FURLS Device Registration & Listing

Annual Registration

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

Division of Industry and Consumer Education (DICE)

Instructions for

Annual Registration

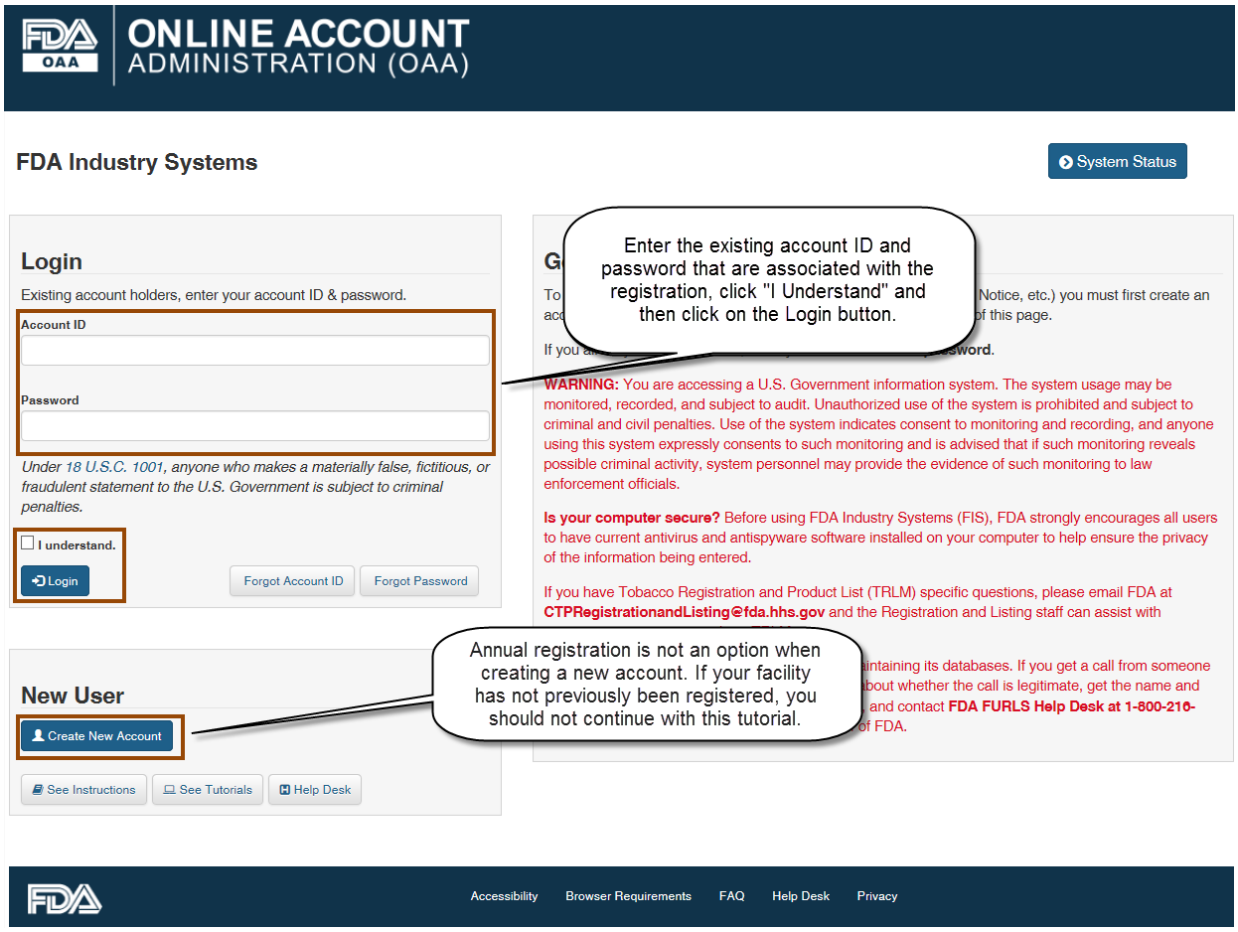
This tutorial should only be used when 1) reregistering a facility that has an existing registration, that is currently active and 2) you have already paid the annual registration user fee and received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN)

