Registration of Food Facilities with the FDA

US Food and Drug Administration **(FDA)**

International Office for Latin America

US-FDA-LAO@fda.hhs.gov po

Agenda

- FDA in Brief
- General information about the Export of Food to the USA.
- Registration of Food Facilities

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What is the FDA?

US federal public health agency, regulatory issues, belongs to the Department of Health and Human Services.

- **Drugs for human use**
  - –Prescription, over-the-counter (OTC), generic
- **Biological products such as vaccines, blood supply, blood products.**
- **Medical devices**
  - –From simple items like tongue depressors to complex technologies like pacemakers
- **Products that emit radiation –** Microwave ovens, tanning beds, laser pointers

- **Food**
  - Food safety
  - Food additives (including radiation used to treat food)
  - Baby formula
  - Dietary supplements
  - Food utensils
  - Containers-packaging
- **Cosmetics**
- **Veterinary Products**
  - Livestock and pet food
  - Animal drugs
- **Tobacco Products**
- **Color additives (food, medicine, cosmetics).**

Important Aspects of the US Food Safety System

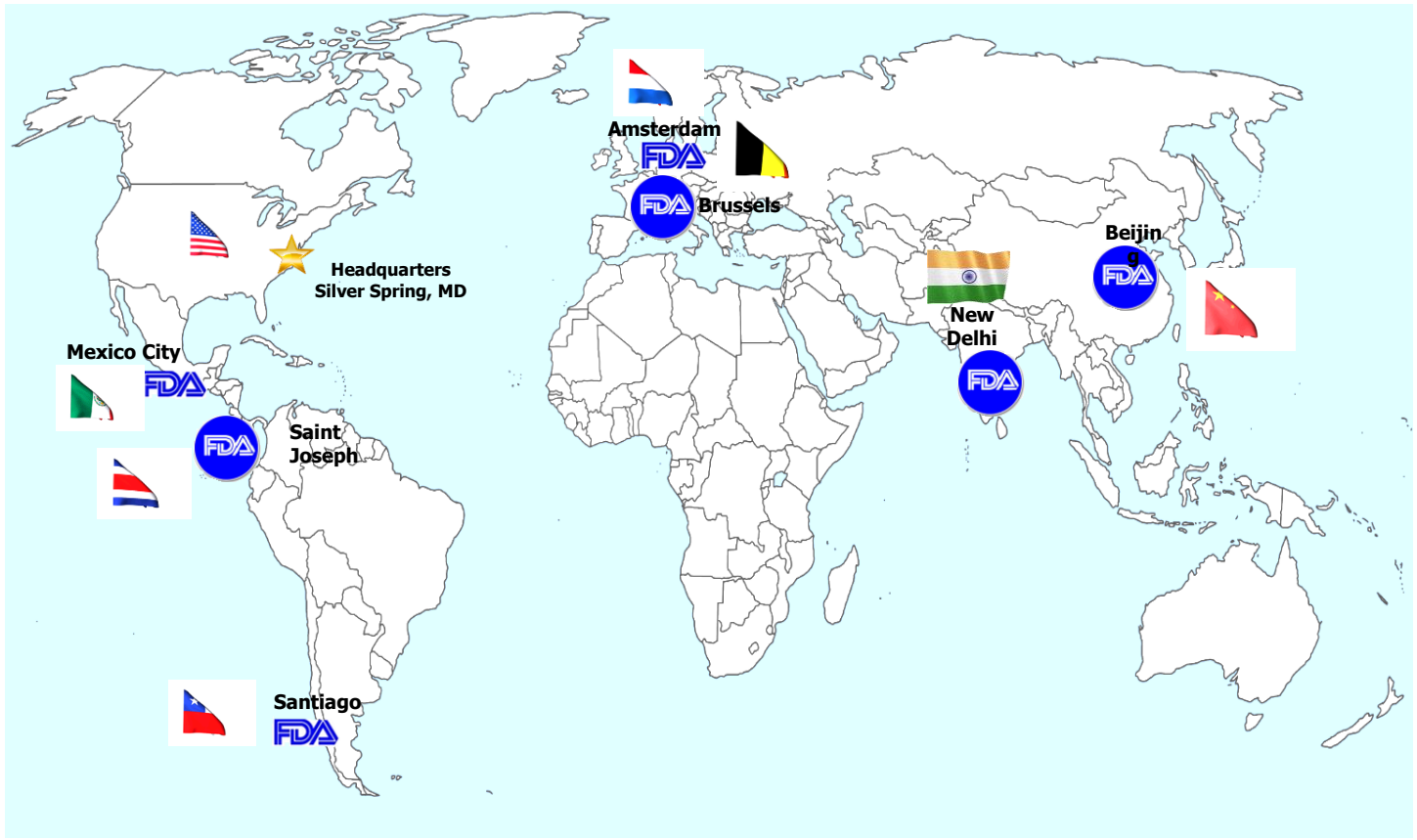
- FDA is responsible for the safety of 80% of all food consumed in the US, both domestically produced and imported.
  - **Exceptions**
    - **Meats and meat products**
    - **Poultry and poultry products**
    - **Catfish**
    - **Frozen and processed eggs (liquid, dehydrated)**
    - **Animal and Plant Health**

USDA Regulated

    - **Alcoholic beverages with more than 7% alcohol**

Regulated by TTB: Alcohol and Tobacco Tax and Trade Bureau

FDA International Offices



General information about the Export of Food to the USA

All food intended for import into the United States of America must meet the same requirements as domestic products, including:

- Food safety
- Good Manufacturing Practices, Good Agricultural Practices or others, as appropriate.
- **Registration of Facilities**
- Labelling
- Specific requirements for certain products (acidified products, low-acid products stable at room temperature, milk, fish and shellfish, juices and fruit pulps).
- Compliance with the Food Safety Modernization Act (FSMA).

In addition, you must comply with the Prior Notice system.

You must also be available to receive FDA inspections.

Registration of Food Facilities

- **Why should food facilities be registered?**

- This is a necessary process to be in compliance with US law.

You can find the law in the US Code of Federal Regulations: Title 21, Chapter I, Subchapter A, Part 1, Subpart H.

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-1/subpart-H?toc=1

Registration of Food Facilities

- **Why should food facilities be registered?**

The information supplied allows the FDA to learn about food traders in the US, and also helps determine the possible location and source of foodborne disease outbreaks or potential bioterrorism incidents.

Registration of Food Facilities

- Who must register?
  - Manufacturers or processors
  - Packers
  - Storage operations

- The requirement applies to any and all facilities, *not to firms or joint ventures.*
  - Company with 10 facilities in different locations.
  - Export logistics company.
  - Company with independent headquarters.

About the Registration of Facilities

- It is recommended that registration be done through the FDA website (http://www.access.fda.gov)
- Registration is free

About the Registration of Facilities

- Mandatory requirement to select a US Agent
- The system will verify that the selected US agent agrees to be an agent of the company in question.
- After verification, the system will send the registrant an email with the Registration Number and Personal Identification Number (PIN).

About the Registration of Facilities (cont.)

- The registration must be updated within 60 days of any change made to the facility's registration information.

- If the registered facility changes its address or ownership, or if there is a merger of companies, said registration must be canceled and a new registration made with the updated information.

About the Registration of Facilities (cont.)

Help in the registration process:

The District offices in the United States and the FDA Regional Office for Latin America do not have the resources to provide technical support for the registration process.

There is a dedicated support office for the food facility registration process, which works Monday through Friday, from 9:00 am to 6:00 pm ET time.

Phone: 1-800-216-7331 or 1-240-247-8804

Email: furls@fda.gov

Resources to facilitate the registration process for food facilities

- Account Management
- Registration of Food Facilities Step-by-Step Instructions
- Update Facility Registration
- Biennial Registration Renewal
- Retrieve Registration PIN
- Additional Capabilities in FFRM

Unique Facility Identifier (UFI)

- 21 CFR 1.232(a)(2) requires that as of October 1, 2020, domestic and foreign facilities provide a UFI recognized as acceptable by the FDA.
- The FDA currently recognizes the Data Universal Numbering System (DUNS) number as an acceptable UFI. DUNS numbers are assigned and administered by Dun & Bradstreet
- For information on how to apply for a DUNS number, please use the following link:

https://www.fda.gov/media/143997/download

Recommendations related to the Unique Facility Identifier (UFI)

- Use your own physical address. Do not use agent or shipper information.
- Do not use the location of your headquarters. Every facility must have a DUNS number.
- The legal name and address of the facility on the FDA registration application must match the DUNS information.
- The DUNS number is free, with up to four changes in 90 days.

DUNS Contact Information

- D&B Phone: 1-866-705-5711
- Email: ImportSafetySupport@DNB.com
- D&B website: https://importregistration.dnb.com/

Registration Cancellations

- The FDA will not confirm your registration or provide you with a registration number until it verifies the accuracy of your facility's UFI and ensures that the facility’s specific address associated with the UFI is the same address associated with your registration.

- The FDA verifies the submitted UFI.

  – (21 CFR 1.231(a)(3) and (b)(5))).D&B). Per 21 CFR 1.231(a)(3) and (b)(5)

Registration Cancellations

- Starting March 10, 2023, FDA Food Facility Registrations (FFR) without an accurate Unique Facility Identifier (UFI) are being cancelled. Firms that are impacted by FFR cancelled can have their registration reinstated once they provide the required UFI information.

FDA Food Facility Registration Reinstatement

Step 1 : Obtain the DUNS number

Register with D&B, using the same name and physical address of the facility that you have listed on your FDA Food Facility Registration. There can be no differences.

a. Please visit the **D&B Import Safety Lookup Portal** to either search your existing records and submit update requests, or to obtain new DUNS numbers. Please refer to the user guide for more information –**Import Safety Lookup Portal User Guide to obtain a D-U-N-S Number.**

FDA Food Facility Registration Reinstatement

b. D&B registration requests returned incomplete (e.g. unable to obtain a DUNS number or update existing registrations) can be forwarded to importsafetyregistrations@dnb.com for a second review, with an explanation to support your initial request. For example, location of the new branch (headquarters location DUNS 123456789); Address Update: Relocated Facility; Trade name update.

   i. Note – D&B may contact you to request legal business documents to support the registration application(s). D&B phone calls may be made on a recorded line.

FDA Food Facility Registration Reinstatement

- **Step 2** :

Once you have received a specific DUNS number for the facility's address, request your FFR and UFI verification by emailing cfsanfoodfacilityregistration@fda.hhs.gov using the format described below:

FDA Food Facility Registration Reinstatement

Subject: UFI accuracy verification

Email body:

- Food Facility Registration Number
- DUNS number
- Food Facility Registration (FFR) Section 2 – Facility Name
- Food Facility Registration (FFR) Section 2 - address, city, state/province, mailing/zip code.

Note:

Section 2 of the FFR is for the legal business name and physical address; Section 6 is for trade names and alternate trade names; Section 3 is for the mailing address; Section 4 is for the parent company. In the body of the email, only include relevant information from section 2 of the FFR.

FDA Food Facility Registration Reinstatement

Please follow the steps above to submit an accurate UFI and to have the FDA verify the accuracy of your UFI. Upon UFI accuracy verification, the facility may use the same registration number.

FDA Food Facility Registration Reinstatement

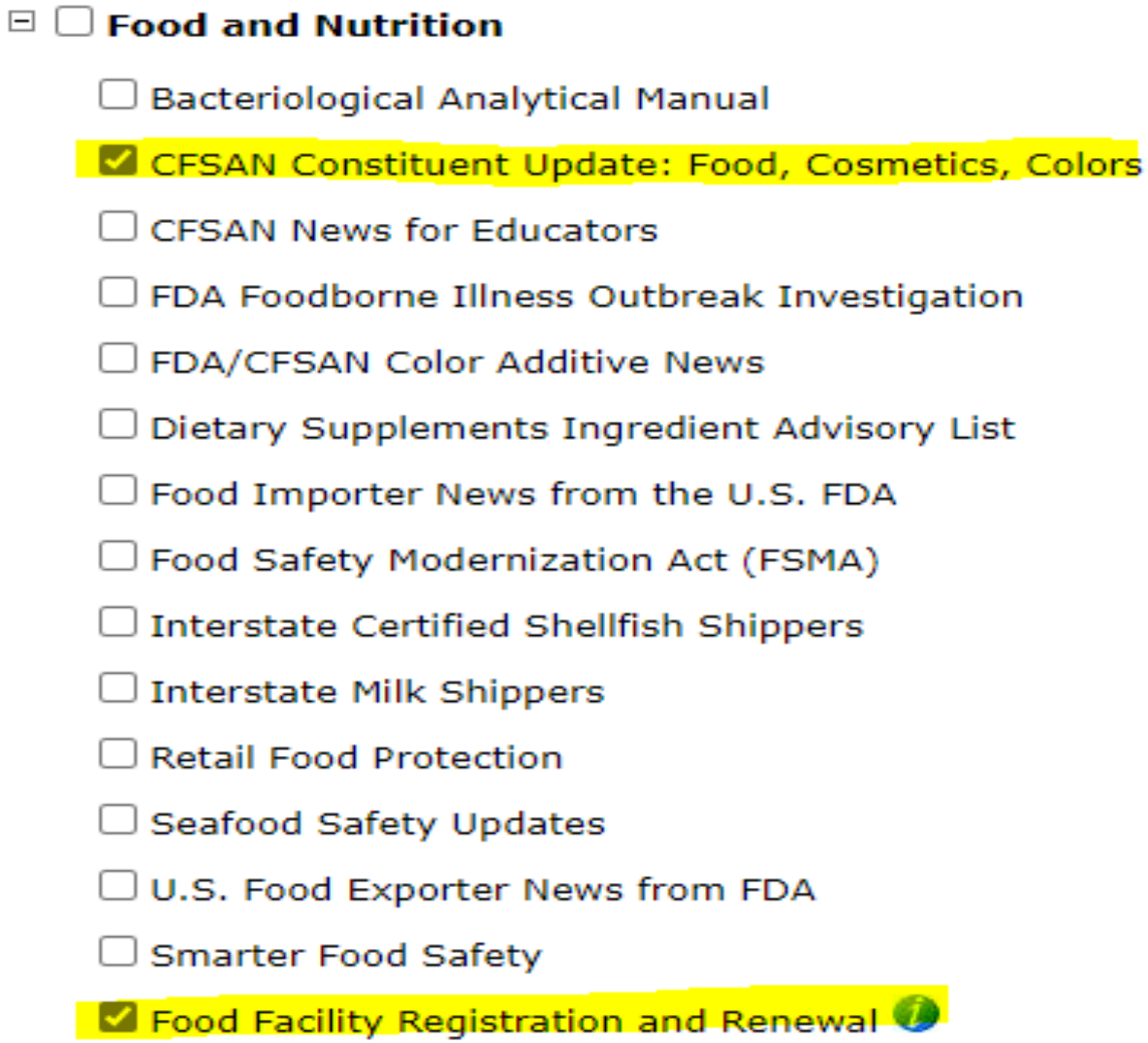
➢ Will the facility receive a new FFR number?

- No, after the facility provides an accurate UFI (DUNS number) they will be able to utilize the same number

➢ How can the industry stay up to date with the FFR requirements?

- The FURLS team has sent several emails and conducted a webinar. You can stay up to date by signing up for FDA emails using the following link: US Food and Drug Administration (govdelivery.com)

FDA Food Facility Registration Reinstatement



FDA Food Facility Registration Reinstatement

- Who can I contact for help?

Please contact FURSL by phone at 1-800-216-7331 or by email at FURLS@fda.gov .

