FURLS Device Registration & Listing

Initial Registration

U.S. Food and Drug Administration
Center for Devices and Radiological Health

Division of Industry and Consumer Education (DICE)

Instructions for

Foreign, First Registration in Account

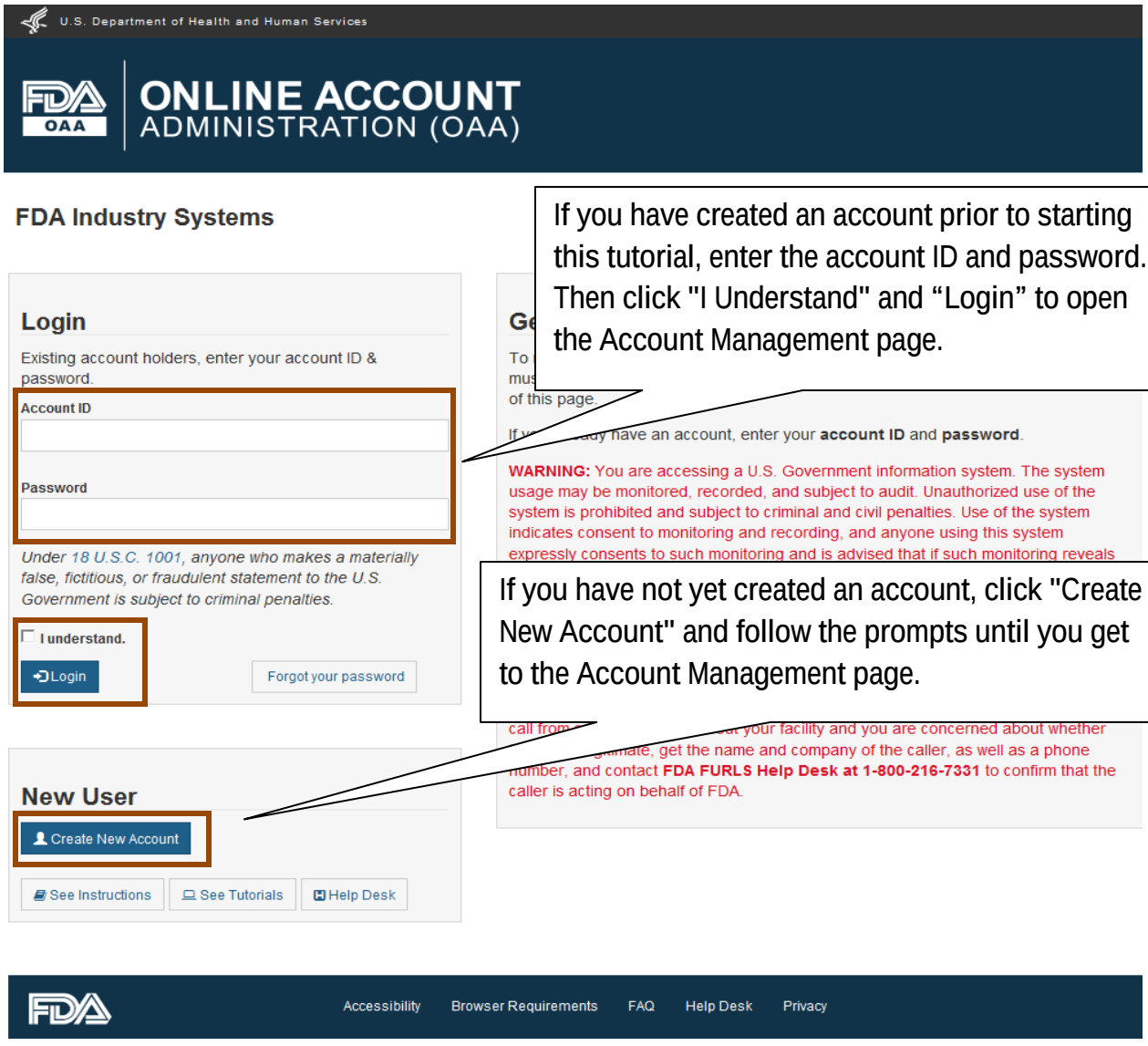
This tutorial should only be used when 1) registering a facility that is located outside of the U.S.; 2) you have already paid the annual registration user fee and received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN); and, 3) the owner/operator has no other registered facilities.

Step 1: Click https://www.access.fda.gov/oaa/ to open the FDA Industry Systems Website.

If you have created an account prior to starting this tutorial, enter the account ID and password, click “I Understand” and then click on the Login button.

If you have not yet created an account, click on “Create New Account” and follow the prompts until you get to the Account Management page.

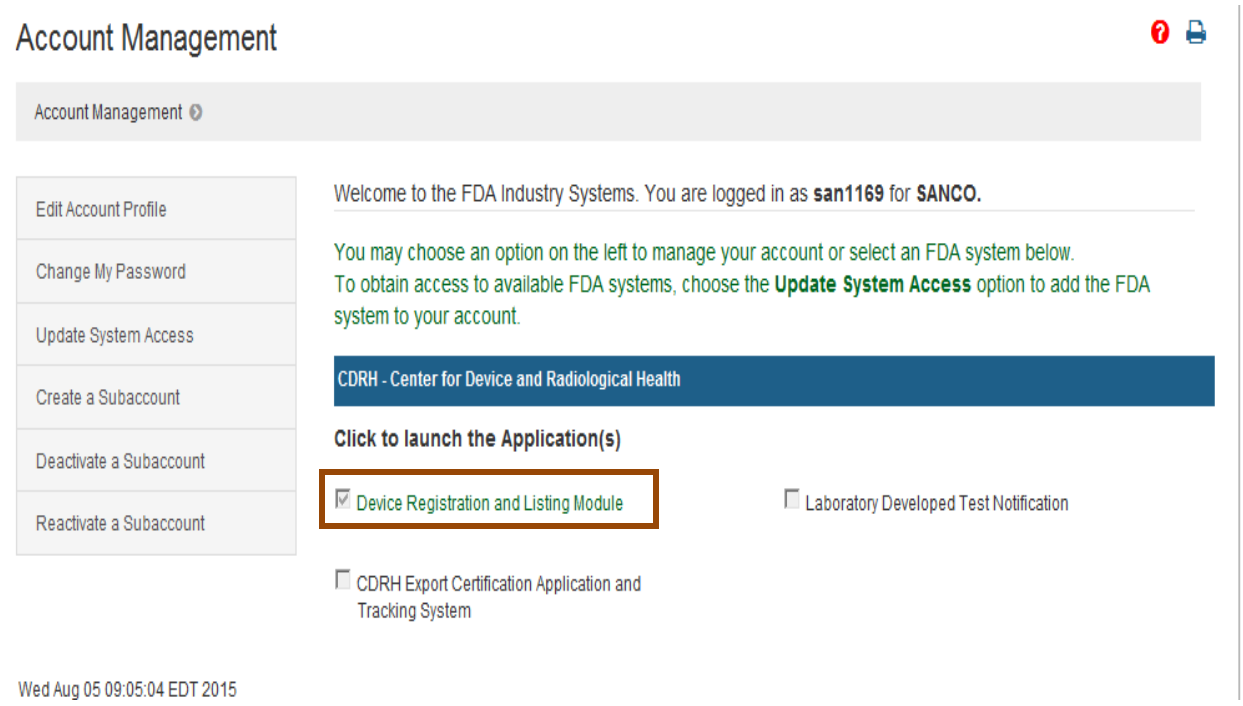
Proceed to Step 2.



Step 2: Click "Device Registration & Listing" to begin the registration.

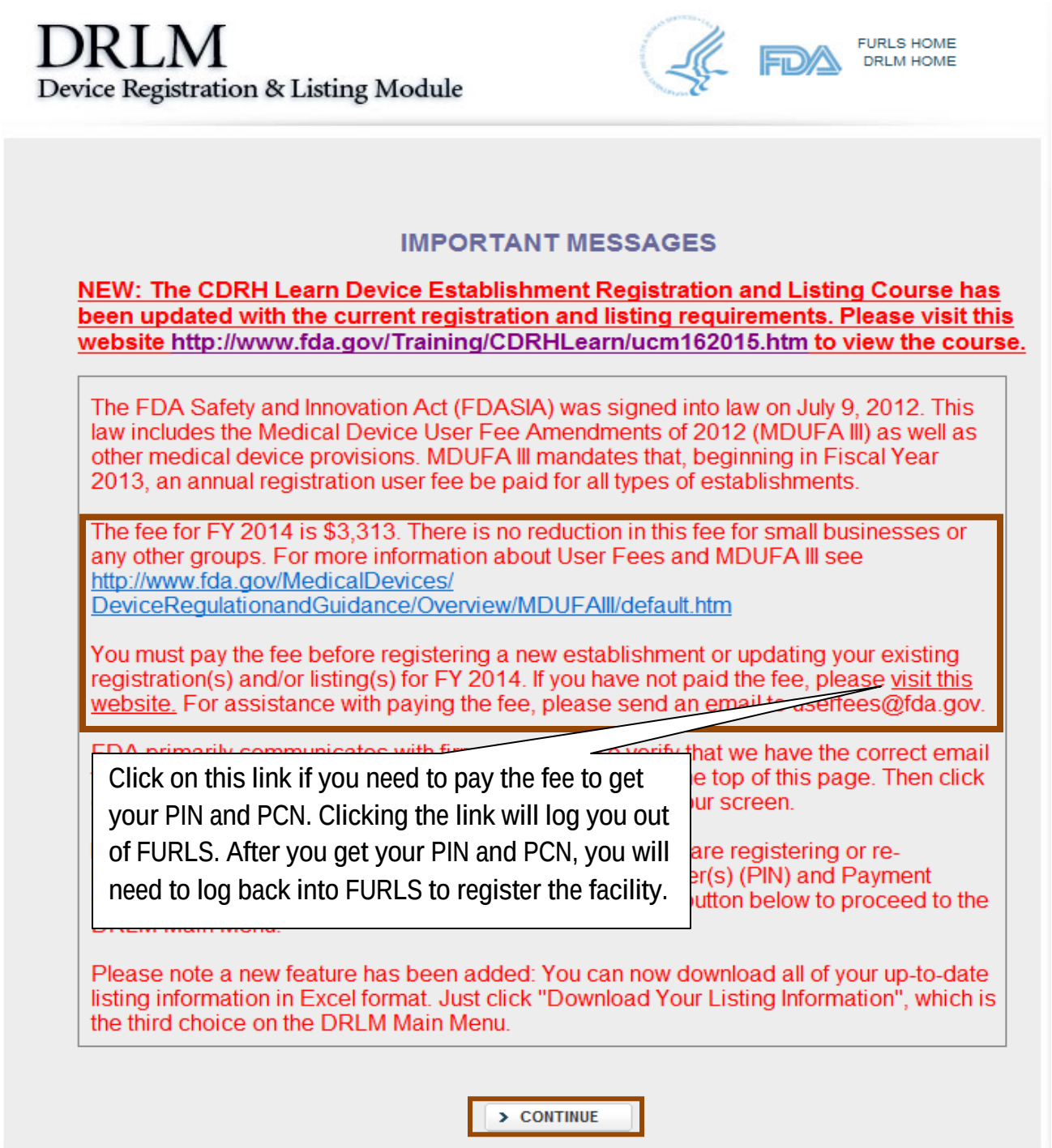
Proceed to Step 3.