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

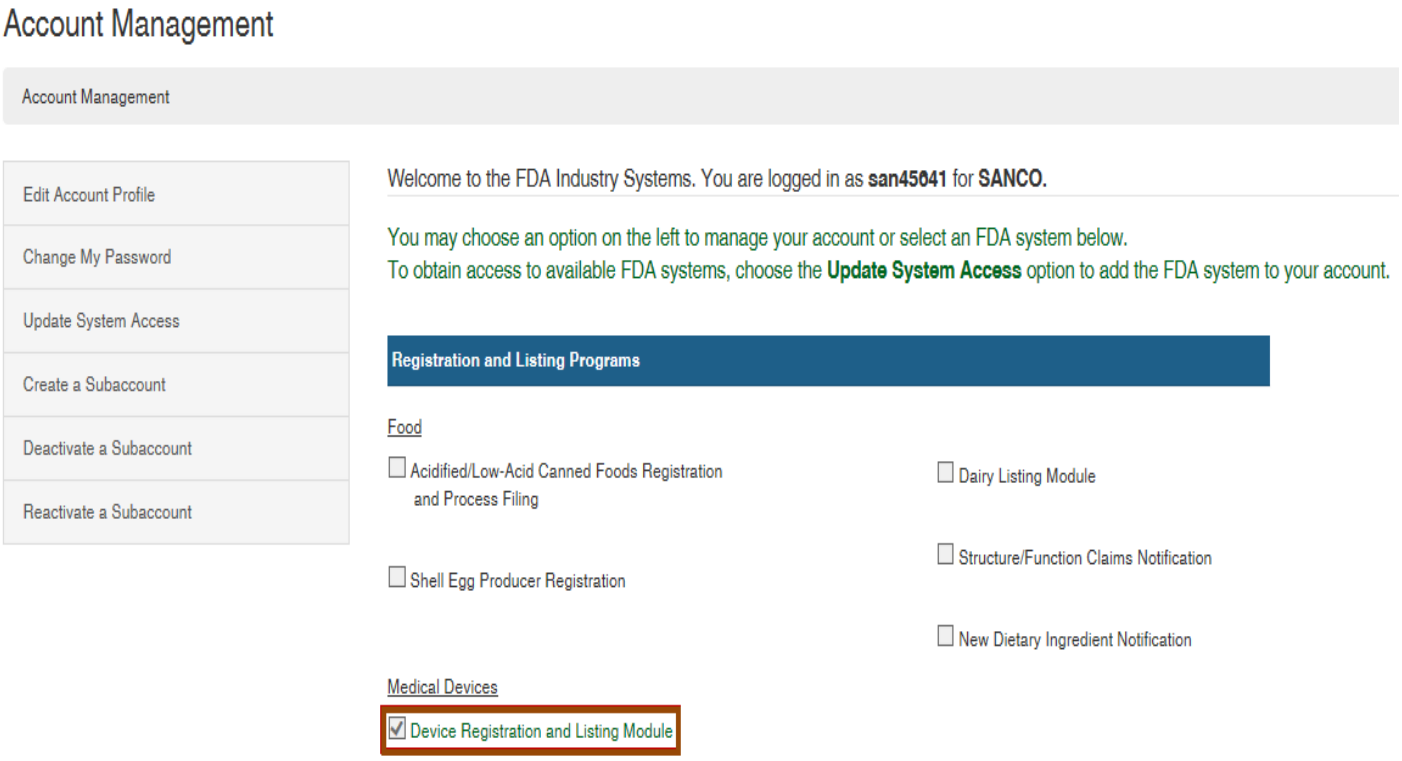
Enter the existing account ID and password that are associated with the registration record, click “I Understand” and then click on the Login button.

Note: If you are unable to find the correct account information, contact reglist@CDRH.FDA.GOV for assistance. You cannot access an existing registration if you create a new account.

Proceed to Step 2.



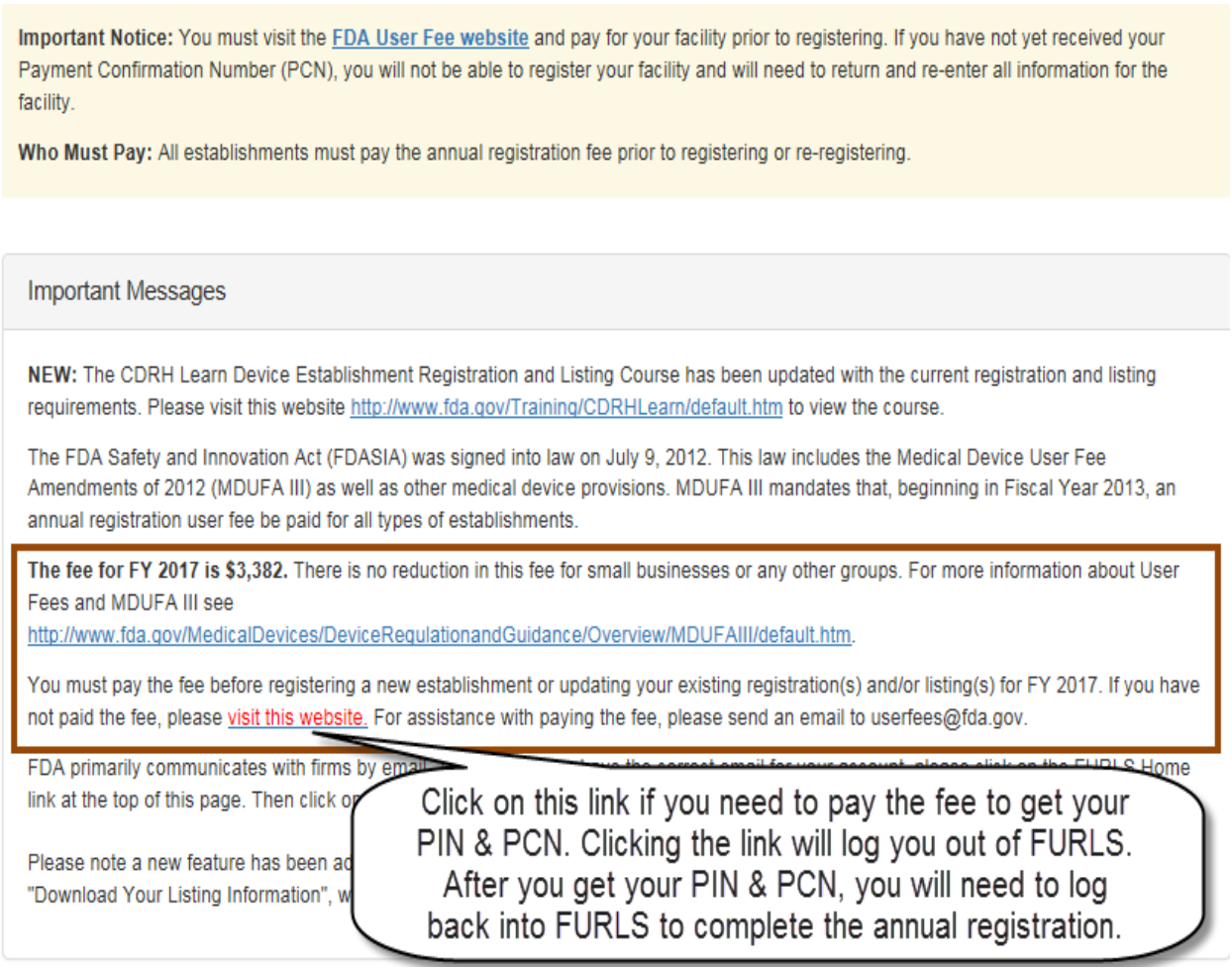
Step 2: Click "Device Registration & Listing Module" (DRLM) to access your registrations. Proceed to Step 3.