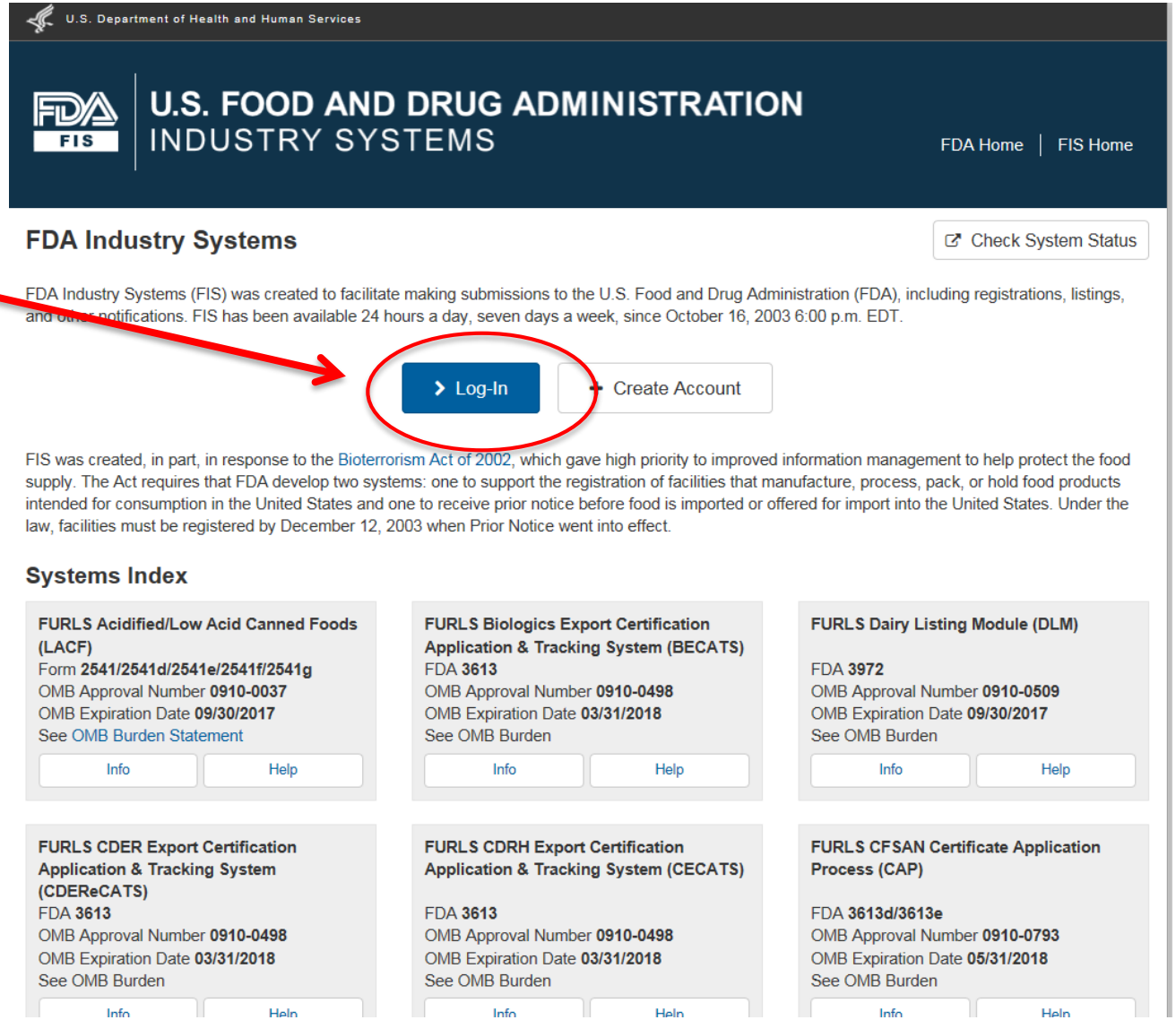
How to carry out the Facility Registration?

Enter the following link:

https://www.access.fda.gov/

Opening an account in the system (Food Facility (FFR) system)

Click on:
Login



ONLINE ACCOUNT ADMINISTRATION (OAA)

FDA Industry Systems

System Status

08/31/2016 See The 2016 Food Facility Registration Biennial Renewal period begins at 12:00 AM on October 1st 2016.

08/04/2016 See CDERECATS is not accepting applications or issuing export certificates for the Foreign Exported CPP.

Login

Existing account holders, enter your account ID & password.

Account ID

Password

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.

☐ **I understand.**

Login | Forgot your password

Click on : **Create New Account**

New User

Create New Account

See Instructions | See Tutorials | Help Desk

Getting Started

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page.

If you already have an account, enter your **account ID** and **password**.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

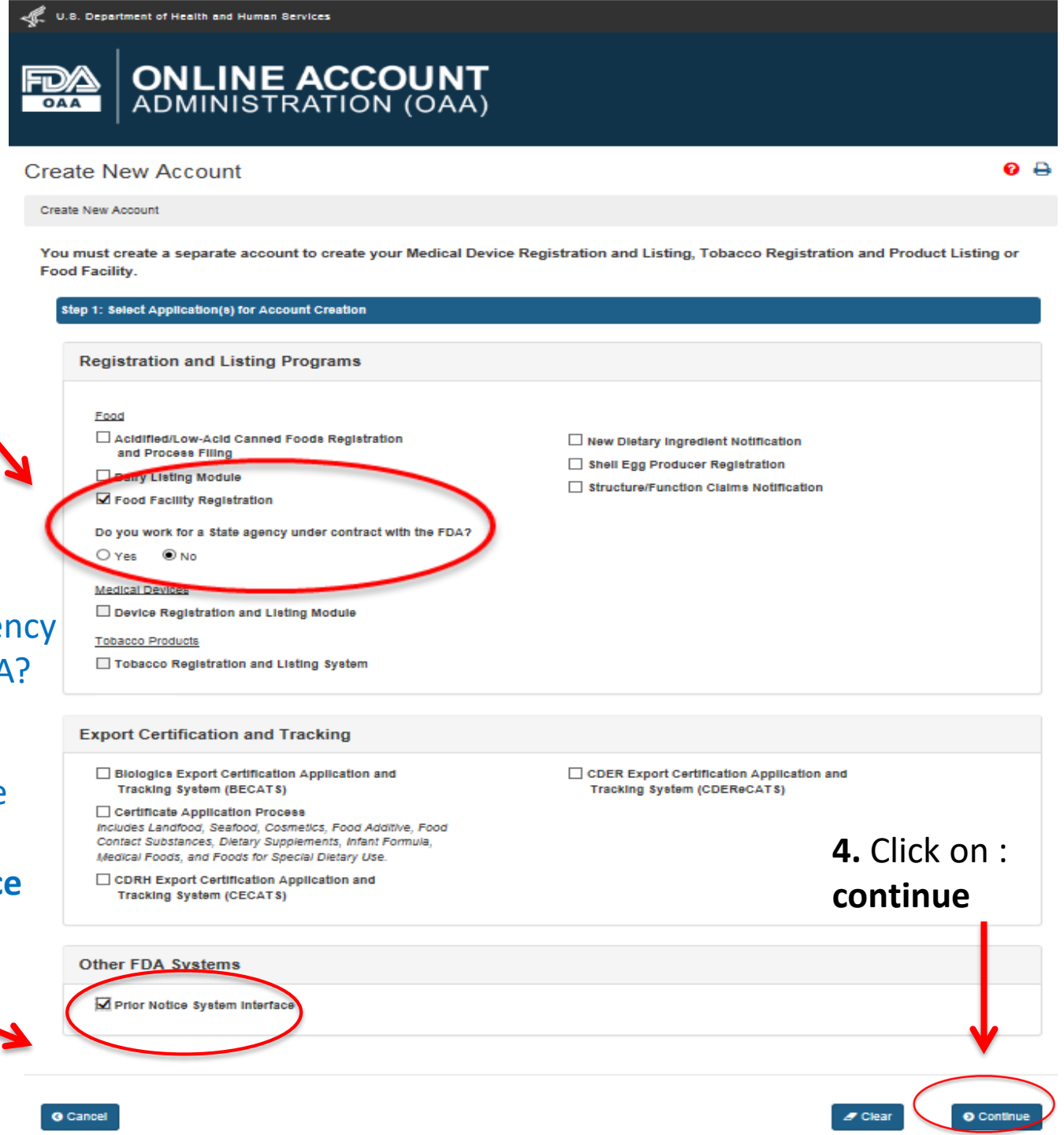
If you have Tobacco Registration and Product List (TRLM) specific questions, please contact **AskCTP at 1-877-287-1373 or AskCTP@fda.hhs.gov** and the AskCTP staff can assist with answering your questions about TRLM.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Help Desk at 1-800-216-7331** to confirm that the caller is acting on behalf of FDA.

1. Check:
Food facility Registration

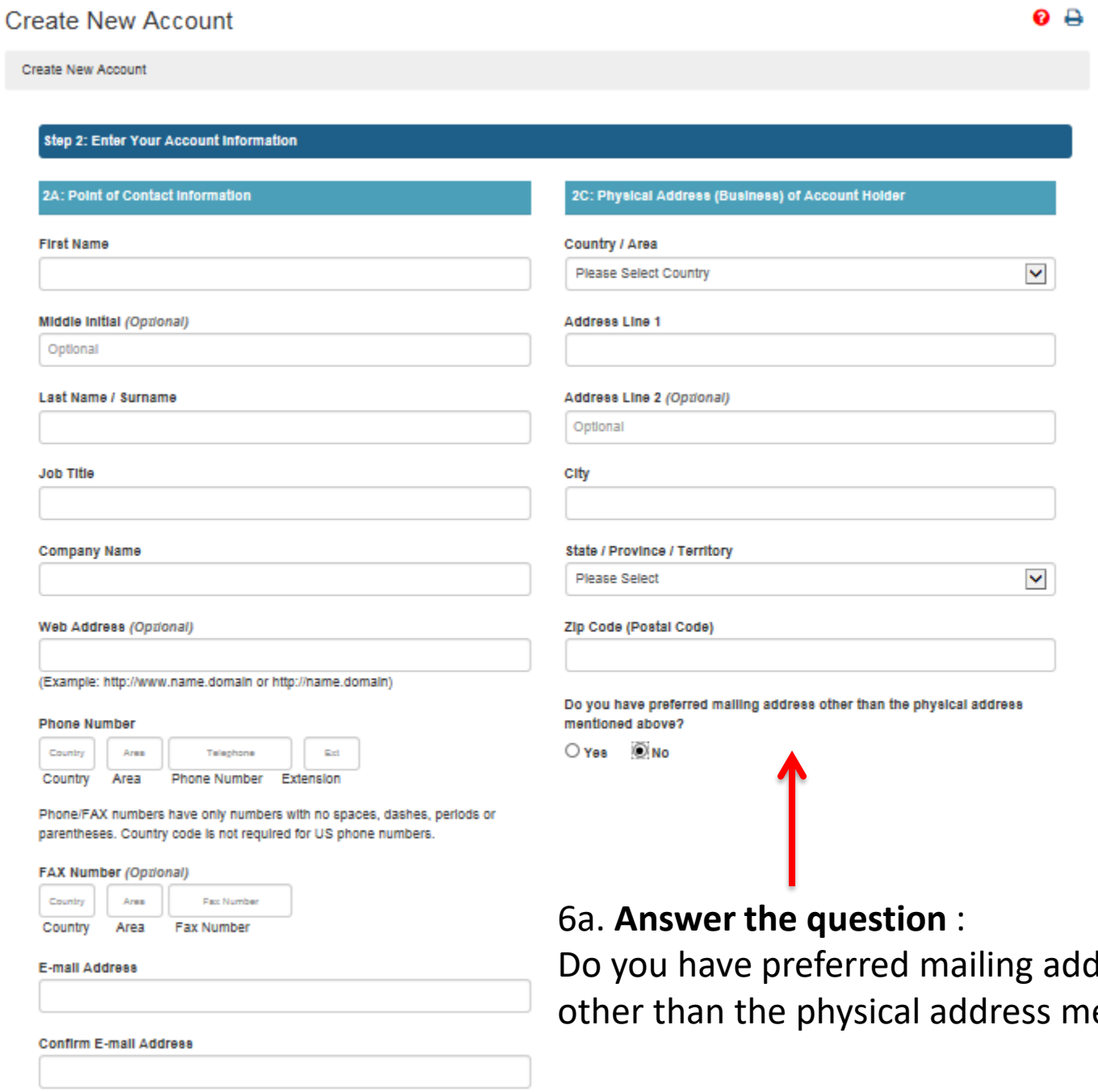
2. And answer the question which will appear:
Do you work for a State agency under contract with the FDA?