Note: If you have only created an owner/operator account, the same contact information will appear on the registration record for both the owner/operator and official correspondent. If a different person is acting as official correspondent, you must create a sub account for that person before beginning the registration process.

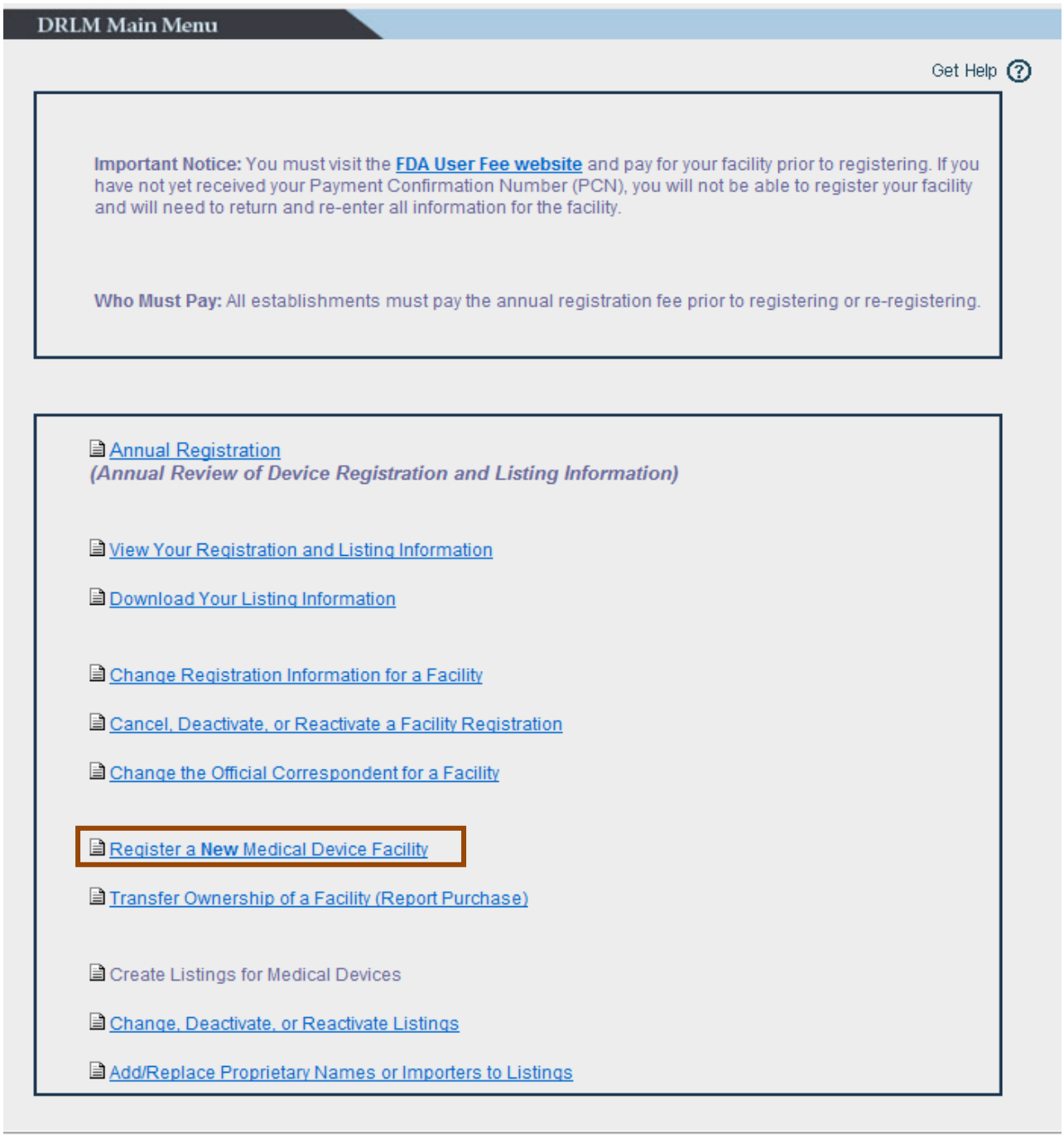


Step 3: Review “Important Messages” and click "Continue" to proceed to the DRLM Main Menu. Proceed to Step 4.

Note: You must pay the fee to receive your Payment Identification Number (PIN) & Payment Confirmation Number (PCN) before you can register your facility.



Step 4: Review the “Important Notice” at the top of the DRLM Main Menu screen. Click on "Register a New Medical Device Facility”. Proceed to Step 5.

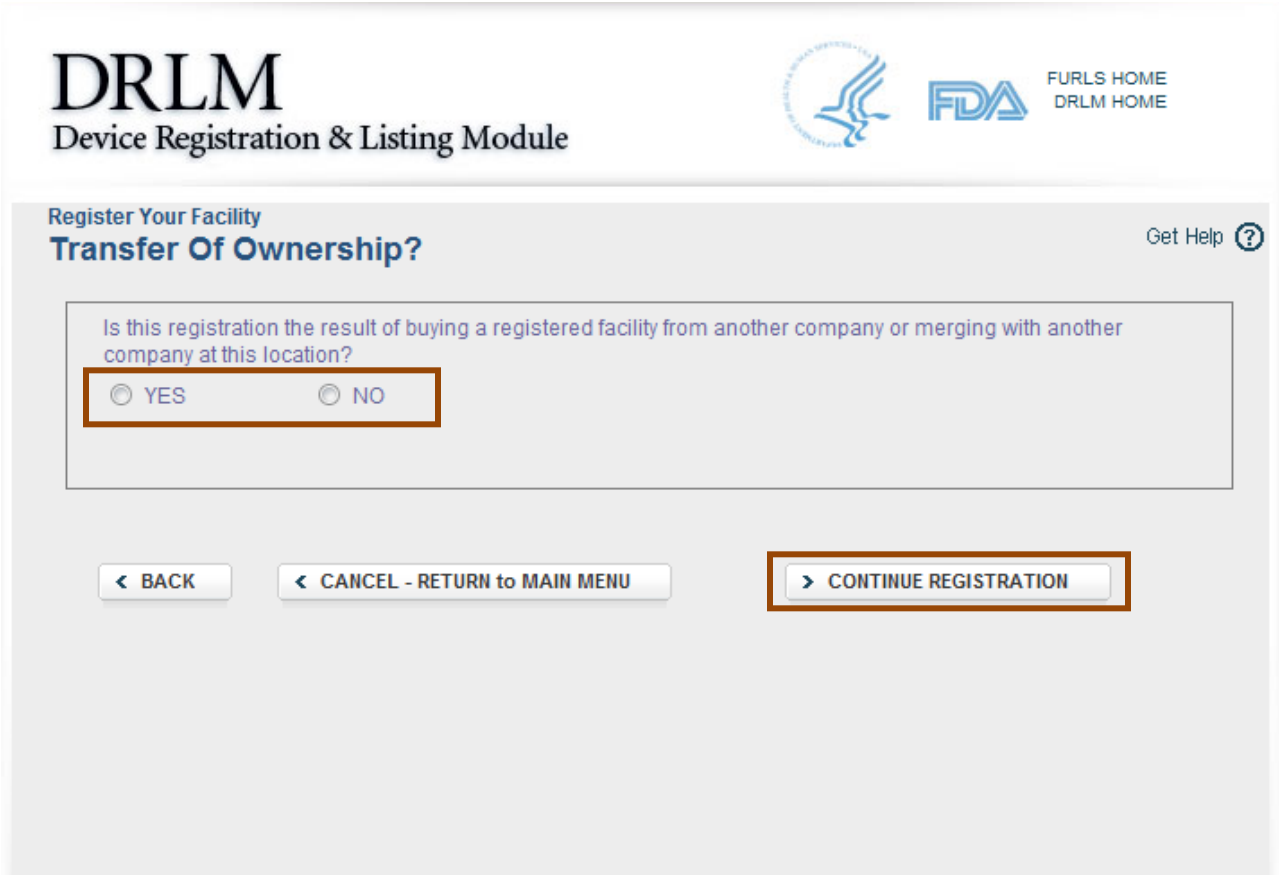


Step 5: If the facility was previously registered, enter the Registration Number or Owner/Operator Number and click "Search." If the facility has not been registered, leave the search fields empty and click "No Existing Registration or OO Number" and follow the prompts to register. Proceed to Step 6.

Step 6: The Registration Requirements page provides links to pay the annual registration user fee, to determine if your product is exempt, to get your FDA product codes, and to register your facility. If you have both your PIN and PCN, and have determined your device listing information, including the facility activies, click “Register My Facility”. Proceed to Step 7.

Step 7: On the Transfer of Ownership page, select "Yes" or "No" to indicate if the registration is for a facility that you have acquired that is already registered by another company. Then click “Continue Registration”. Proceed to Step 8.

If you select “Yes” the system will take you through the Transfer of Ownership process. Follow the prompts through the transfer process. If you need assistance, contact reglist@CDRH.FDA.GOV.

