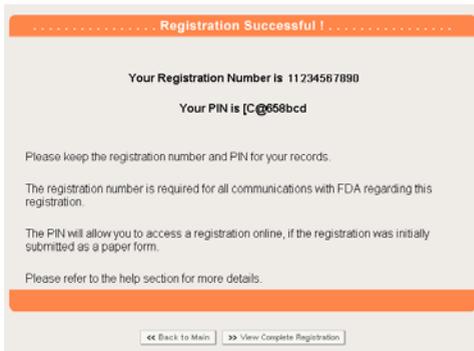
Review Registration

Review your registration before submitting it for processing. Selecting the EDIT button for a section brings up the corresponding data entry screen, from which you can edit and save changes. Select SUBMIT to submit the registration as the final step.

Note: The Facility Location under Section 1: Type of Registration (in which you indicate whether this is a domestic or foreign facility) cannot be changed at this point. If you wish to change the Facility Location, you must cancel this registration and begin a new one.

Successful Registration

A message indicates that your registration was submitted successfully, and your registration number and PIN are displayed. Keep these numbers in your records.



View Completed Registration

To view the entire registration in its final form, select View Complete Registration. Using the buttons at the bottom of the screen, you can print a copy of the registration for your records. Or, you can return to the FFRM Main Menu to enter another registration or complete other registration tasks.

Note: The registration number and PIN are displayed at the top of the registration form.

Next Steps

Your FDA Registration number must be indicated in your commercial invoice for a given shipment to the United States.

The FDA also has a regulation known as *Prior Notice* that requires advance notice of shipments of imported food for human or animal consumption. This function is usually handled by the importer but may be filed by the exporter, a broker, U.S. Agent, or anyone else who has the necessary shipping and consignment details. The individual filing the *Prior Notice* must know the FDA registration number as this is required information.

U.S. Agent Firms for Hire

Prices listed here were reported by the companies interviewed as of 2010, but may not be valid at the time of future inquiries.

U.S. Agent Firm	Website	Fees (US\$)		
		Facility Register	U.S. Agent	Annual Renewal
AGDE Corporation	www.agdecorp.com	150	450	150
Diverstech Co.	www.usagentforfda.com	N/A	495	495
FDA Agents	www.fdaagents.com	389	a	249
FDA Designated Agent	www.fdadesignatedagent.com	750	a	450
FDA Imports	www.fdaimports.com	750	a	750
FDALink Regulatory Consulting	www.spherelink.com	500	a	200
FoodAdviz	www.foodadviz.com	189	a	139
Food-Agent	www.food-agent.com	300	a	300
Global Trading Hub	www.gthub.com	395	a	395
Register FDA	www.registerfda.com	150	350	350
Register-FDA	www.register-fda.com	145	295	295
Registrar Corp	www.registrarcorp.com	595	a	\$445
The Roberts Group	www.therobertsgroup.net	500	a	500
U.S.A. Register, LLC	www.usfdaregister.com	550	N/A	N/A
Wellkang LLC	www.fda-registration.com	499	a	499

a Agent fee included with registration.

Plot 401, Omofade Crescent
Omole Phase 1, Ikeja
Lagos 01-8742001/2

www.nigeriaexport.org