3. If you are going to use the Prior Notice system, select
Prior Notice system interface



4. Click on :
continue

5. Fill in the information requested

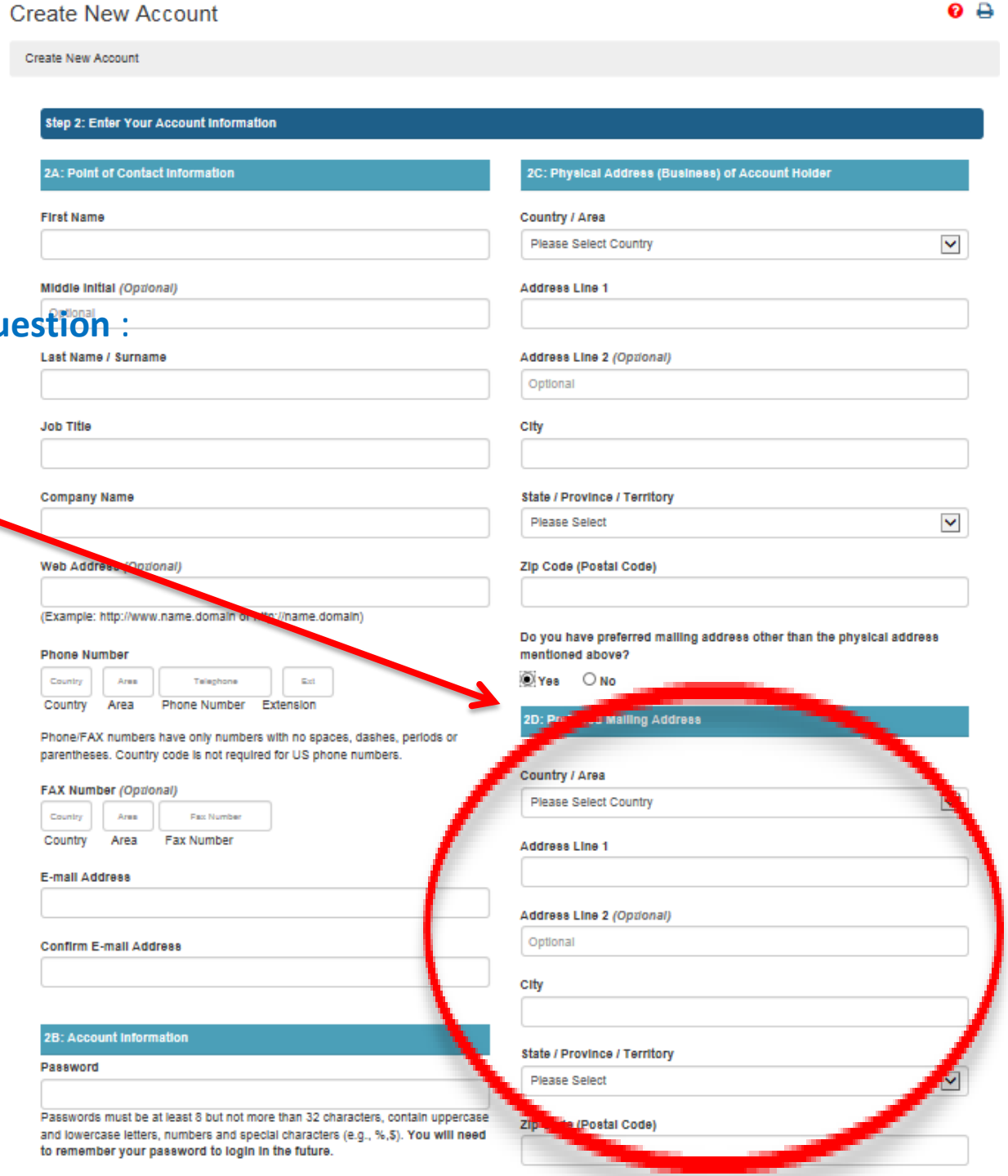


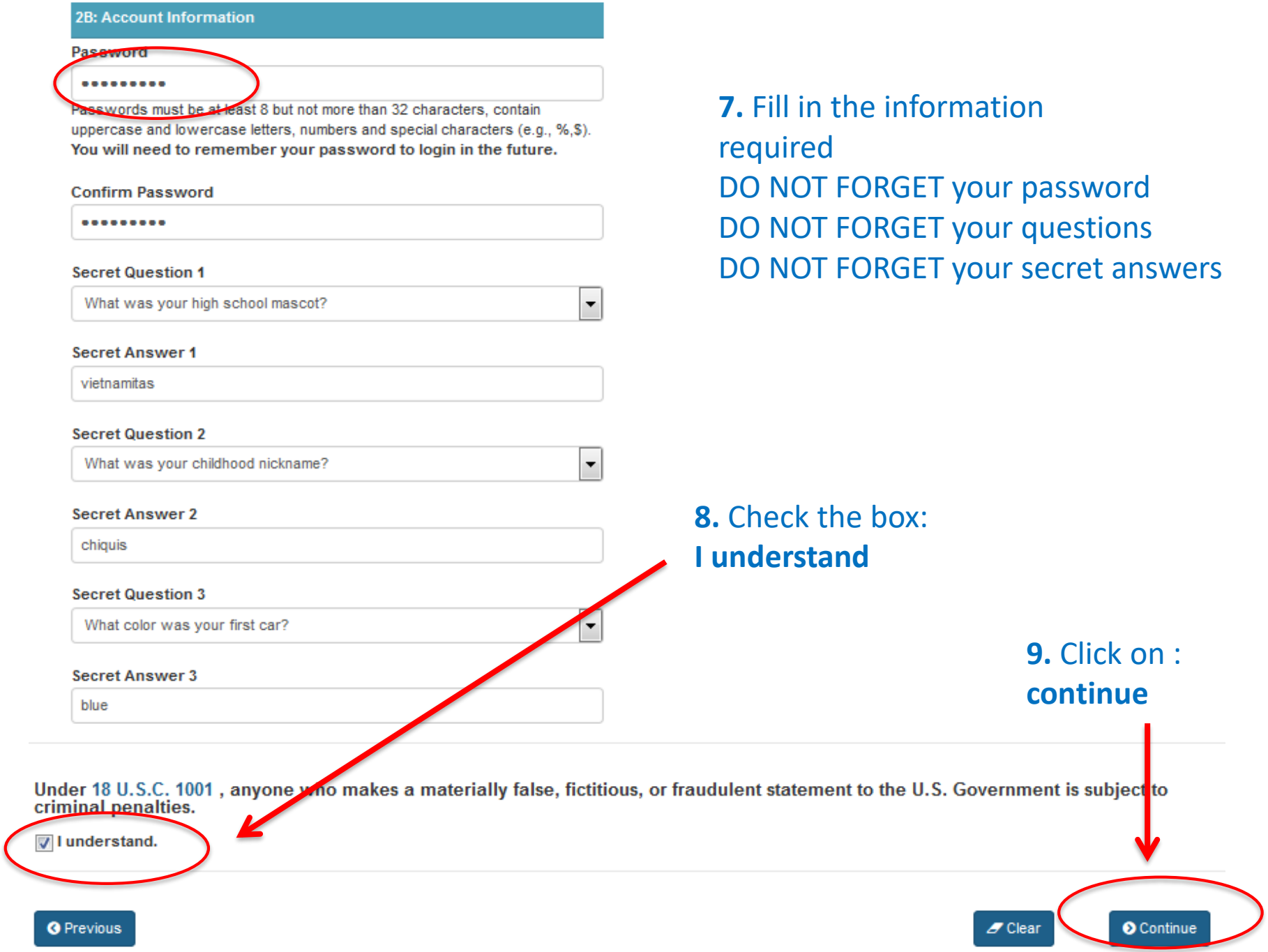
6a. **Answer the question** :
Do you have preferred mailing address
other than the physical address mentioned above?

6. If you answered “YES” to the question :

Do you have preferred mailing Address other than the physical address mentioned above??

- Then enter the requested information

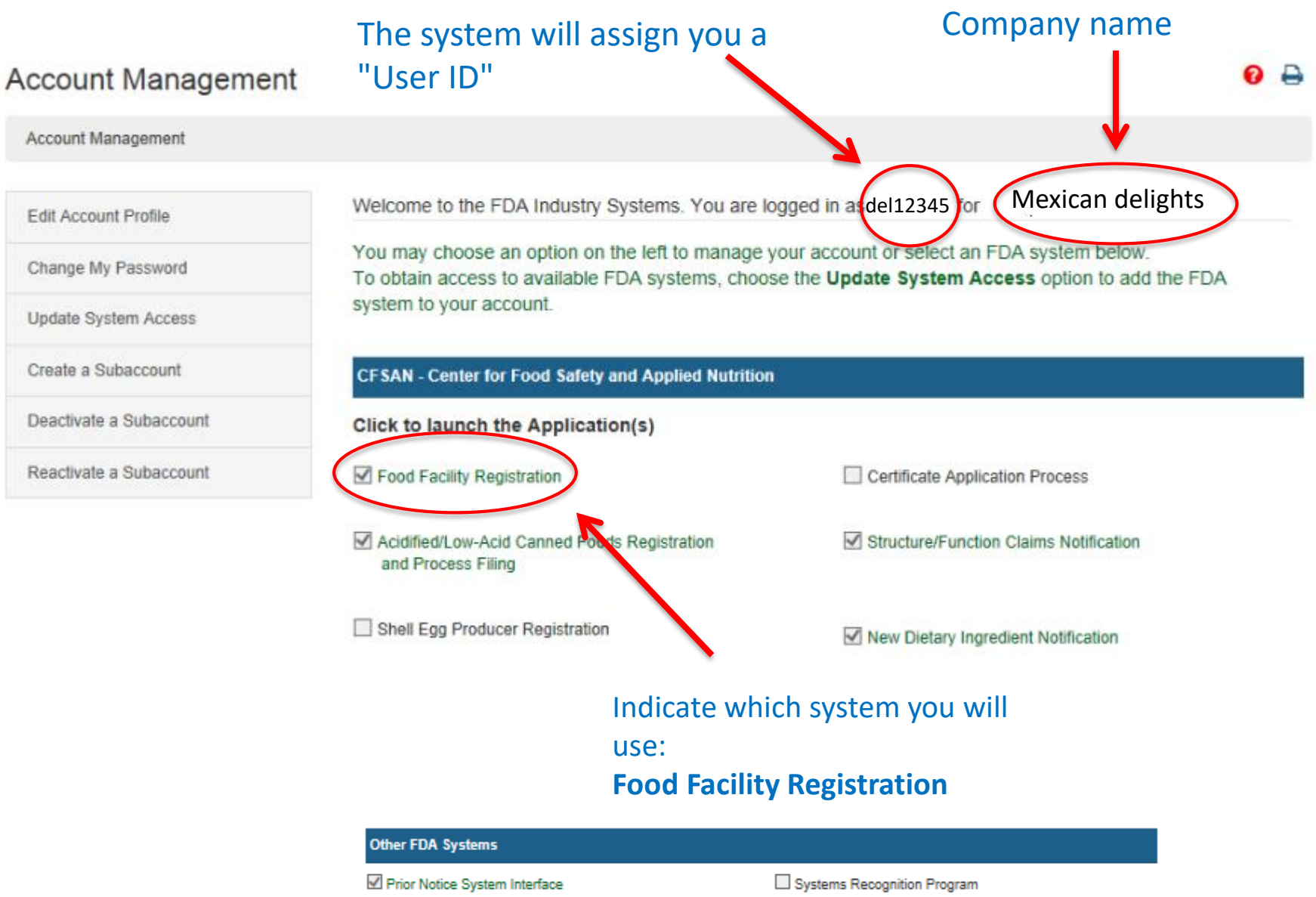




7. Fill in the information required
DO NOT FORGET your password
DO NOT FORGET your questions
DO NOT FORGET your secret answers

8. Check the box:
I understand

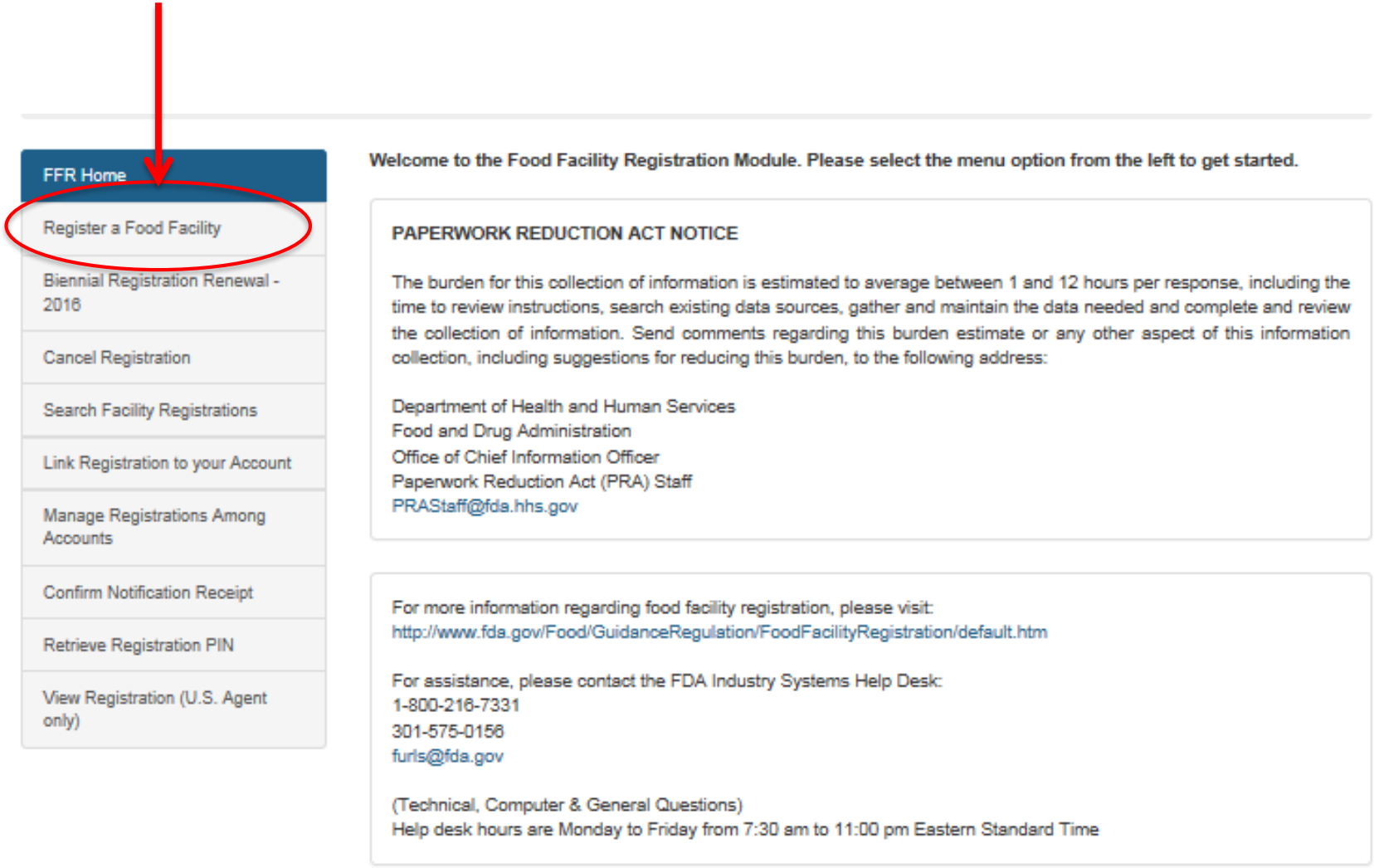
9. Click on :
continue



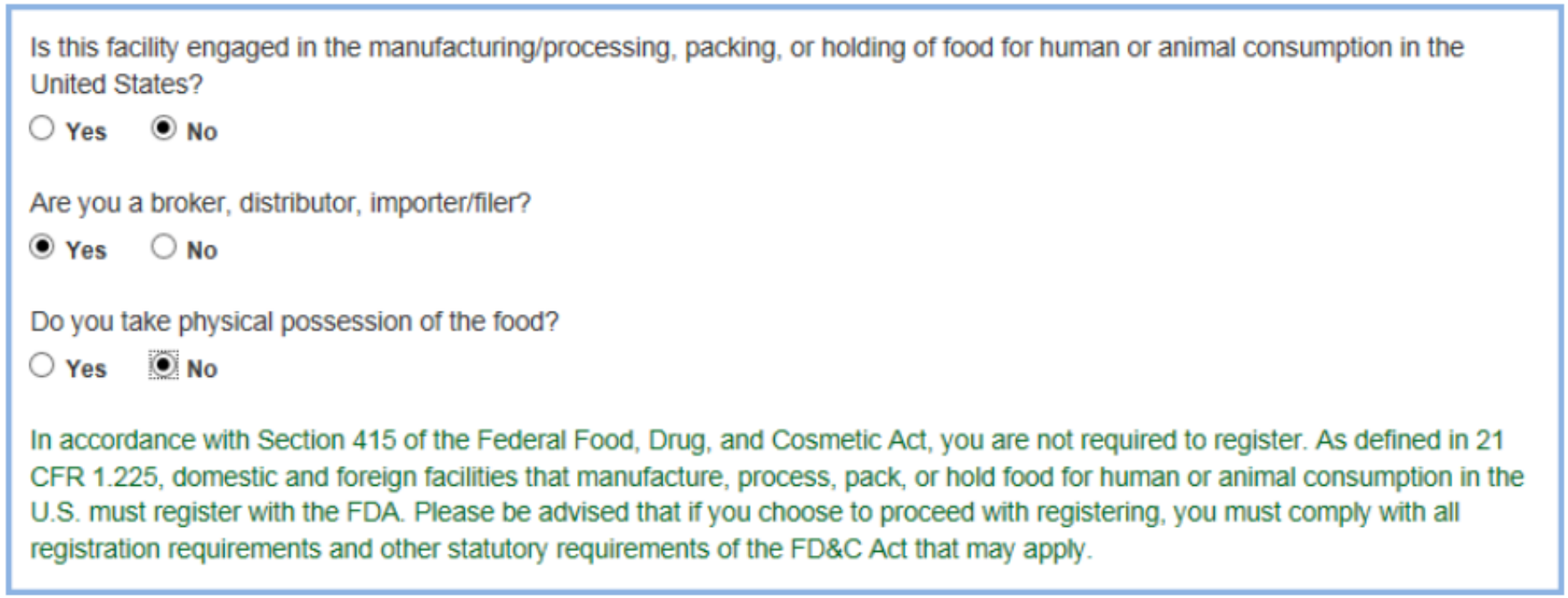
Now you have an account in the system. You may proceed to the registration.