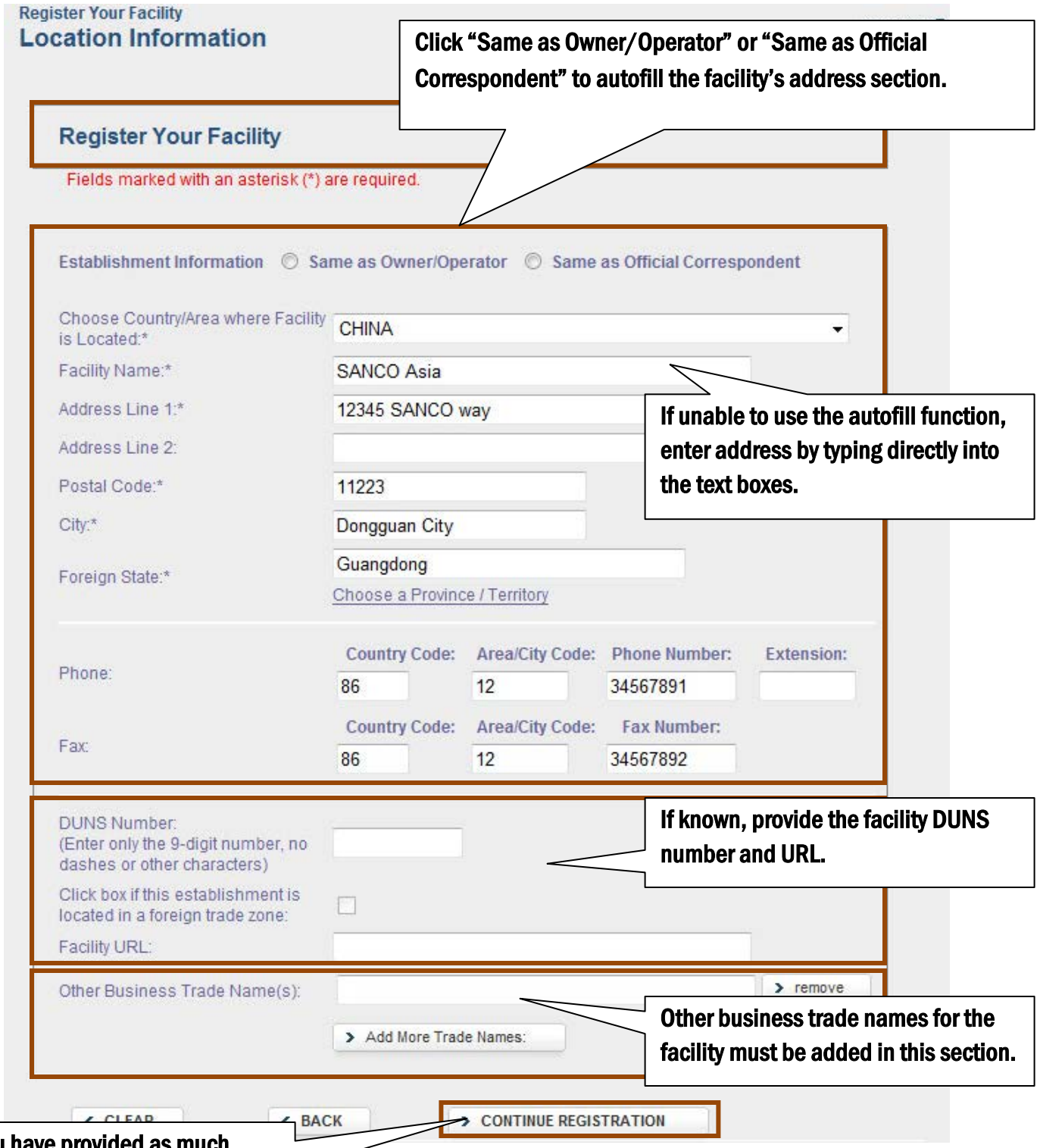


Step 8: The Owner/Operator and Official Correspondent Information page displays contact information for both owner/operator and official correspondent. Review for accuracy and then click “Continue Registration.” Proceed to Step 9A.

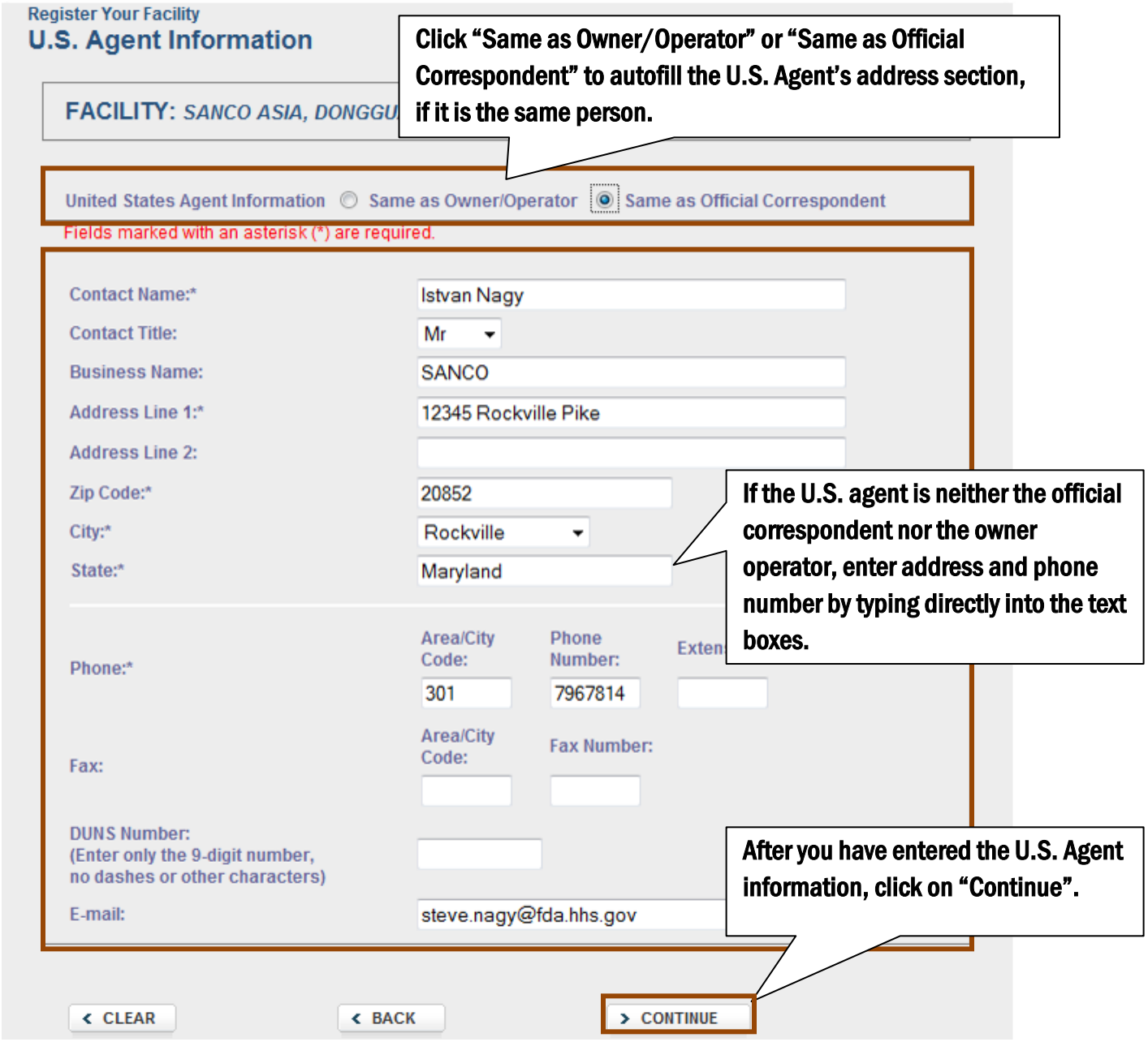
Edit: Edit the information on this form by clicking “Return to Account Management.” When you have completed your edits, return to Step 2.

Subaccounts: If there are no subaccounts, the owner/operator contact person’s information will display for both the owner/operator and the official correspondent . If you created sub-accounts, the names associated with the sub-accounts will appear in the dropdown menu along with the owner operator contact person. You can choose any of these people to act as the official correspondent.

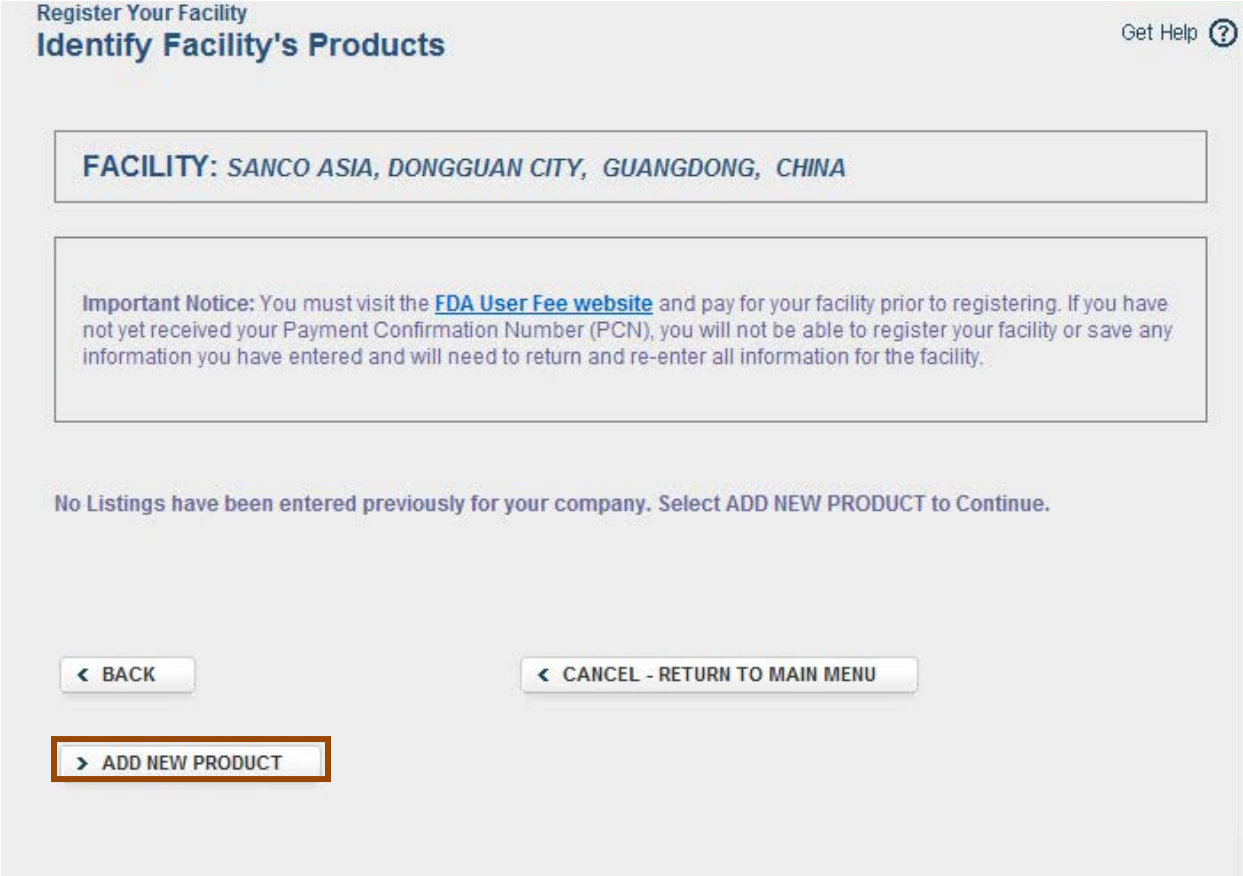
Step 9A: On the Location Information page, enter the facility's physical address. If the facility's information matches that of either the owner/operator or official correspondent, click on the radio button next to owner/operator or official correspondent to autofill the location. You must also add any other business trade names for the facility. If known, you may also enter the facility DUNS number, facility URL. Then, click "Continue Registration." Proceed to Step 9B.



Step 9B: On the U.S. Agent Information page, enter the name, physical address, phone number, and email address of the facility's U.S. Agent. The U.S. Agent must be located in the United States. The responsibilities of a U.S. Agent can be viewed at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053196.htm After you have entered the U.S. Agent information, click on "Continue". Proceed to Step 10A.