Food Facility Registration

Choose the option: **Register a Food facility**

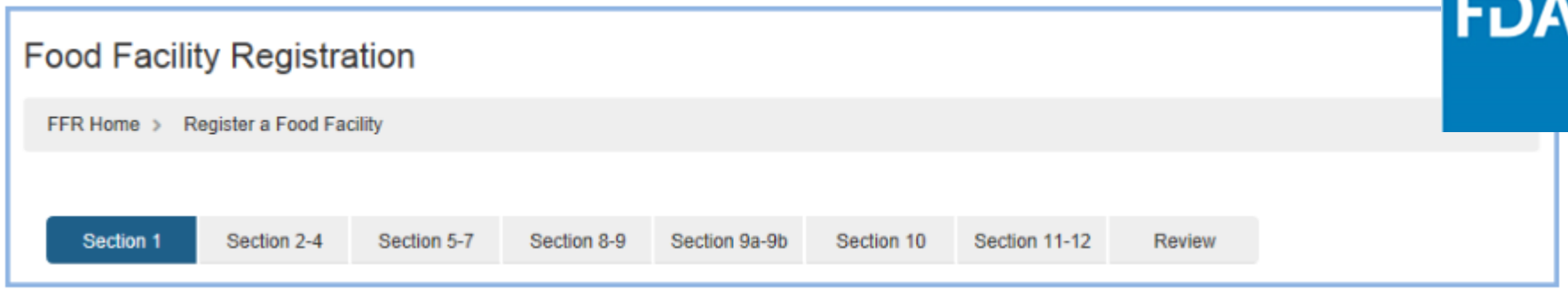


If you are registering for the first time, the following questions will appear before Section 1 appears.



Regardless of the answers you choose, you can continue to register your food facility

Section 1. Type of Registration



Section 1:Type of Registration

Facility Location

Please Select

Choose option: **Foreign Registration**

Are you the new owner of a previously registered facility?

◯ **Yes** ◯ **No**

If "Yes", provide the following information, if known.

Select:

YES, if you are trying to register as owner of a previously registered facility

NO, if the facility you are trying to register has never been registered

Previous Owner's Title *(Optional)*

Please Select

Indicate previous owner title, Mr., Mrs., Ms. , Dr., Other

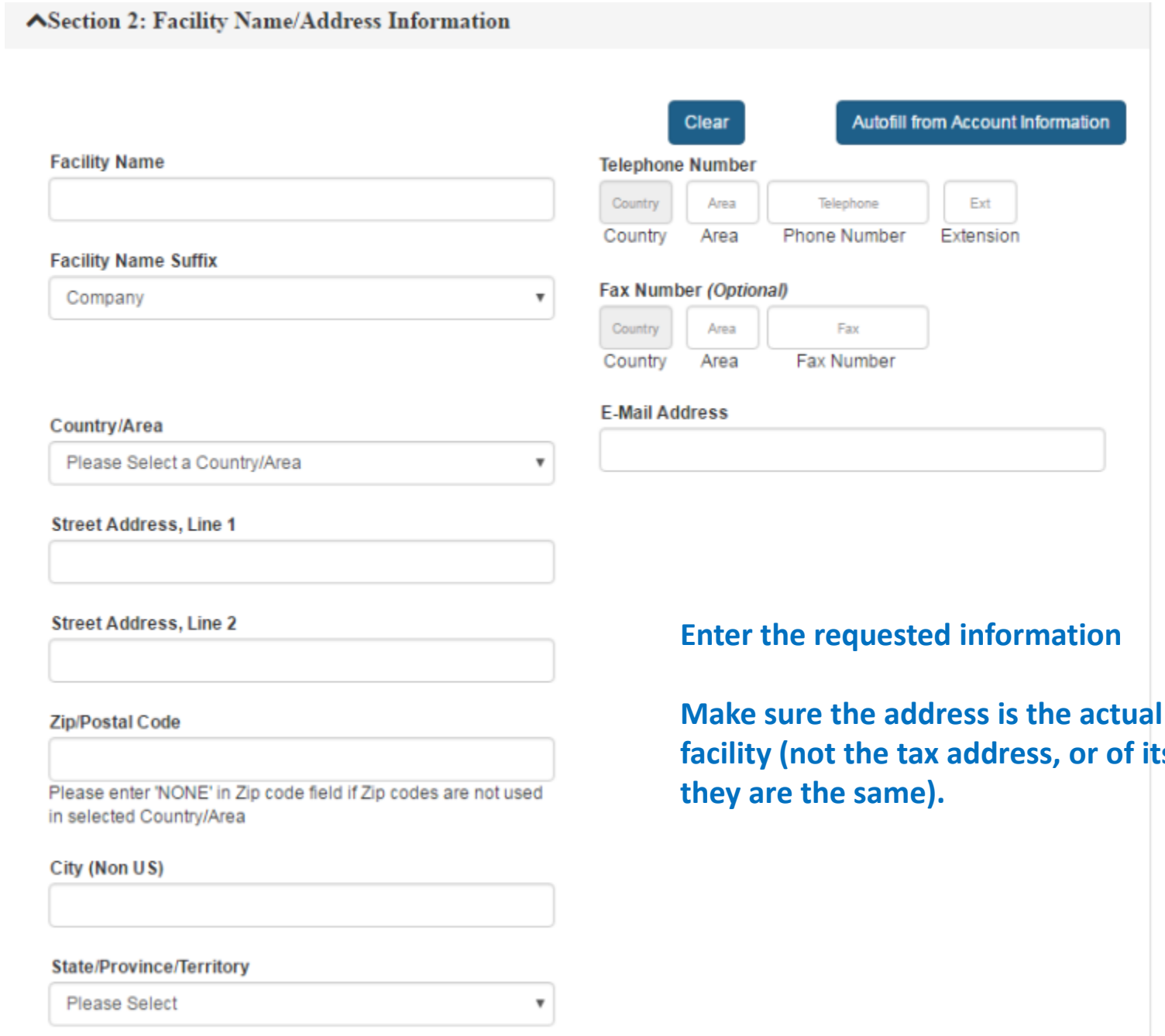
Previous Owner's Name *(Optional)*

Please provide name of previous owner, if known

Previous Owner's Registration Number *(Optional)*

Indicate the previous owner's registration number

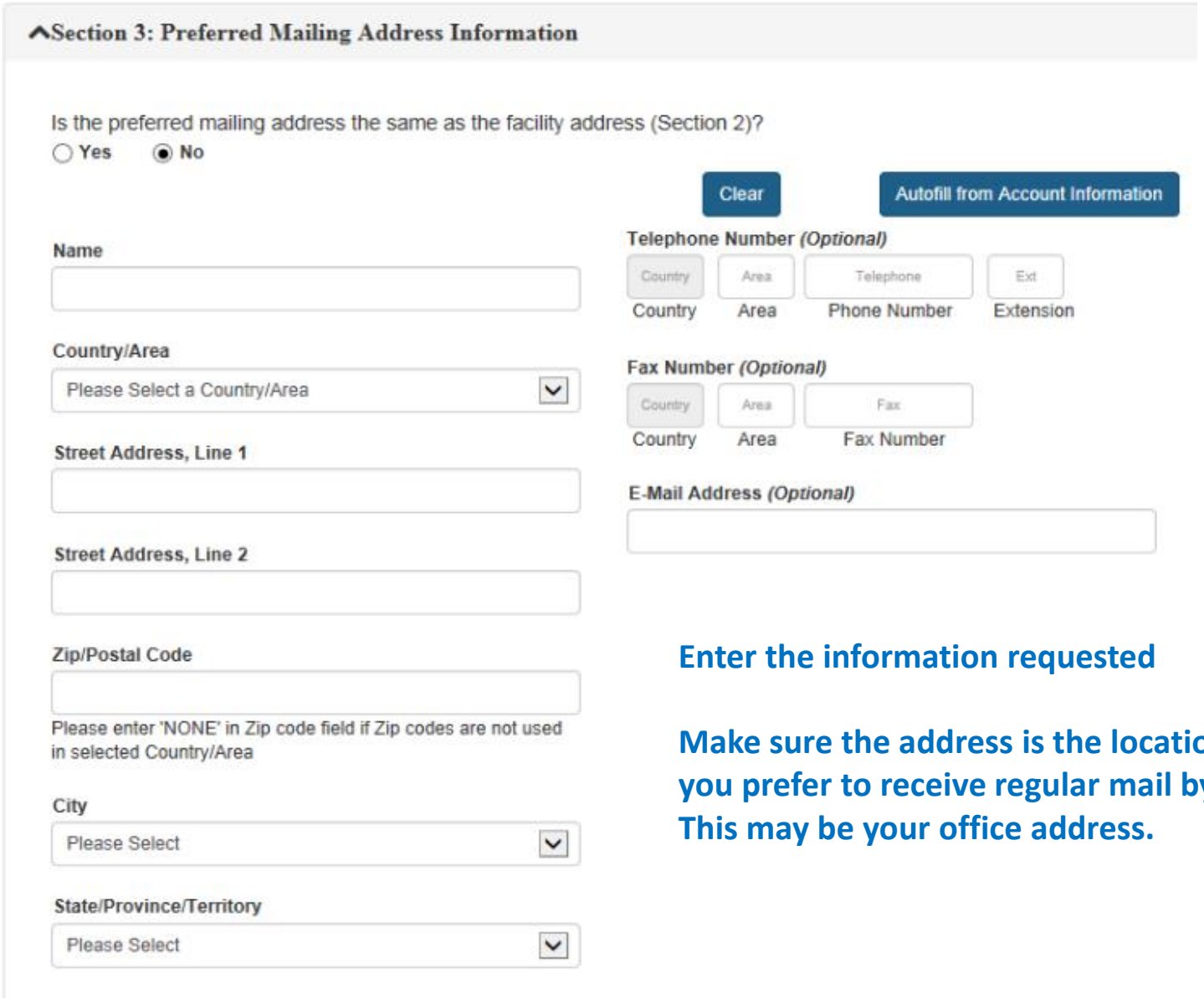
Section 2. Name and Address of Facility



Enter the requested information

Make sure the address is the actual location of the facility (not the tax address, or of its offices, unless they are the same).

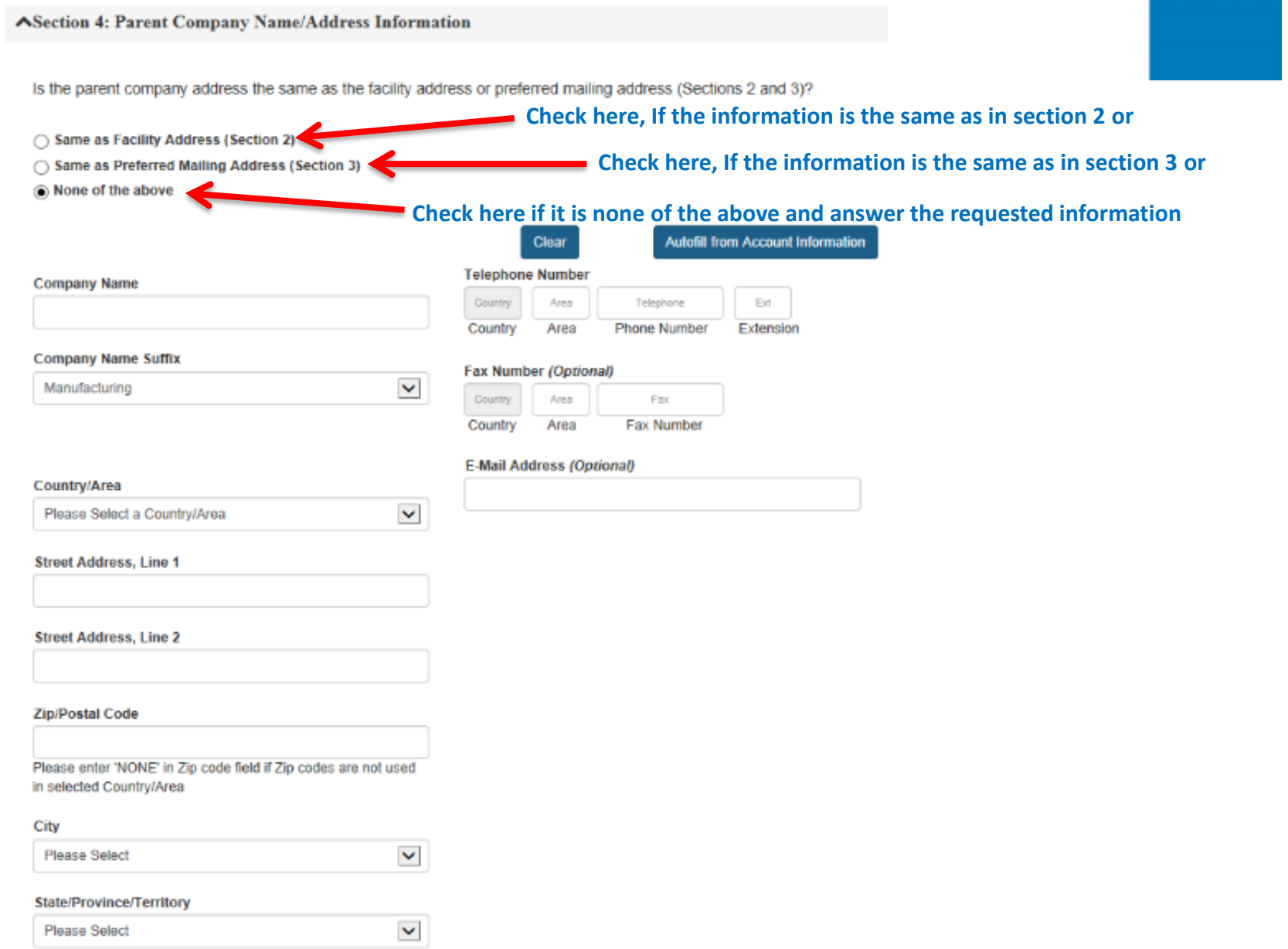
Section 3. Preferred Mailing Address Information– Optional