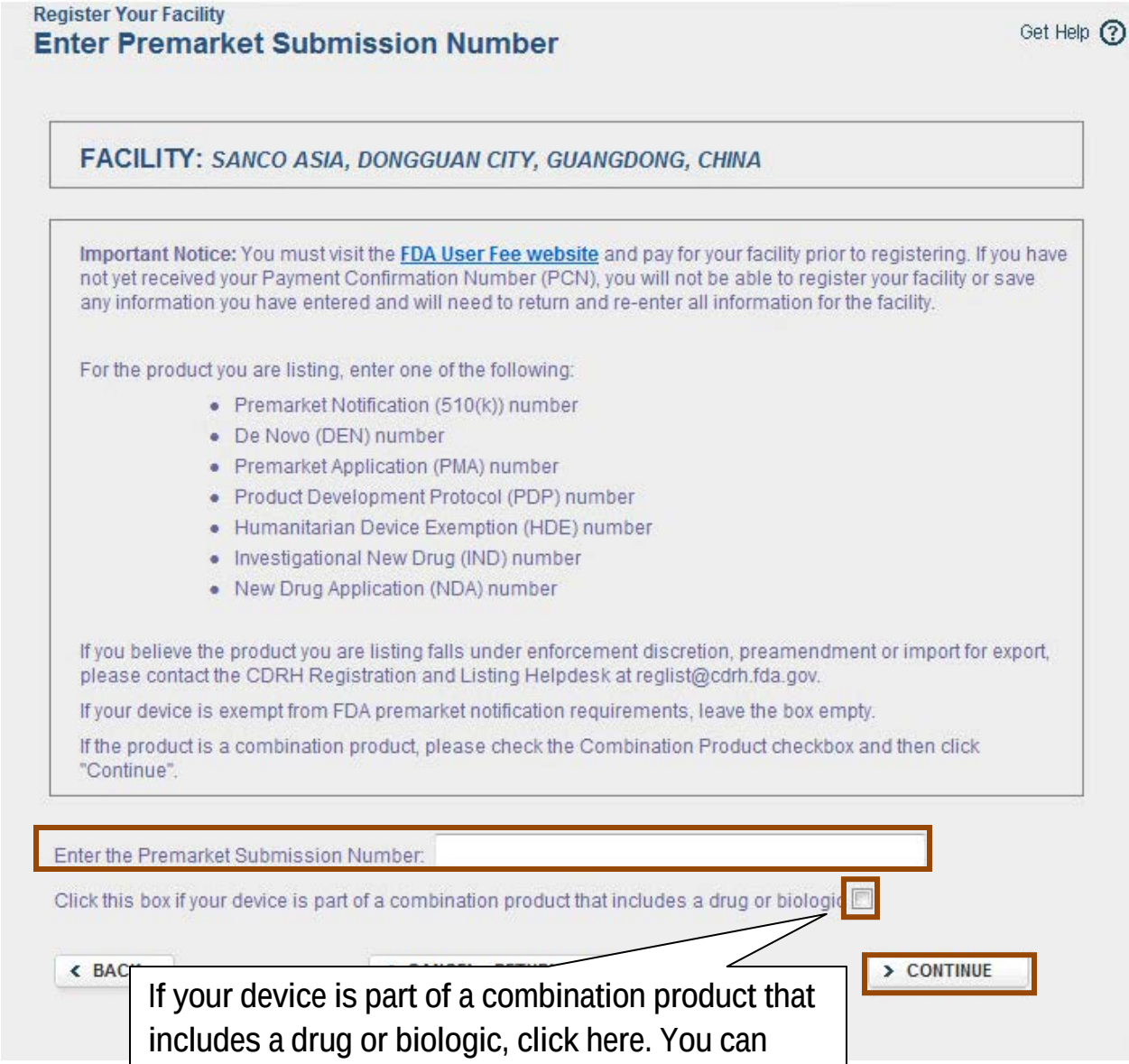
Step 10A: On the Identify Facililty's Products page, click "Add New Product". Proceed to Step 10B.



Step 10B: On the Enter Premarket Submission Number page, if the device is not exempt, enter the premarket submission number, and click "Continue." Proceed to Step 11.

If the device is exempt, click "Continue." Proceed to Step 10C.

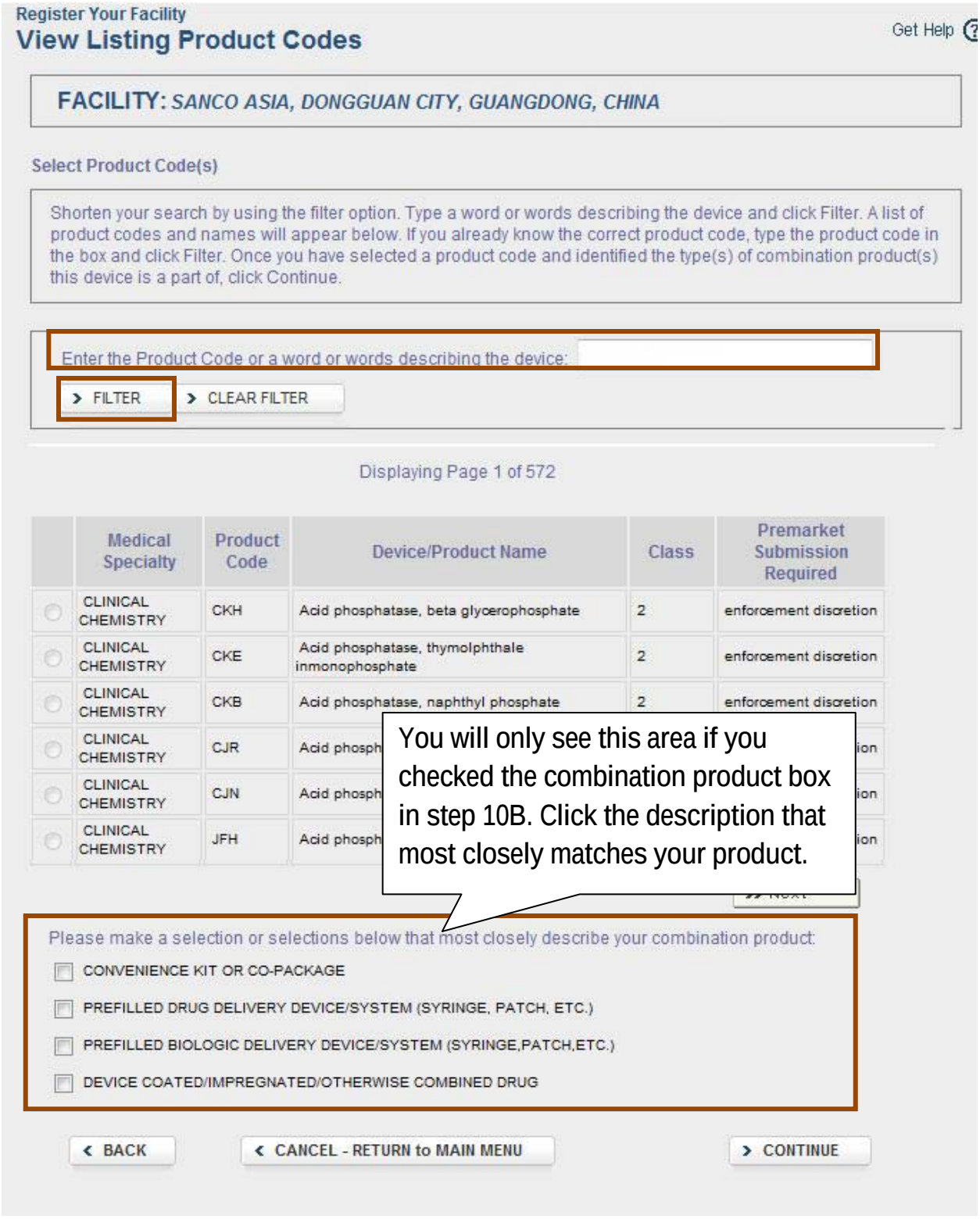
If the device is part of a combination product that includes a drug or biologic, click the box (indicated below).



If your device is part of a combination product that includes a drug or biologic, click here. You can view information about combination products at http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm

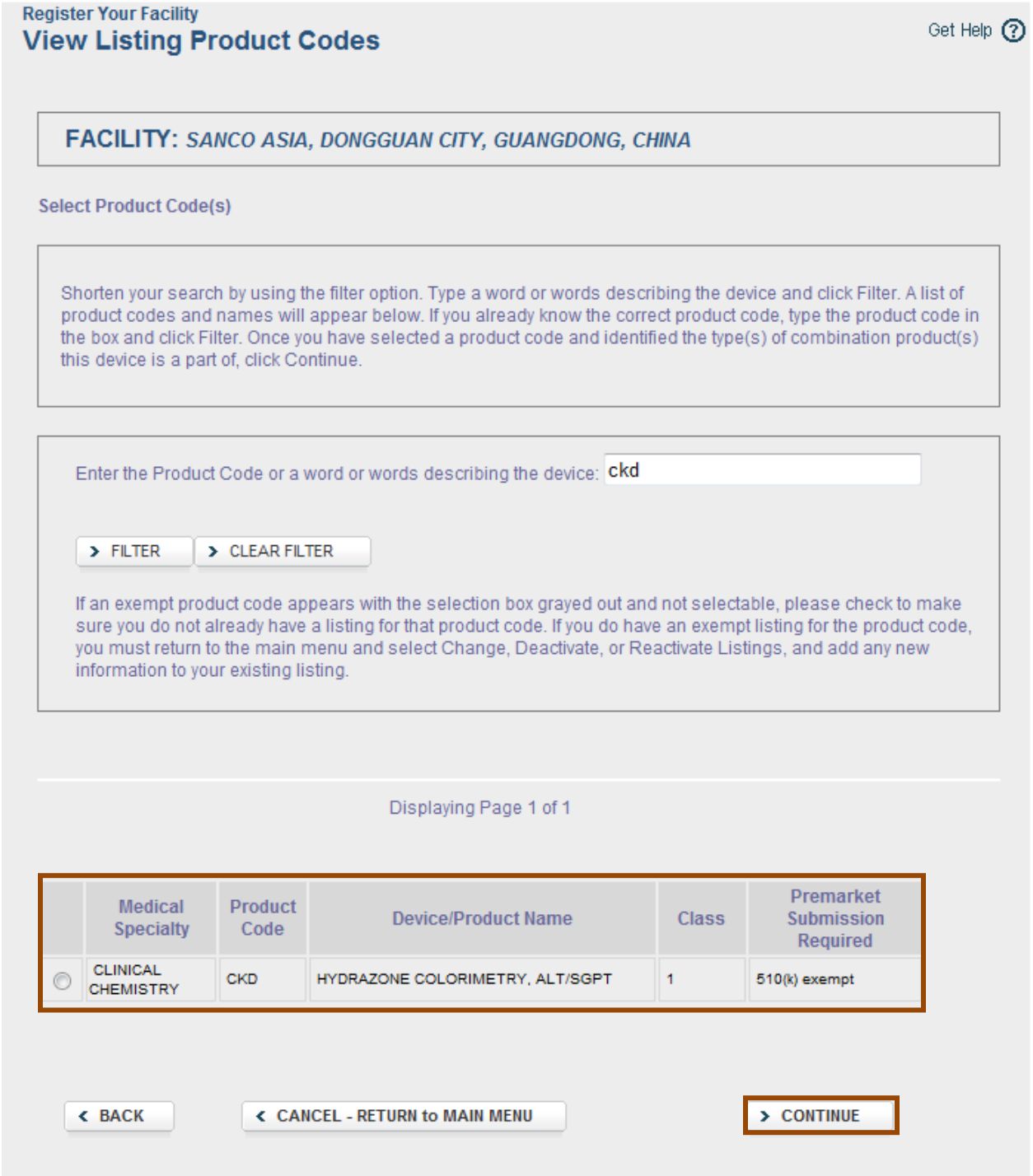
Step 10C: On the Dental Laboratory Question page, preview the question and click “Yes” or “No.” Click “Continue” to proceed to Step 10D.