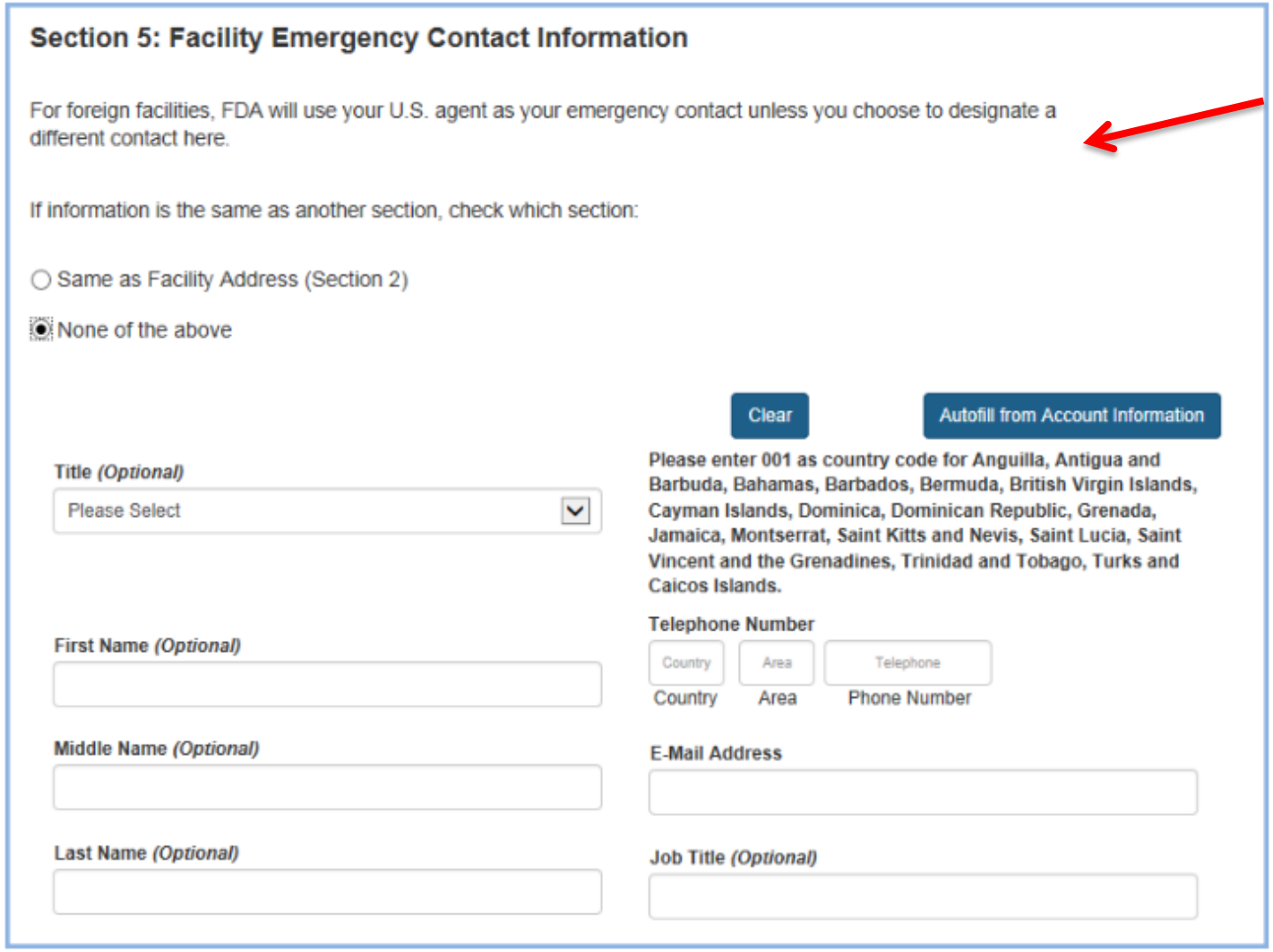
Enter the information requested

Make sure the address is the location where you prefer to receive regular mail by post. This may be your office address.

Section 4. Parent Company Name/Address - Optional



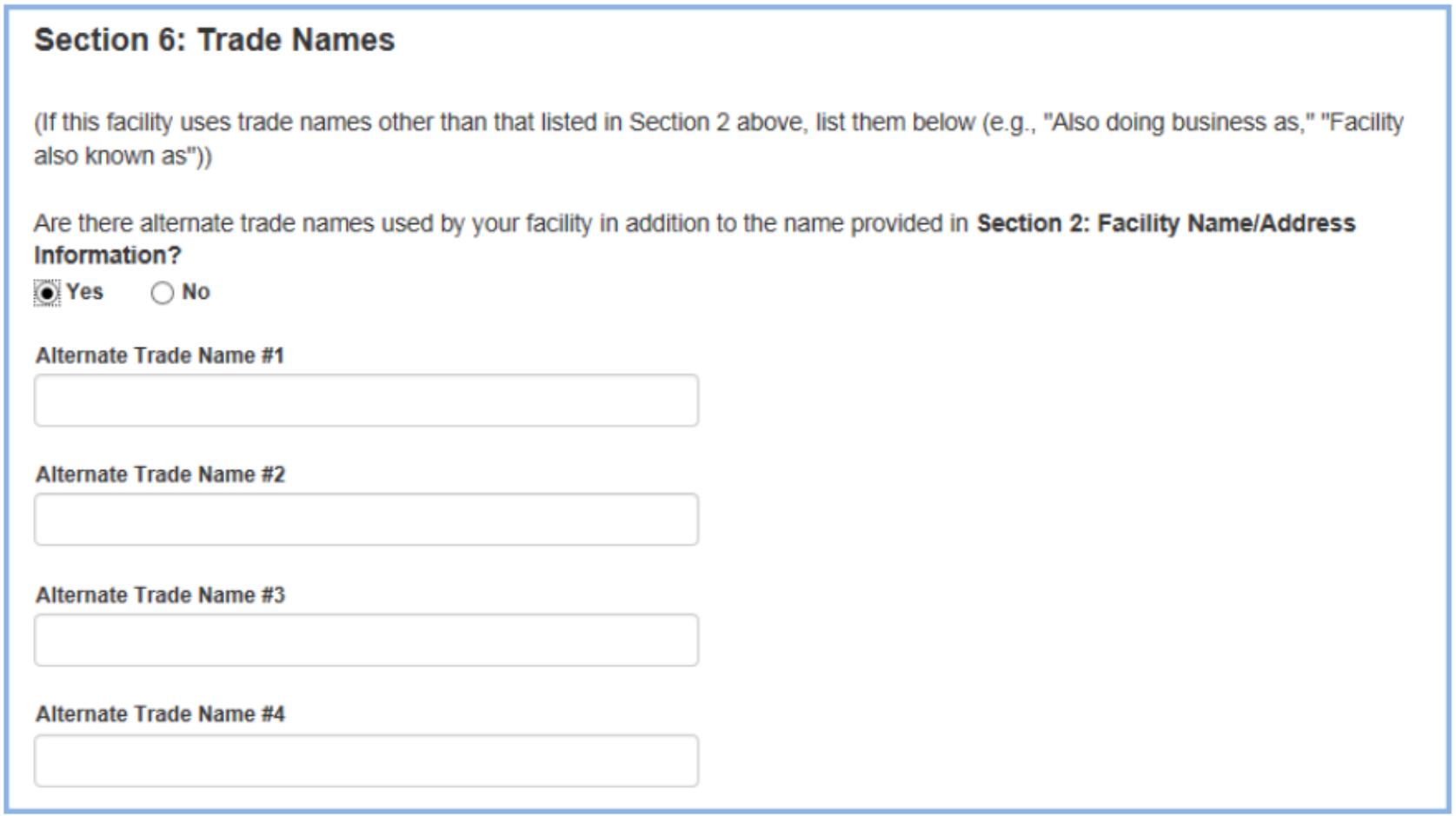
Section 5. Facility Emergency Contact Information



For foreign facilities, FDA will use the US Agent as your emergency contact unless you designate a different contact in this section.

Enter the requested information

Section 6. Trade Names



Section 6: Trade Names

(If this facility uses trade names other than that listed in Section 2 above, list them below (e.g., "Also doing business as," "Facility also known as"))

Are there alternate trade names used by your facility in addition to the name provided in **Section 2: Facility Name/Address Information?**

(•) Yes ( ) No

Alternate Trade Name #1

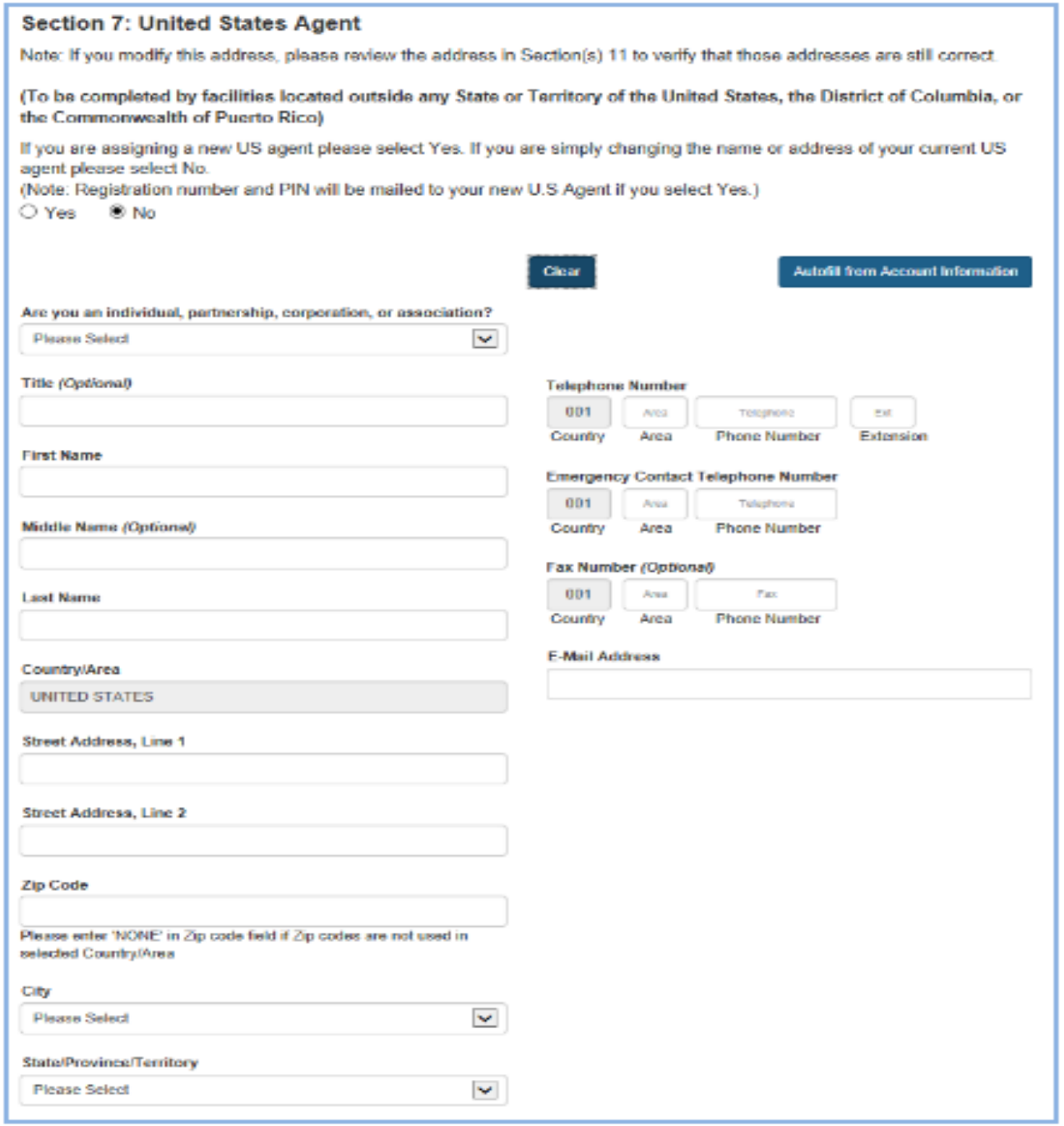
Alternate Trade Name #2

Alternate Trade Name #3

Alternate Trade Name #4

If this facility is known by other names, indicate them here

Enter the requested information about the US Agent



Section 7: United States Agent

Note: If you modify this address, please review the address in Section(s) 11 to verify that those addresses are still correct.

(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)

If you are assigning a new US agent please select Yes. If you are simply changing the name or address of your current US agent please select No.
(Note: Registration number and PIN will be mailed to your new U.S Agent if you select Yes.)

○ Yes ◉ No

Clear | Autofill from Account Information

Are you an individual, partnership, corporation, or association?
Please Select

Title (Optional)

First Name

Middle Name (Optional)

Last Name

Country\Area
UNITED STATES

Street Address, Line 1

Street Address, Line 2

Zip Code

Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country\Area

City
Please Select

State/Province/Territory
Please Select

Telephone Number
001 (Country) | Area | Telephone Number | Extension

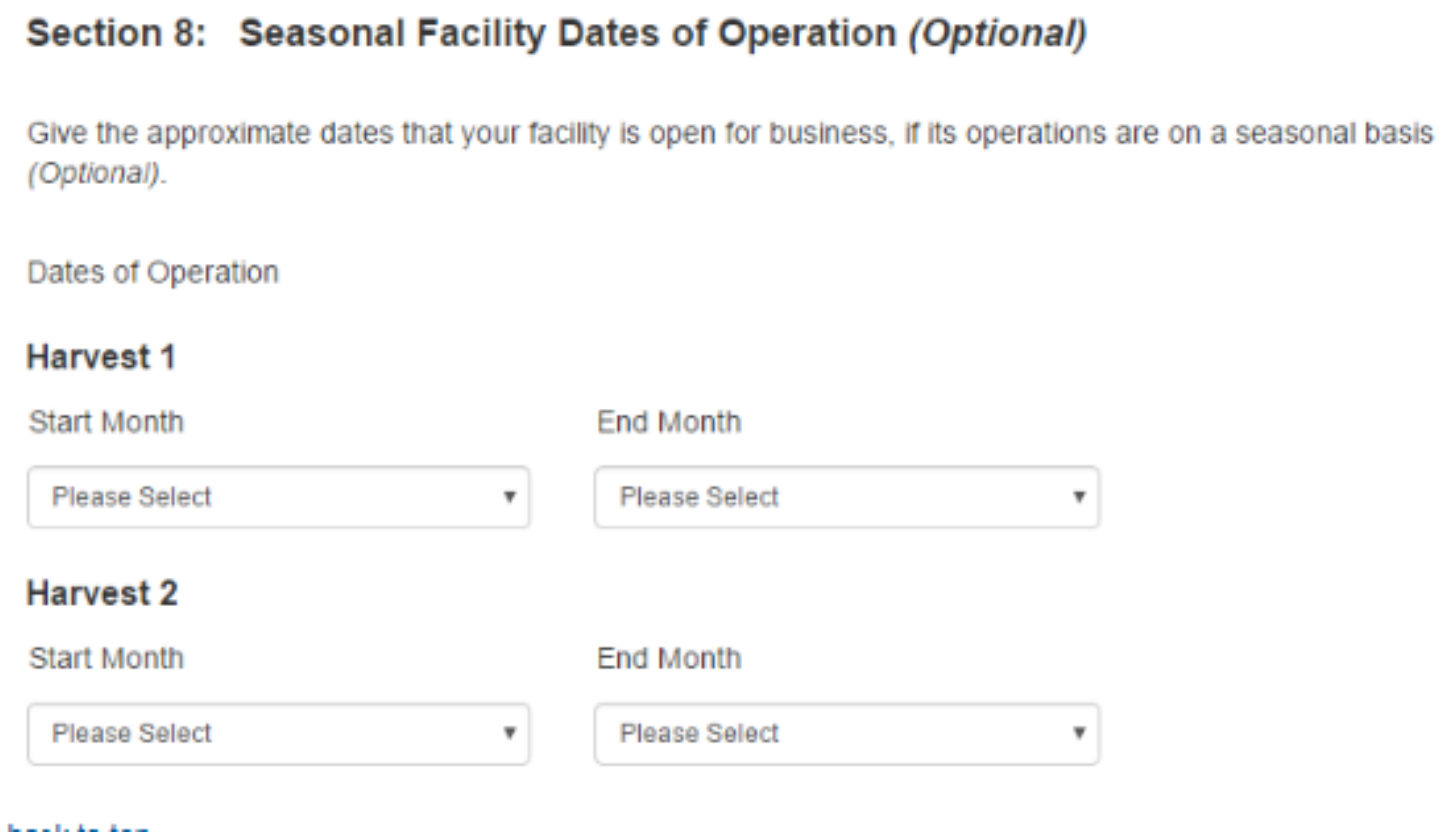
Emergency Contact Telephone Number
001 (Country) | Area | Telephone Number

Fax Number (Optional)
001 (Country) | Area | Fax Number

E-Mail Address

Section 8. Seasonal Facility Dates of Operation

Give the approximate dates that your facility is open for business and if its operations are on a seasonal basis (optional)



Section 8: Seasonal Facility Dates of Operation *(Optional)*

Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis *(Optional)*.