Step 10D: If the device is exempt, enter the 3 letter FDA product code or word(s) that describe the device in the "Enter the Product Code or a word or words describing the device" text box on the View Listing Product Codes page. Click "Filter" to display a list of products. Proceed to Step 10E.



Step 10E: Click the radio-button next to your product code, and then click "Continue." Skip to Step 12A.

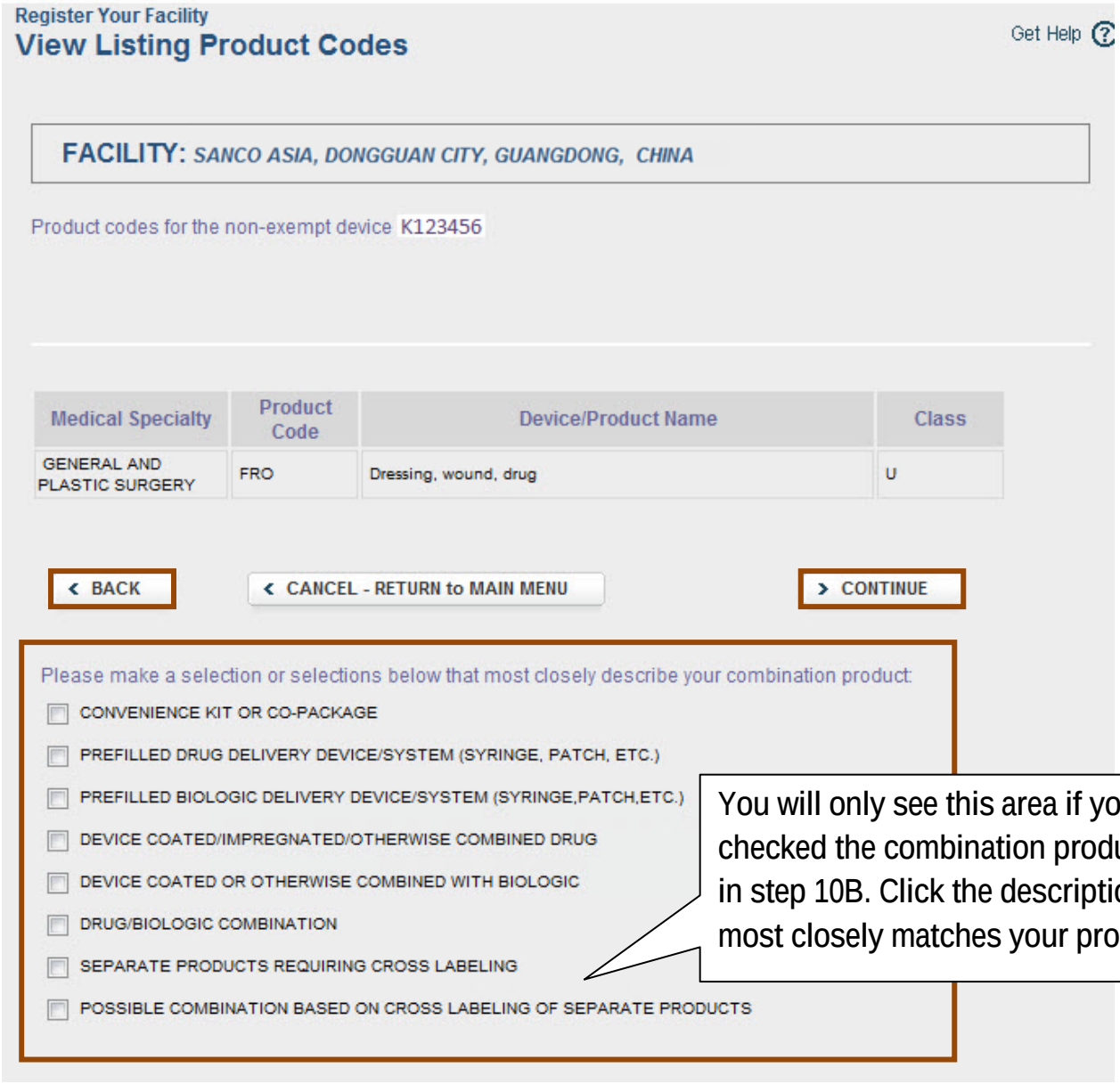
NOTE: If more than one page of potential product matches is generated, make sure to review all pages until you find the product code that matches your device.



Step 11: If a valid premarket submission number was entered, the product code will display. If the product code is correct, click “Continue”. If you think that an incorrect product code is showing for the premarket submission number entered, contact reglist@CDRH.FDA.GOV for assistance.

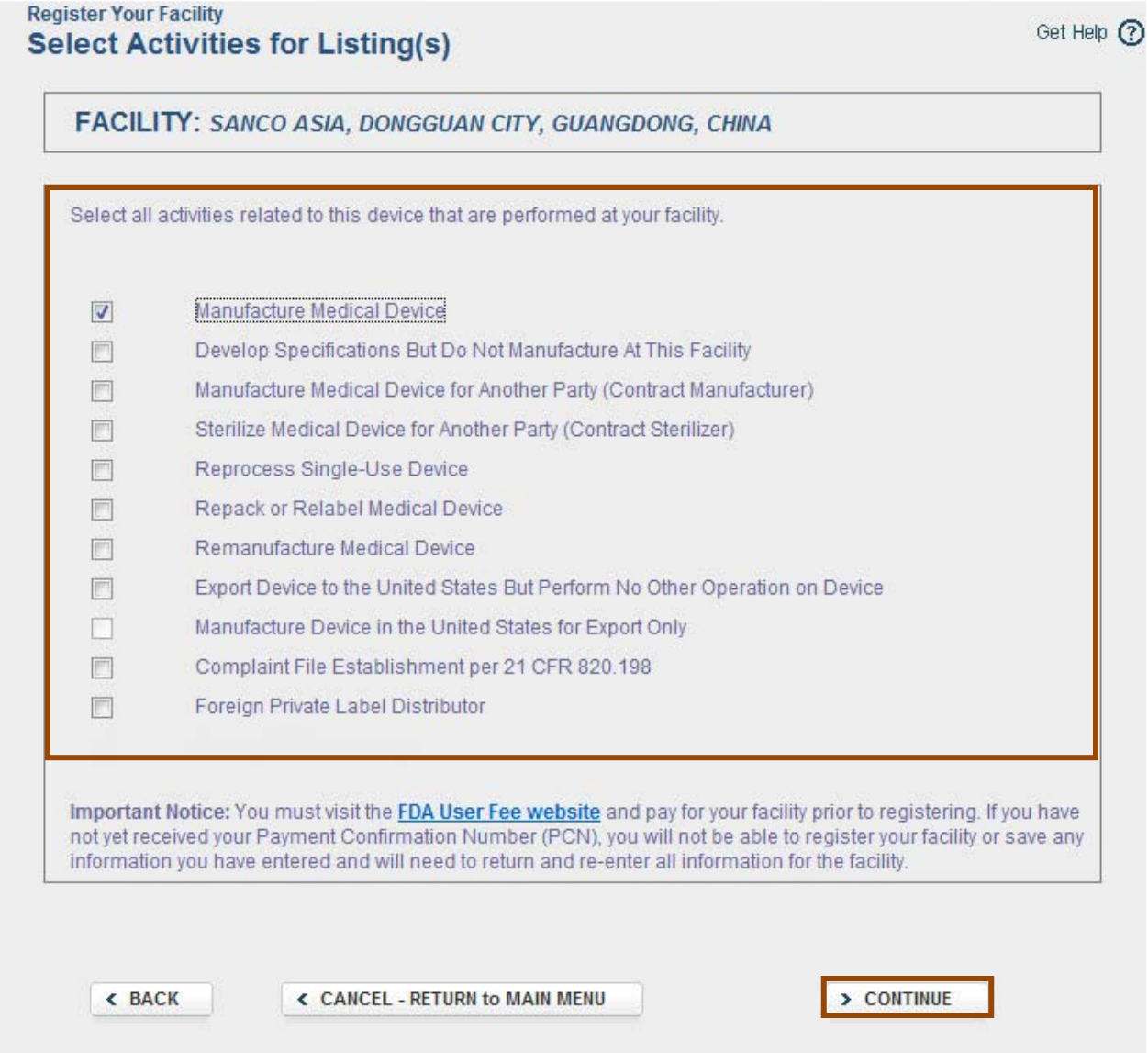
If an incorrect premarket submission number was entered, click “Back” to enter the correct number.

Proceed to Step 12A.

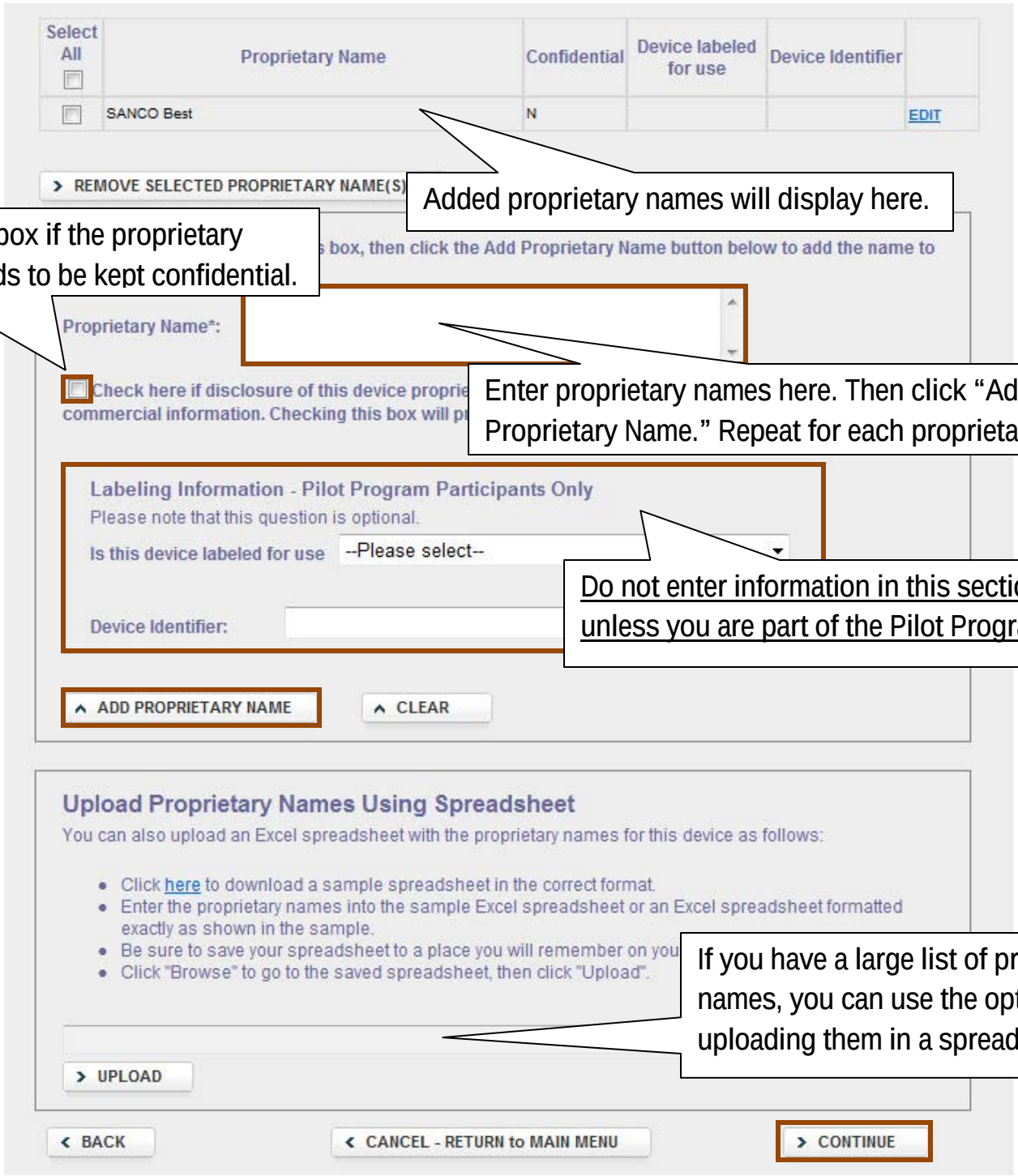


Step 12A: On the Select Activities for Listing(s) page, select the activities related to the device at this facility, and then click “Continue.”