Dates of Operation

Harvest 1

Start Month: Please Select

End Month: Please Select

Harvest 2

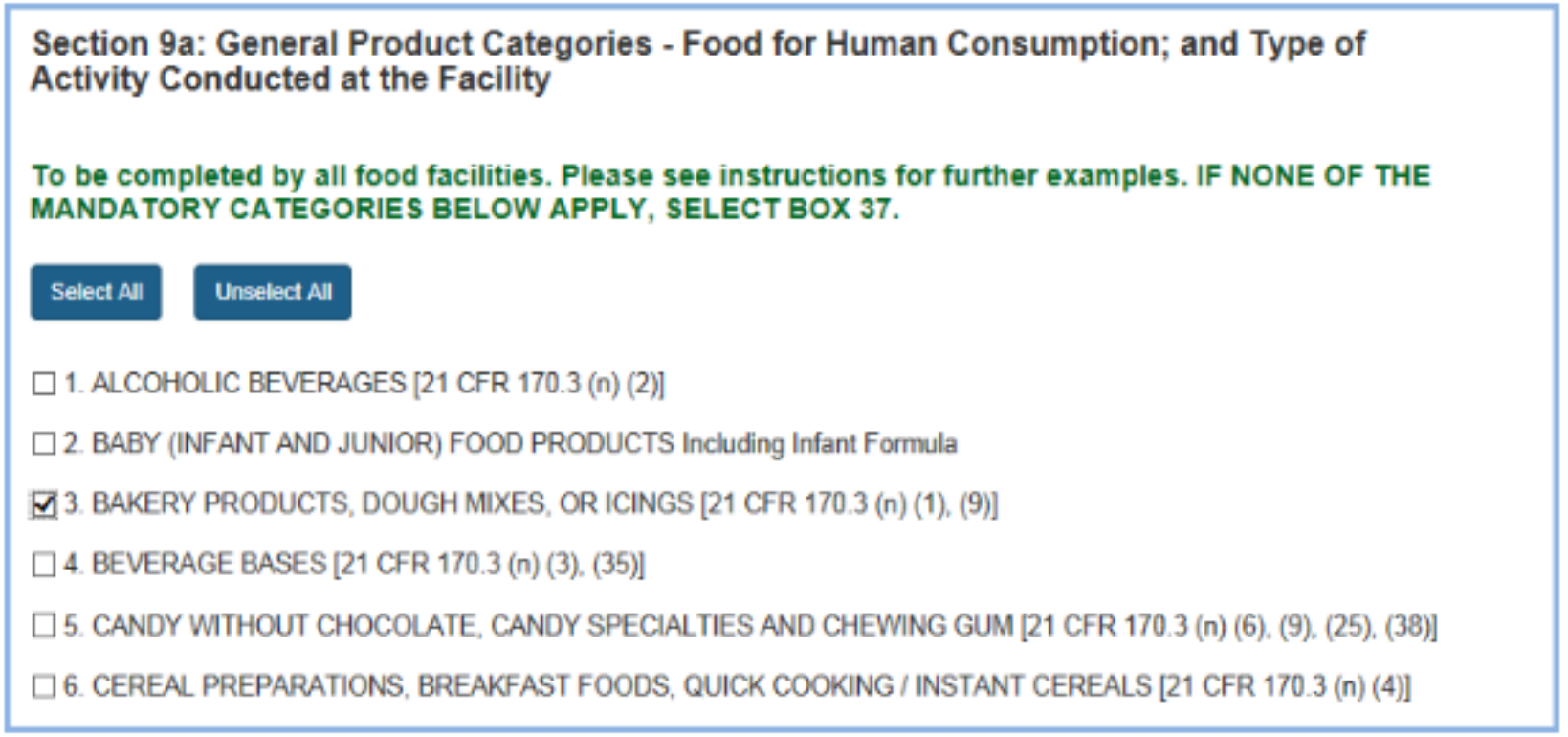
Start Month: Please Select

End Month: Please Select

Section 9. General Product Category– Human/Animals/Both

Based on the activities of your facility, you can choose food for human or animal consumption; or both

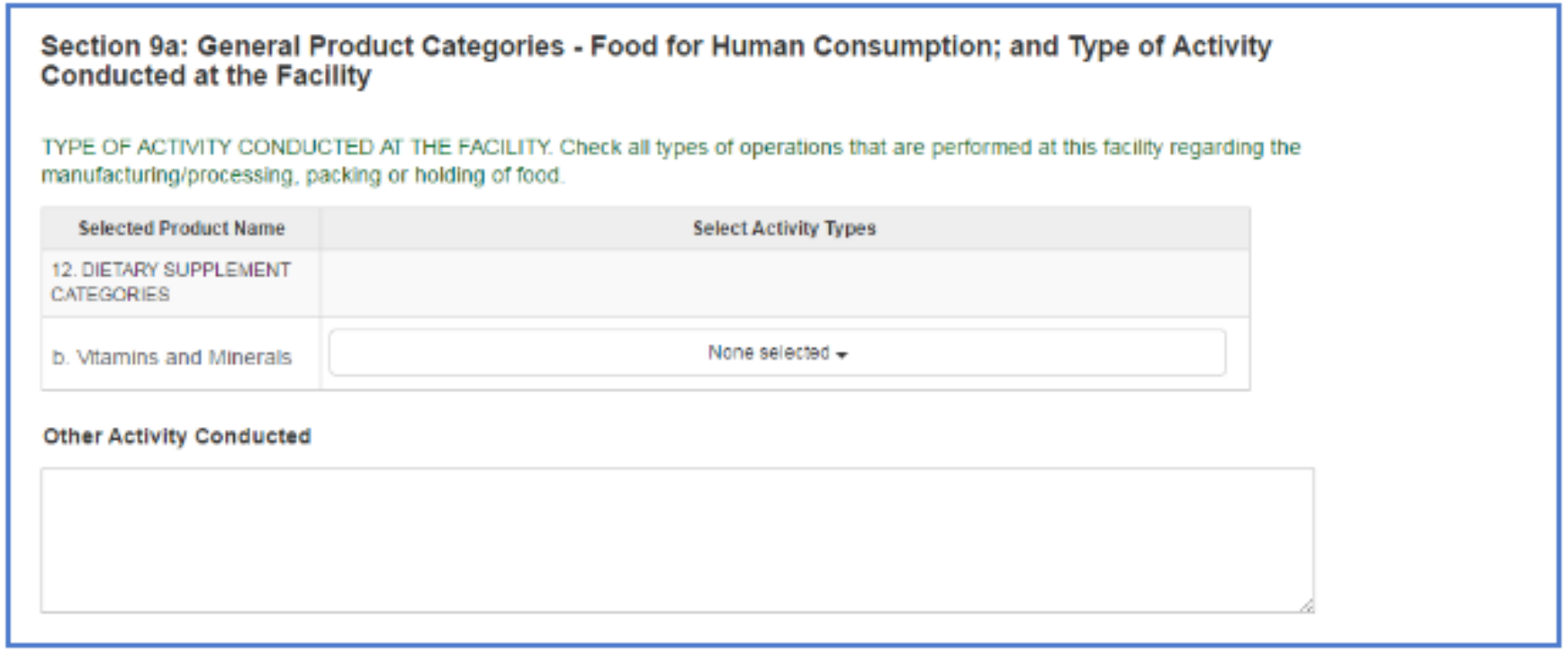
Section 9a – General Product Categories –
Food for human consumption; and Type of Activity Conducted at the facility



Categories or types of Products

If your facility does not manufacture, process, pack, or hold food for human consumption, select box 37: "…NONE OF THE ABOVE FOOD CATEGORIES APPLY". You can enter your own description in the box provided.

Section 9a – General Product Categories –
Food for human consumption; and
Type of Activity Conducted at the facility (continuation)



Section 9a: General Product Categories - Food for Human Consumption; and Type of Activity Conducted at the Facility

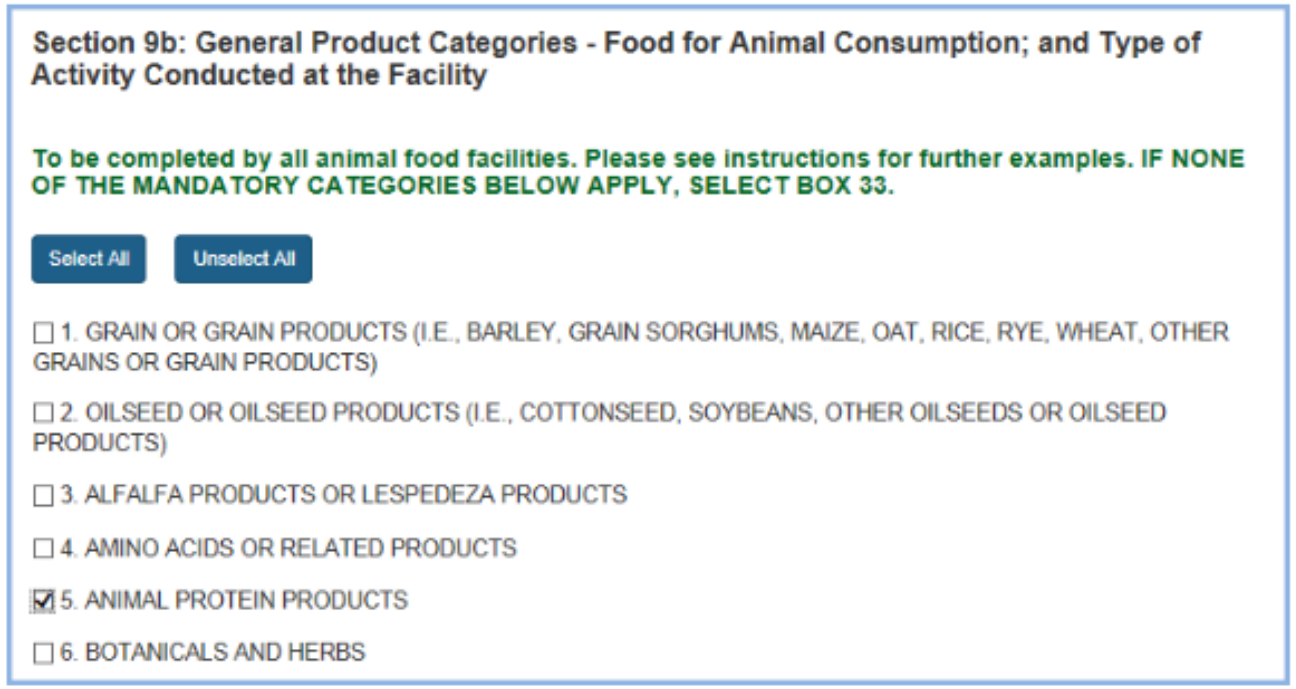
TYPE OF ACTIVITY CONDUCTED AT THE FACILITY. Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.

Selected Product Name	Select Activity Types
12. DIETARY SUPPLEMENT CATEGORIES	
b. Vitamins and Minerals	None selected

Other Activity Conducted

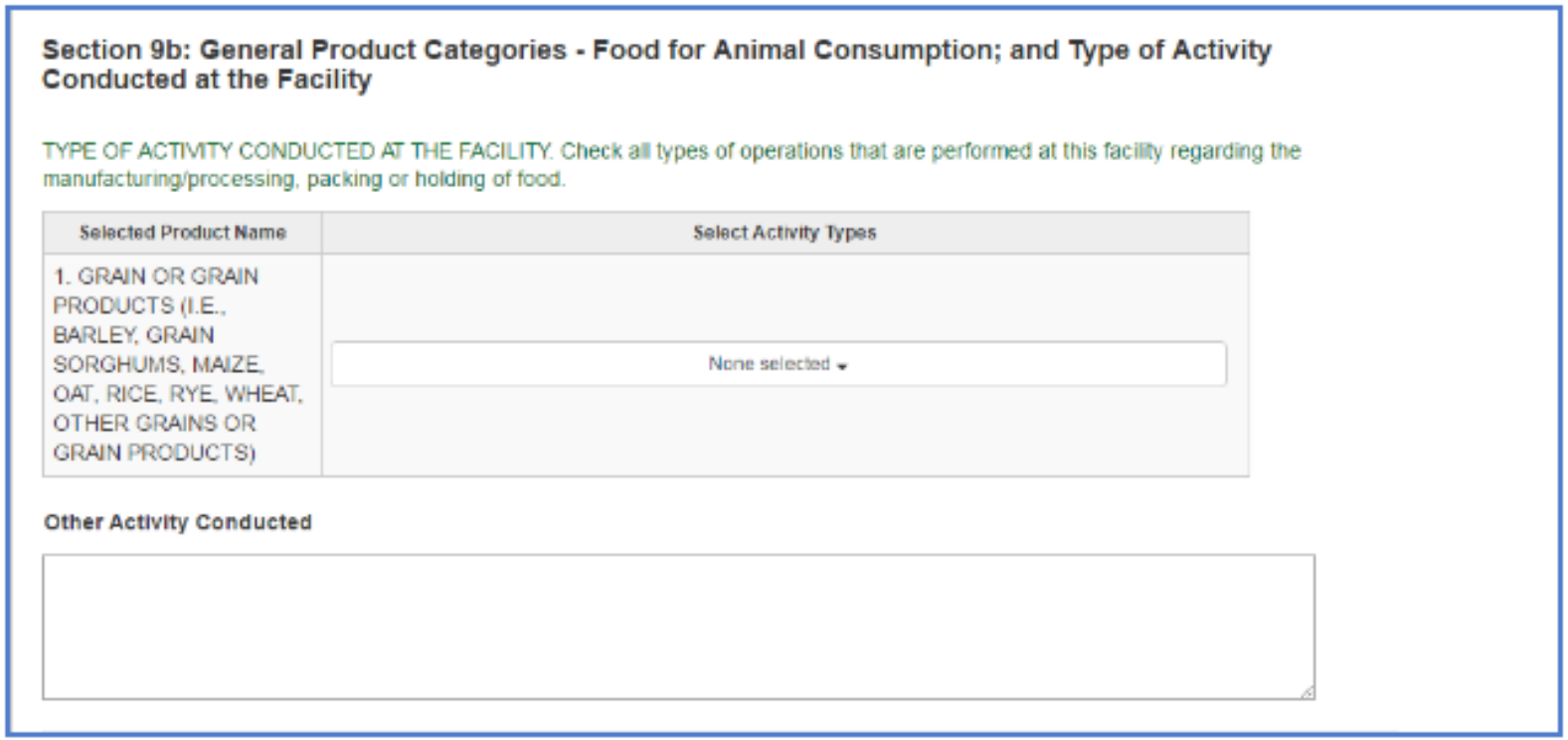
Select the type of **activities conducted at the facility** . You may check all types of operations that are performed at this facility regarding the **manufacturing and processing, packing, or holding of food.** For example, if you select the product category “alcoholic beverages, number 1” and you work as a “manufacturer / processor”, you must select that option on line 2 of column 8.

Section 9b – General Product Categories –
Food for animal consumption; and
Type of Activity conduted at the facility (continued)



Of the 32 **categories,** select as many as apply. If none of the required categories apply, select box 33: "…NONE OF THE ABOVE FOOD CATEGORIES APPLY". You can then enter your own description in the box provided.