Proceed to step 12B.



Step 12B: On the Enter Proprietary Name(s) page, enter the proprietary name(s) in the Proprietary name text box. Click "Add Proprietary Name" to move the entered name up to the Proprietary Name section. If the proprietary name needs to be confidential, check the disclosure statement box. Once all proprietary names have been added, click "Continue". Proceed to step 12C.

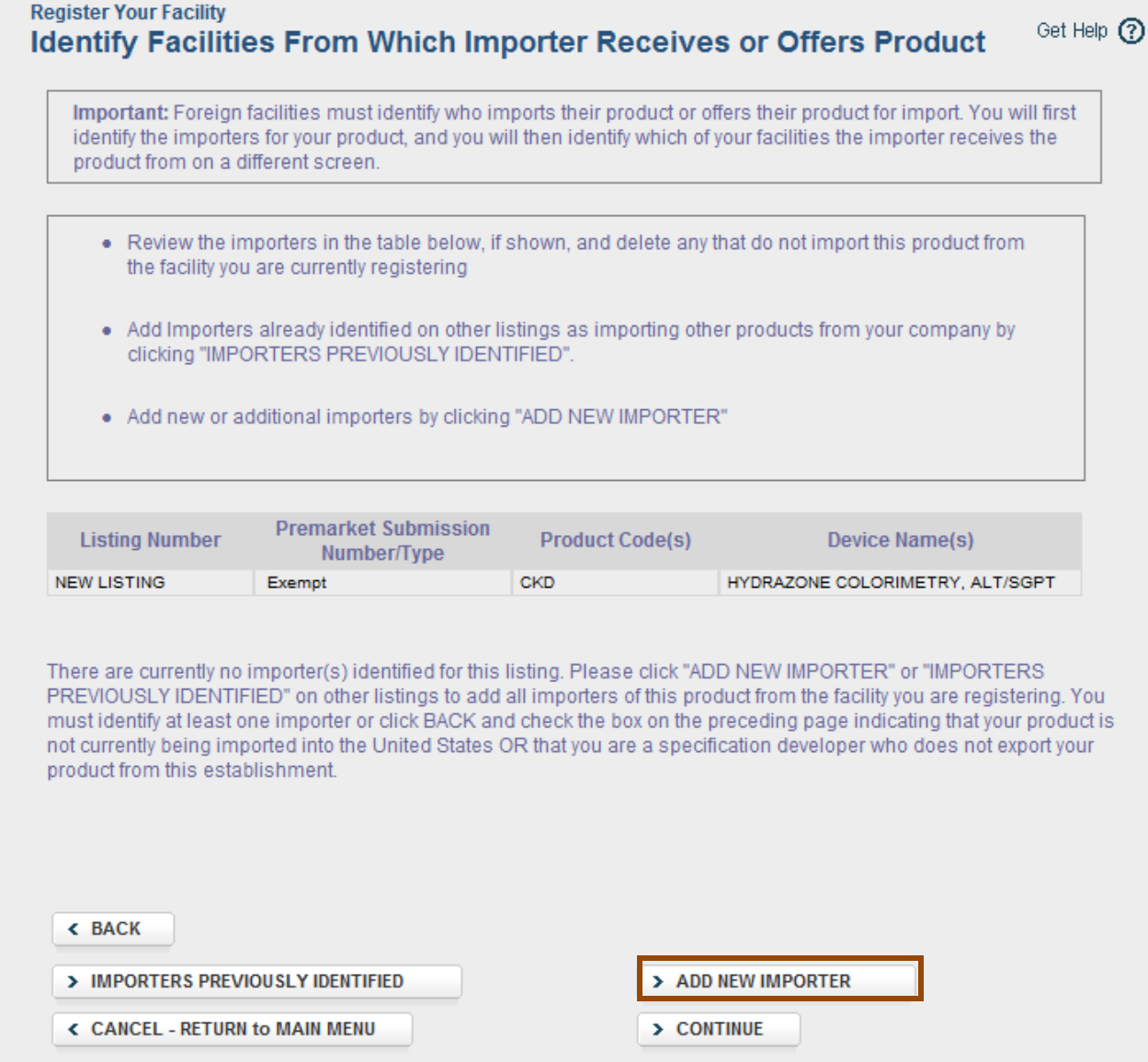


Step 12C: On the Add Importer(s) page, if the facility is currently exporting the device to the U.S., click “Add New Importers”. Proceed to step 12D.

If the facility is not yet exporting to the U.S. or is a specifications developer that does not ship the product from this location to the U.S., click the box indicated below and then click “Continue”. Proceed to step 13.

Step 12D: In an intial registration, there are no existing importers listed for you to choose from.

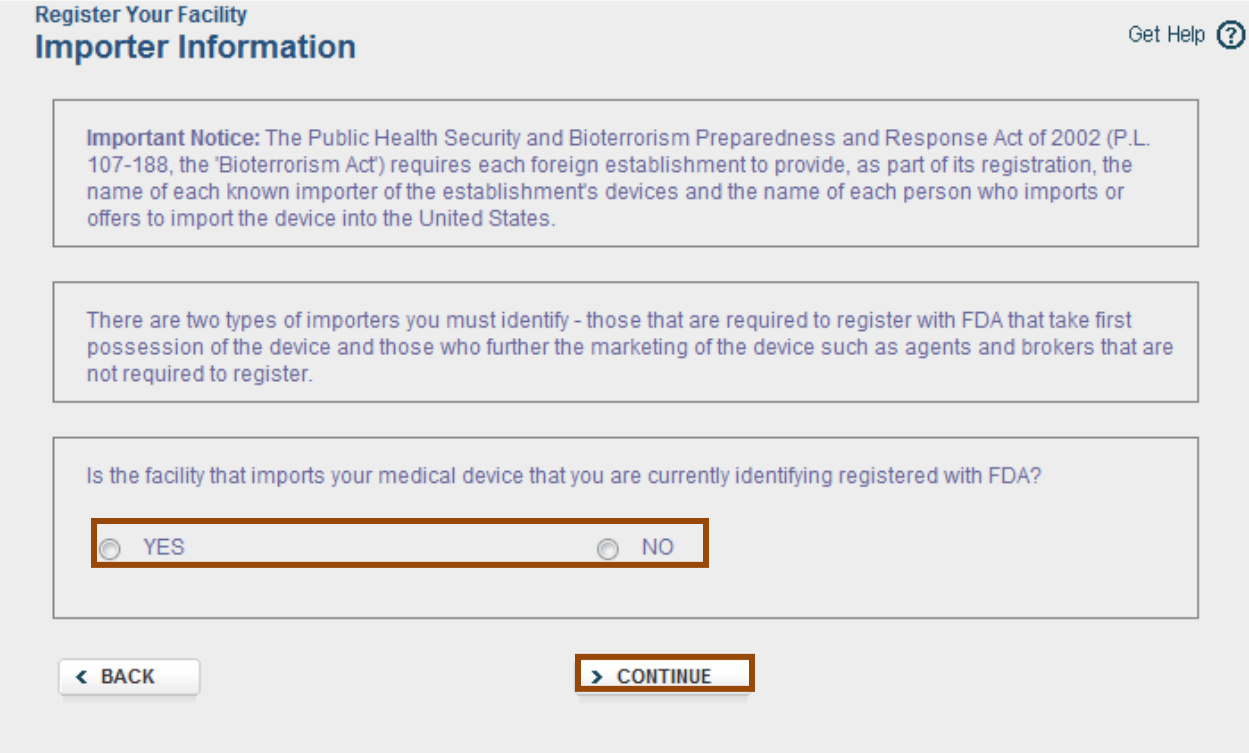
On the Identify Facilities From Which Importer Receives or Offers Product page, click “Add New Importer”. Proceed to step 12E.



Step 12E: On the Importer Information page, you will be asked to indicate whether or not the importer being identified is registered with the FDA. Click on the radio button for either Yes or No and then “Continue”.

If you indicated No, proceed to step 12F.

If you indicated Yes, proceed to step 12G.

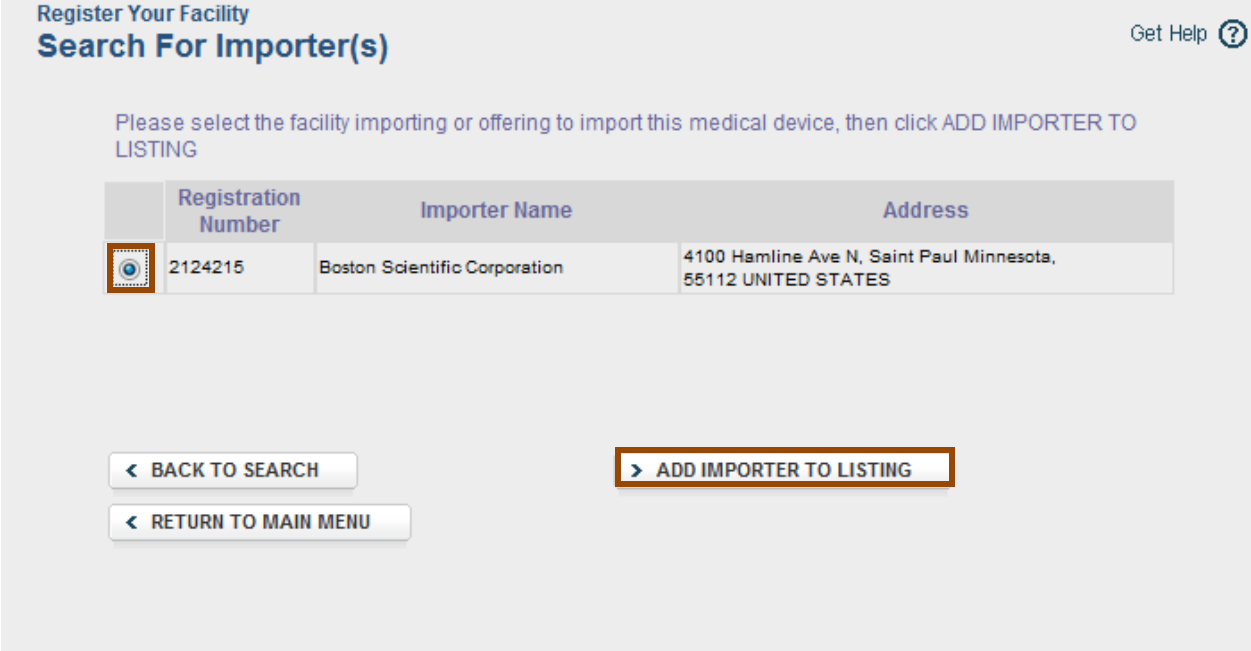


Step 12F: On the Enter Importer Information Page, select the importer country from the drop down menu and then enter the importer's address. If known, enter the facility phone number, fax number, email address, and DUNS number. You are also required to select the importer type from the drop down menu. After you enter the importer information, click "Continue". Proceed to step 12l.