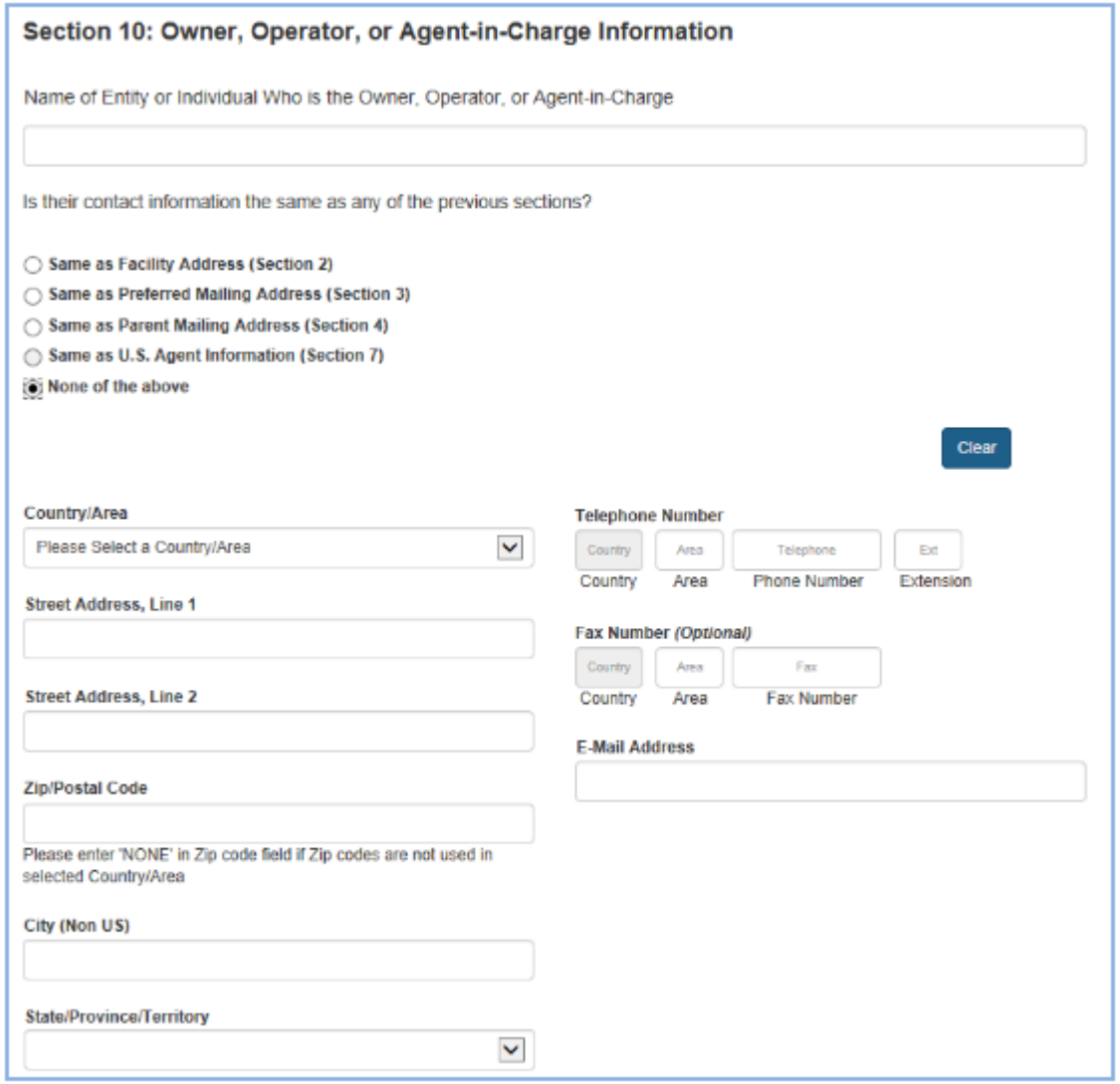
Section 9b – General Product Categories –
Food for animal consumption; and
Type of Activity conducted at the facility (continued)



Activities.

The “Select all” and “Deselect All” options are also available, which allow users to select or deselect all available options at the same time.

Section 10. Owner, Operator, or Agent-in-Charge Information



Section 10: Owner, Operator, or Agent-in-Charge Information

Name of Entity or Individual Who is the Owner, Operator, or Agent-in-Charge

Is their contact information the same as any of the previous sections?

- ○ Same as Facility Address (Section 2)
- ○ Same as Preferred Mailing Address (Section 3)
- ○ Same as Parent Mailing Address (Section 4)
- ○ Same as U.S. Agent Information (Section 7)
- ◉ None of the above

Clear

Country/Area

Please Select a Country/Area

Street Address, Line 1

Street Address, Line 2

Zip/Postal Code

Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area

City (Non US)

State/Province/Territory

Telephone Number

Country | Area | Telephone | Ext

Country | Area | Phone Number | Extension

Fax Number *(Optional)*

Country | Area | Fax

Country | Area | Fax Number

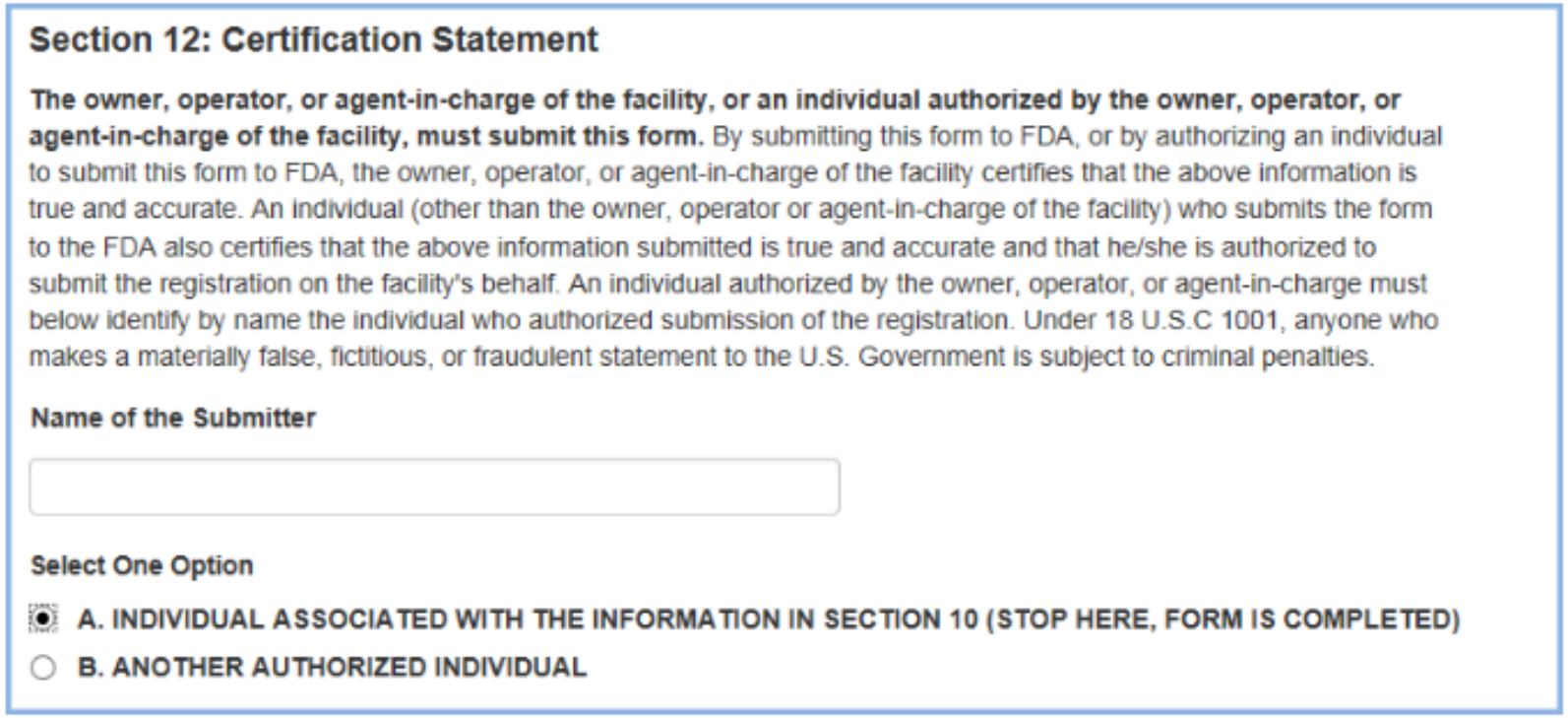
E-Mail Address

If the contact details of the owner, operator or agent-in-charge are the same as in any other section of the form, select the circle corresponding to that section; if not, enter the requested information.

Section 11. Inspection Statement

The FDA may inspect the facility as permitted by the Federal Food, Drug, and Cosmetic Act.

Section 12. Certification Statement



Section 12: 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.

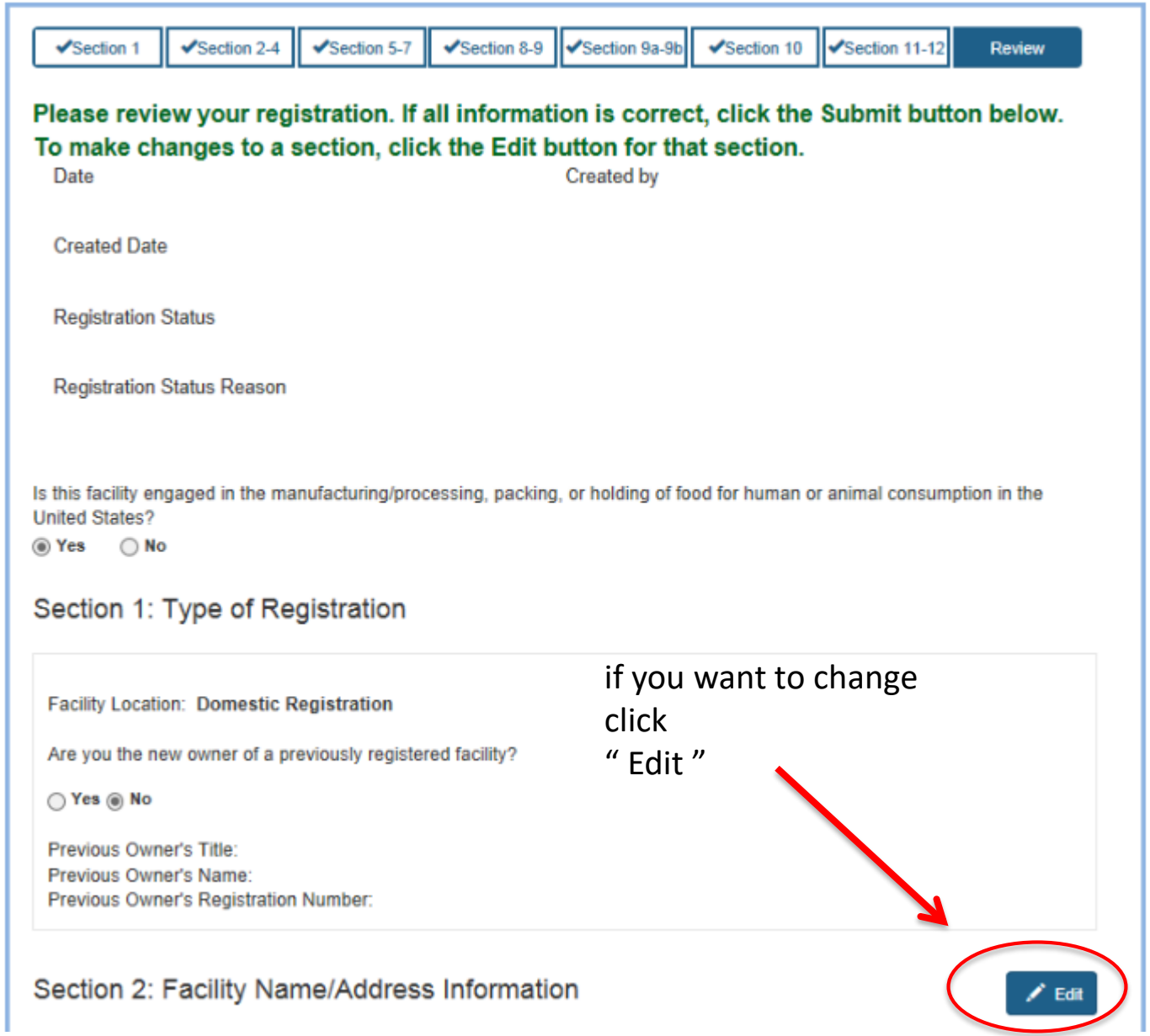
Name of the Submitter

Select One Option

- (●) A. INDIVIDUAL ASSOCIATED WITH THE INFORMATION IN SECTION 10 (STOP HERE, FORM IS COMPLETED)
- ( ) B. ANOTHER AUTHORIZED INDIVIDUAL

Enter your name as the submitter of this registration.
Indicate the person who authorized the registration application.

Registration Information Review



NOTE: The address of the facility indicated in Section 1: Type of Registration (where you indicated whether this was a domestic or foreign facility) cannot be changed at this point. If you wish to change the facility's location, you must cancel this registration and start a new one.

Click on the “Submit ” button and you will see the following message

US Agent Verification

This must be done by the US Agent

- Once all 12 registration sections are filled out and submitted, the system will send an email to the US Agent.

- The US Agent must follow the instructions included in the email and respond whether or not to they agree to become the agent of the facility in question. This must be done within 30 calendar days after receiving the mail.

NOTE: The agents are advised to check their "spam" or "junk" folders if they have not received the notification in their inbox, since the email may have gone to one of these folders.

US Agent Verification

From: <CFSANFoodFacilityRegistration@fda.hhs.gov>
Date: Nov 14, 2016 11:24 PM
Subject: Initial Agent Assignment Notification
To:
Cc: **US Agent Email .**

The US agent will receive an email like this

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
5001 Campus Drive, HFS-681
College Park, MD 20740

Date: November 15, 2016

Dear Sir/Madam,

The U.S. Food and Drug Administration (FDA) is hereby notifying you that FDA received a food facility registration listing you as the U.S. Agent for the foreign food facility identified below. The registration was submitted to FDA as required by section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 350d] and FDA's food facility registration regulation at Title 21, Code of Federal Regulations (CFR) Part 1, Subpart H. Under section 415 of the FD&C Act and 21 CFR Part 1, Subpart H, a foreign food facility engaged in manufacturing/processing, packing, or holding of food for consumption in the United States must be registered with FDA and such registration must include, among other things, the name and contact information of the U.S. Agent for the facility.

Food Facility Name:	**Facility name**
Food Facility Address:	**Installation address**
Receipt Code:	**AbC#d #**

Name of U.S. Agent:	**This is where the contact information will be**
Title of U.S. Agent:	
Street Address Line 1:	**US Agent**
Street Address Line 2:	**Name**
City:	**Address**
ZIP Code:	**Country**
Country/Area:	

US Agent Verification

Click on the link and enter the code sent to you by the system

In accordance with 21 CFR 1.231(a)(5) and (b)(7), FDA will not confirm a registration or provide a registration number until the person identified as the U.S. agent for a foreign facility confirms that person has agreed to serve as the U.S. Agent. We are requesting your action within 30 calendar days of receipt of this notification. If you take no action within 30 calendar days, the registration information will be removed from our database and the facility will be required to submit another registration submission.

To confirm or decline this listing, please click on the following link and provide the above listed receipt code when prompted: https://www.access.fda.gov/.

If you confirm this listing, you will assume the responsibilities of the U.S Agent and the registrant will receive their registration number. Please note that you will need to save the above listed receipt code to maintain access to this registration in the future.

If you decline this listing, the registrant will be notified that you have not agreed to serve as the U.S. Agent for the facility. We will then request that the facility amend its registration to designate another U.S. Agent who has affirmatively agreed to serve.

If you confirm this listing as the U.S. Agent for the foreign food facility listed above, but your contact information is incorrect, 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 update this information within 60 calendar days of any change to the previously submitted contact information using Form FDA 3537. The authorized individual may be, but is not required to be, the U.S. Agent for the facility. When using Form FDA 3537, the owner, operator, or agent in charge, or the individual authorized by one of them, must check the items being updated in Section 1 of the form. If the facility has an existing electronic account (established when the facility is registered electronically) that is linked to this registration, the registration may be updated electronically via https://www.access.fda.gov/.

Alternatively, the owner, operator, or agent in charge of the facility, or an individual authorized by one of them, may submit an update by mail or fax to:

U.S. Food and Drug Administration
5001 Campus Drive, HFS-681
College Park, MD USA 20740
Fax: 301-436-2804

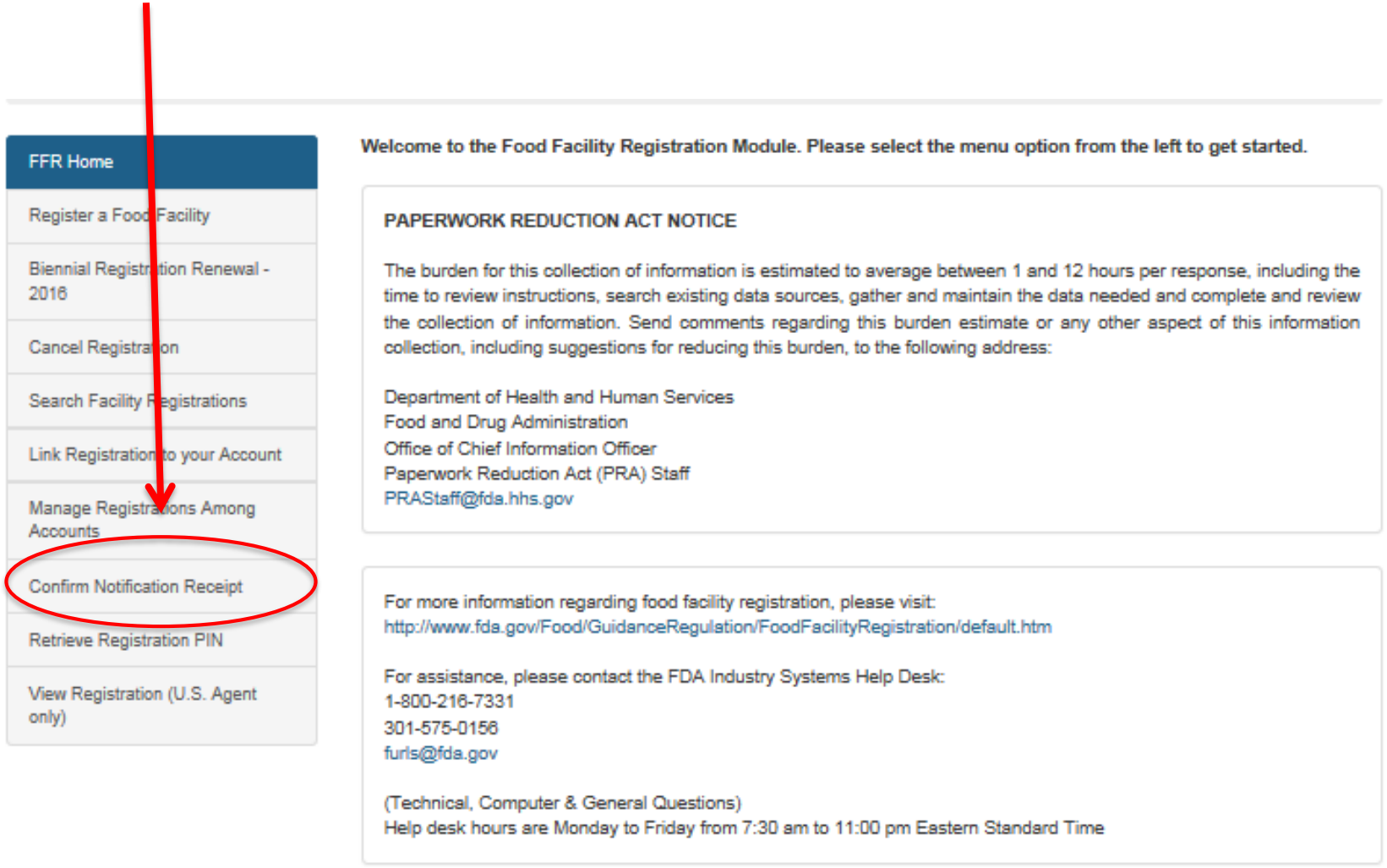
Section 743 of the FD&C Act [21 U.S.C. 379j-31] authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the reinspection fees [21 U.S.C. 379j-

The US Agent must:
1. Click on "Create an Account"
2. Choose "Food Facility Registration"
3. Enter the information needed to create an account.
4. Once the account is created in the system, your US Agent will have a user ID (provided by the system) and a password (created by the US agent).
5. You must log into the system with your user ID and password
6. You will see a menu on the left side. Select the option "Confirm Notification Receipt"
7. Enter the "Receipt Code" that should have arrived in a separate email

Once your US Agent has competed all of the above steps, the person who entered the registration information will receive an email with the Facility Registration number and Personal Identification Number (PIN) .

Agent Confirmation

Choose the option: **Confirm Notification Receipt**



The next time you need to:

- Modify your account information
- Carry out the Biannual Renewal of the Registration (always on even-numbered years and between October and December)
- Modify your registration information
- Register another facility
- Cancel a registration
- Link an account to an existing record

You will have to log in with your user ID (which was assigned to you by the FDA) and password (which you created) as explained in the following link:

https://www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1

FDA Industry Systems

System Status

08/31/2016 See The 2016 Food Facility Registration Biennial Renewal period begins at 12:00 AM on October 1st 2016.

08/04/2016 See CDERECATS is not accepting applications or issuing export certificates for the Foreign Exported CPP.

1. Enter your **User ID**

2. Enter your **Password**

3. Check: **I understand**

Login

Existing account holders, enter your account ID & password.

Account ID

del12345

Password

elp@sword1

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.

☑ I understand.

Login

Forgot your password

New User

Create New Account

See Instructions | See Tutorials | Help Desk

Getting Started

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page.

If you already have an account, enter your **account ID** and **password**.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

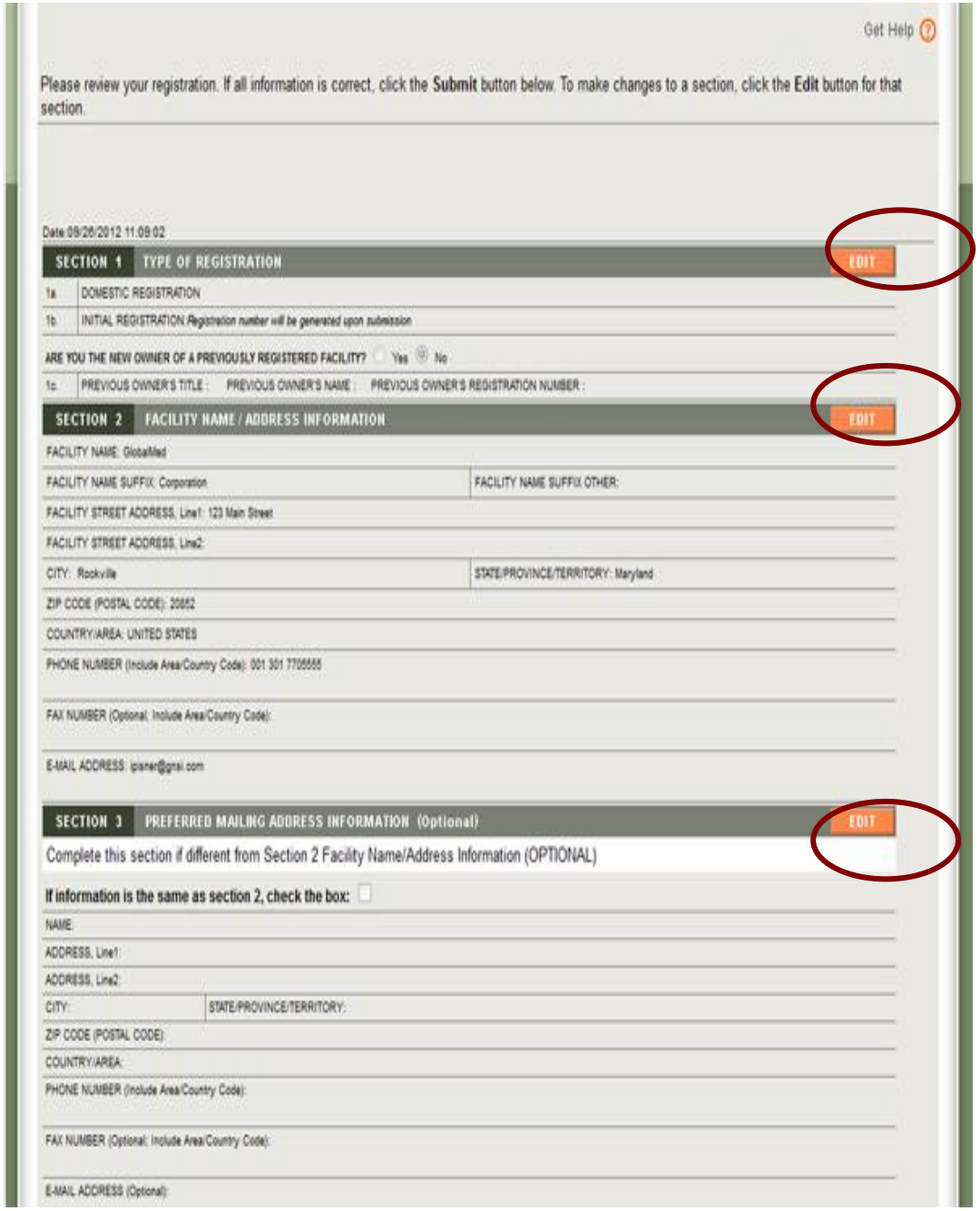
Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

If you have Tobacco Registration and Product List (TRLM) specific questions, please contact **AskCTP at 1-877-287-1373 or AskCTP@fda.hhs.gov** and the AskCTP staff can assist with answering your questions about TRLM.

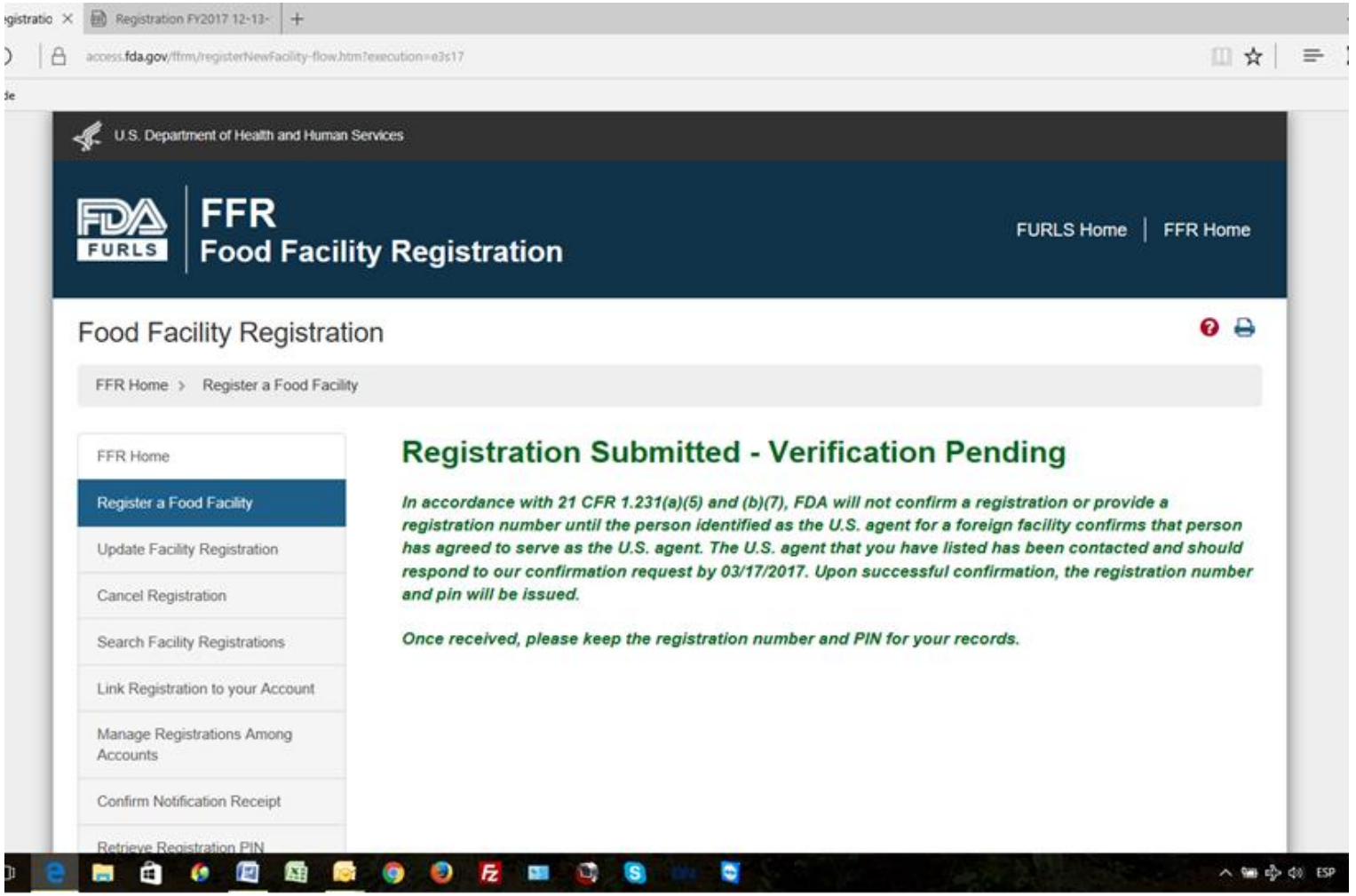
FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Help Desk at 1-800-216-7331** to confirm that the caller is acting on behalf of FDA.

Registration Renewal


FFRM Food Facility Registration Module
FDA
» FURLS Home
FFRM MAIN MENU
Biennial Registration Renewal
Register a Food Facility
Update Facility Registration
Cancel Registration
Search Facility Registrations
Link Registration to your Account
Manage Registrations Among Accounts
Confirm Notification Receipt
Form Approval: OMB No.0910-0502
Expiration date: 08/31/2013
See OMB Statement at end of form
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.
Please Note:
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.



You can update the information whenever the “edit” option is enabled



Done!

To complete the process, your US agent must confirm your role.

Remember that you need to renew your registration every two years.

How to Get Help

Contact FDA Industry Systems Helpdesk

1-800-216-7331
301-575-0156
furls@fda.gov
(For geeral and technical questions on the registration process)
Hours: Monday to Friday from 7:30 am to 11:00 pm- Atlantic time

How to access the system:

www.fda.gov/furls
http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm

How to retrieve your PIN, if necessary: "How to Retrieve Registration PIN":

http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm408769.htm

Step-by-step instructions, in English and Spanish:

http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073706.htm

THANK YOU

U.S. FOOD & DRUG ADMINISTRATION