Step 12G: On the Search For Importer(s) page, enter as little information as possible to narrow the search results. Enter only the registration number and do not enter information into the other fields. If you do not know the registration number, enter only the name of the facility and do not enter information into the other fields. You can also search by address. After you have entered your search criteria, click "Search Importers". Proceed to step 12H.

NOTE: For a registered importer to display in your search results, the importer must have an active registration for the current fiscal registration year.

Step 12H: After your seach results are displayed, click on the radio button for the facility that is importing your device and then click “Add Importer To Listing”. Proceed to step 12I.

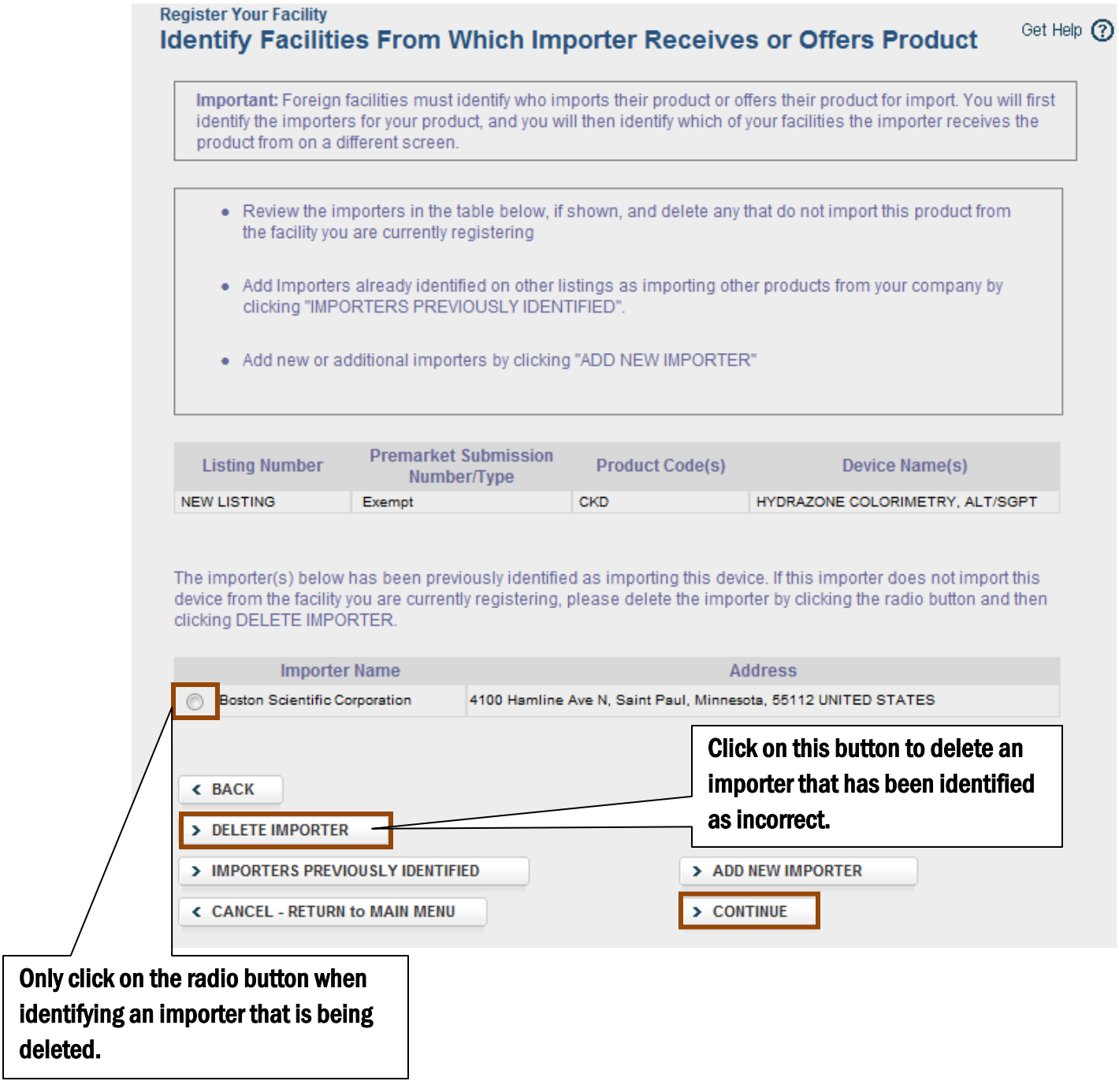


Step 12I: You will be returned to the Identify Facilities From Which Importer Receives or Offers Product page.

If the displayed importer is correct, and you do not need to add another importer for this device, click “Continue” and proceed to step 13.

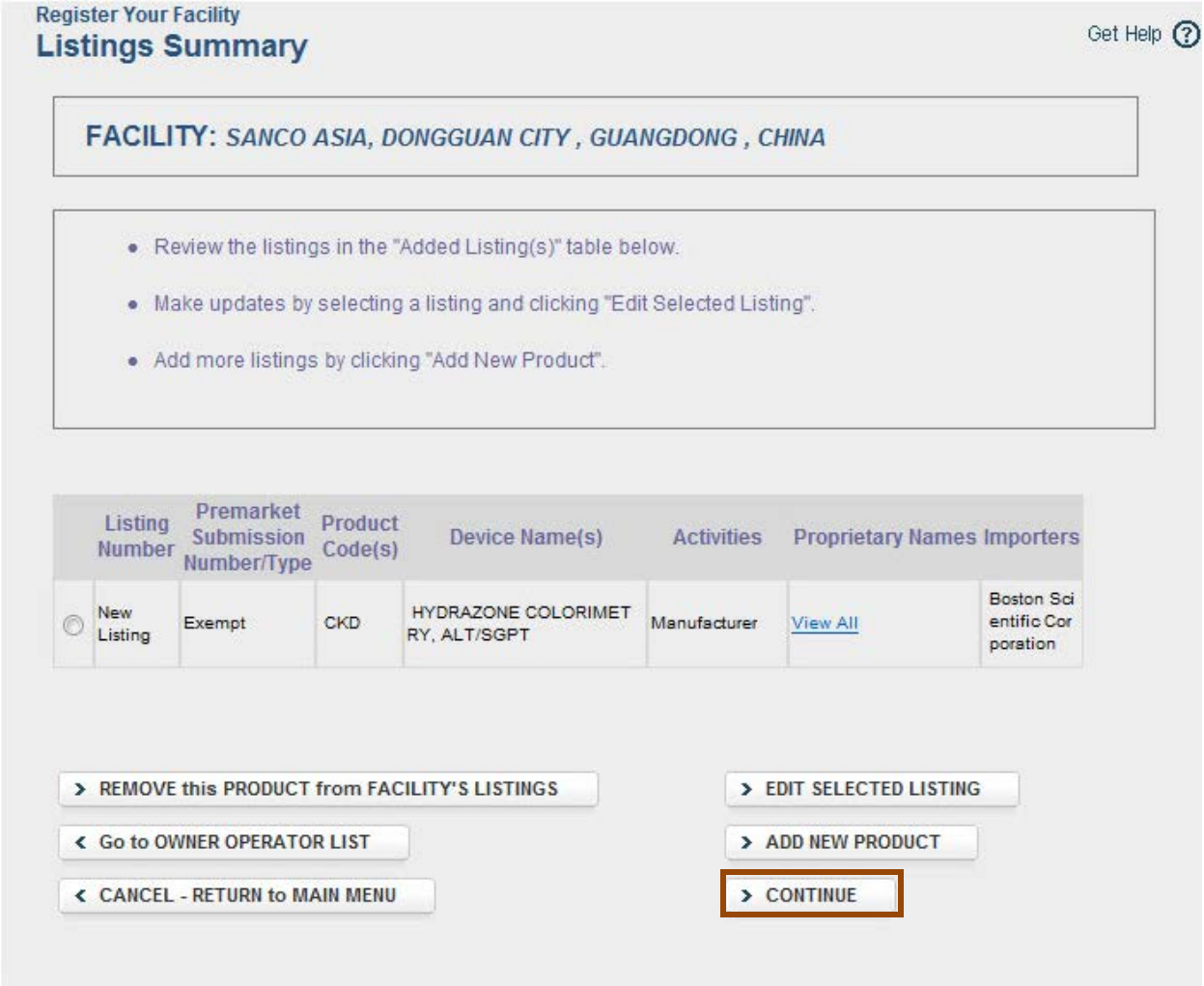
If the displayed importer is incorrect, click the radio button next to the incorrect importer and then click “Delete Importer”.

To add additional importers or to replace a deleted importer, click “Add New Importer” and go back to step 12E.



Step 13: On the Review Listings Summary page, review the device listing and click “Continue” if you do not have any more devices to be listed. Proceed to Step 14A.

To add more devices to the list, click “Add New Product”, go to step 10A.



Step 14A: On the top half of the Registration Review page, review the facility and contact person information for accuracy. If the information is not accurate, click the appropriate “Edit” button and follow the prompts to make corrections. Proceed to Step 14B.

Register Your Facility

Registration Review

Get Help

FACILITY: *SANCO ASIA, DONGGUAN CITY, GUANGDONG, CHINA*

Facility > EDIT

Registration Number:	
Initial Importer:	N
Facility Name:	SANCO Asia
Address:	12345 SANCO way
	Dongguan City , Guangdong , 11223 , CHINA
DUNS Number:	
Foreign Trade Zone:	N
Facility URL:	
Other Business Trade Name(s):	

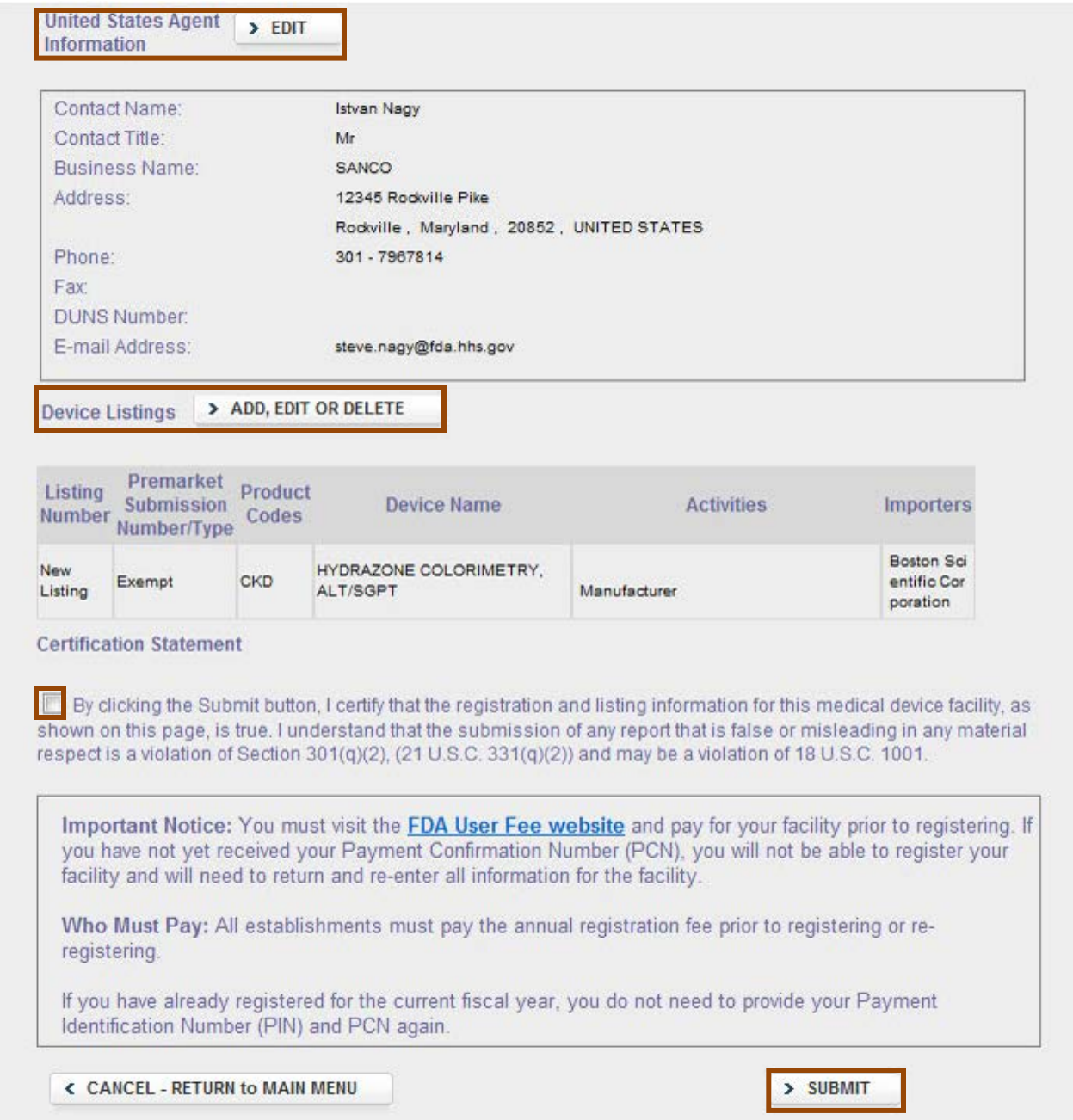
Owner/Operator Information

Contact Name:	Istvan Nagy
Company:	SANCO
Address:	12345 Rockville Pike
	Rockville , MARYLAND , 20852 , UNITED STATES
Telephone:	301 - 7967814
Fax:	
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

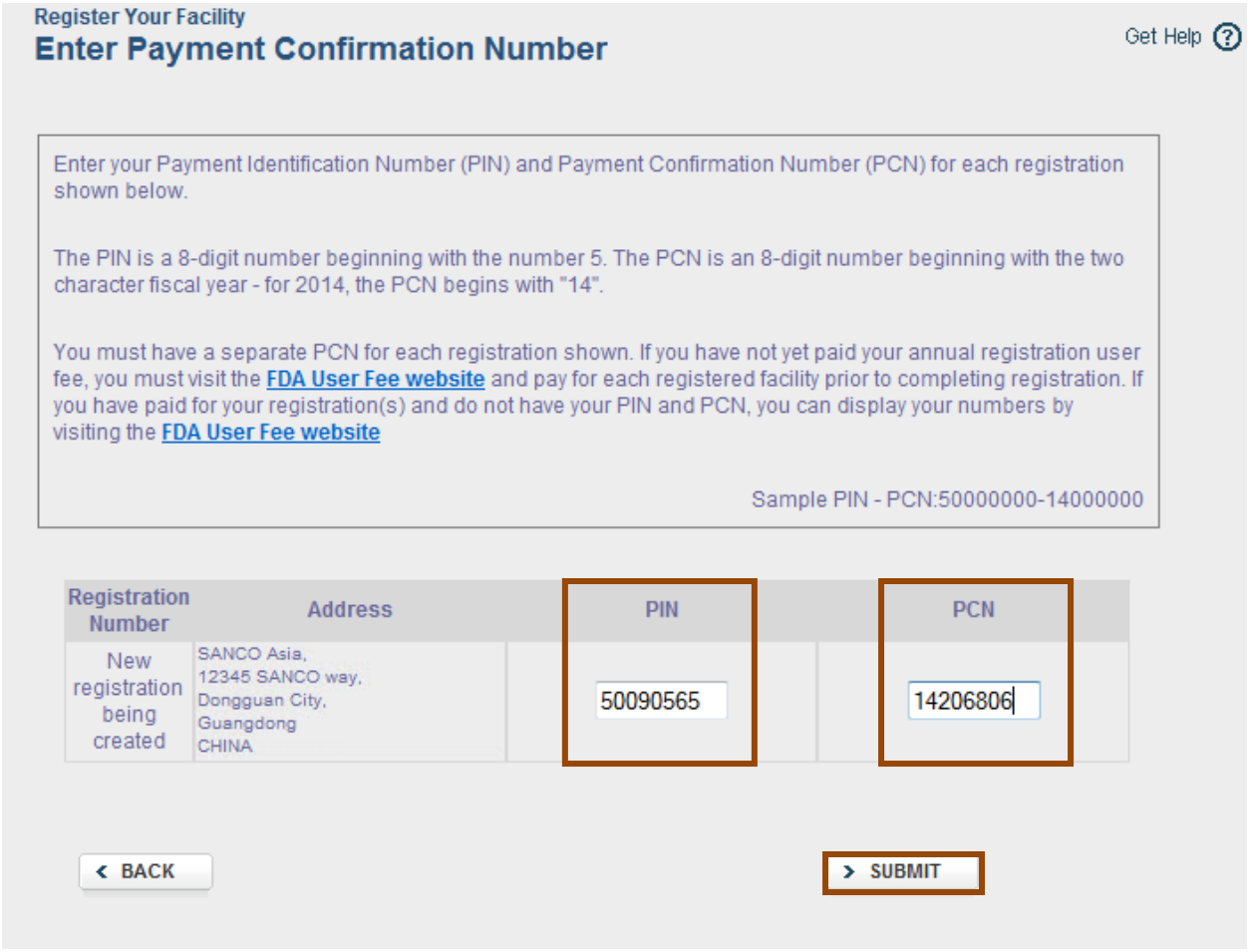
Official Correspondent Information > EDIT

Contact Name:	Istvan Nagy
Company:	SANCO
Address:	12345 Rockville Pike
	Rockville , MARYLAND, 20852 , UNITED STATES
Telephone:	301 - 7967814
Fax:	
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

Step 14B: On the bottom half of the Registration Review page, review U.S. Agent and Device Listings. If the information is not accurate, click the appropriate "Edit" button and follow the prompts to make corrections. If / when all information is correct, click the box next to the certification statement, then click "Submit." Proceed to Step 15.



Step 15: On the Enter Payment Confirmation Number page, enter the 8-digit Payment ID Number (PIN) and 8-digit Payment Confirmation Number (PCN) and click “Submit.” Proceed to Step 16.



Step 16: The Registration Confirmation page displays the registration information you have entered. Return to the main menu to continue other registration and listing actions or return to the Account Management page to log out of the system. Proceed to Step 17.

Register Your Facility

Registration Confirmation

FACILITY: *SANCO ASIA, DONGGUAN CITY , GUANGDONG , CHINA*

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

The Owner/Operator Number for this Registration is: 10048405.

Facility

Registration Number:
Initial Importer: N
Facility Name: SANCO Asia
Address: 12345 SANCO Way
Dongguan City , Guangdong , 11223 , CHINA
DUNS Number:
Foreign Trade Zone: N

Owner/Operator Information

Contact Name: Istvan Nagy
Company: SANCO
Address: 12345 Rockville Pike
Rockville , MARYLAND , 20852 , UNITED STATES
Telephone: 301 - 7967814
E-mail: steve.nagy@fda.hhs.gov

Official Correspondent Information

Contact Name: Istvan Nagy
Company: SANCO
Address: 12345 Rockville Pike
Rockville , MARYLAND , 20852 , UNITED STATES
Telephone: 301 - 7967814
E-mail: steve.nagy@fda.hhs.gov

United States Agent Information

Contact Name: Istvan Nagy
Contact Title: Mr
Business Name: SANCO
Address: 12345 Rockville Pike
Rockville, Maryland, 20852, UNITED STATES
Phone: 301-7967814
E-mail Address: steve.nagy@fda.hhs.gov

Device Listings

Listing Number	Premarket Submission Number	Product Codes	Device Name	Activities	Importers
D226459	Exempt	CKD	HYDRAZONE COLORIMETRY, ALT/SGPT	Manufacturer	Boston Scientific Corporation

< RETURN to MAIN MENU

< RETURN to ACCOUNT MANAGEMENT

Step 17: A confirmation email will be generated and sent to you with the following information:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave., WO66 Room 2621
Silver Spring, Maryland 20993-0002

March 13, 2015

Name of Official Correspondent	ISTVAN NAGY
Address of Official Correspondent	12345 ROCKVILLE PIKE ROCKVILLE, MARYLAND 20852 UNITED STATES STEVE.NAGY@FDA.HHS.GOV
Owner Operator Number	10048405

Dear Sir or Madam,

We have received your registration and listing information for the following medical device establishment

Establishment Name	SANCO ASIA
Establishment Address	12345 SANCO WAY DONGGUAN CITY, GUANGDONG 11223 CHINA

The information submitted has been processed and entered into the FDA Registration and Device Listing Database. Your device establishment is now considered registered. You will be notified of your official registration number within 90 days.

Once you receive a registration number, you are required to re-register on an annual basis from October through December. Failure to re-register every year will invalidate your registration and result in your device establishment and listing information being removed from the FDA Medical Device Registration and Listing Web site.

For inquiries about the status of your registration or assignment of your registration number, please contact the Registration and Listing Program Office at reglist@cdrh.fda.gov or calling (301) 796-7400.

If you have any questions regarding FDA policy related to the Registration and Listing program, please contact the Registration and Listing staff at device.reg@fda.hhs.gov or calling (301) 796-7400.