Step 3: Review “Important Messages” on the DRLM Home page.

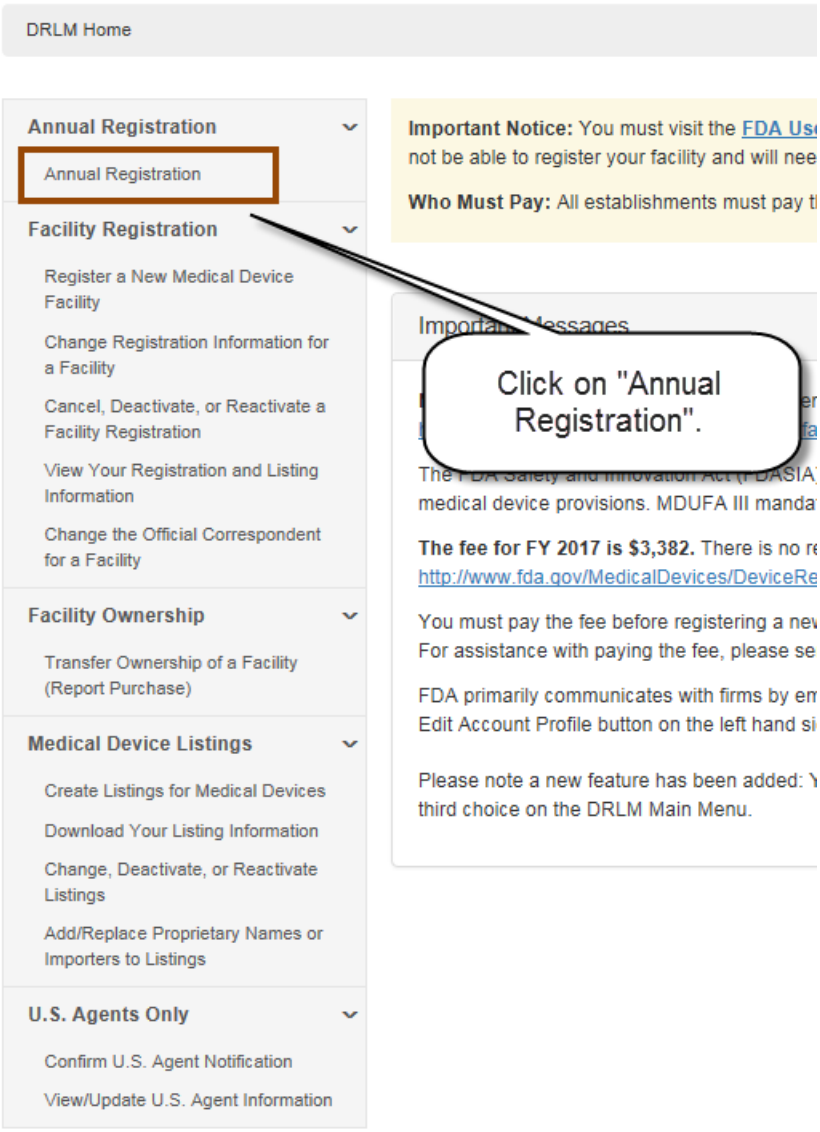
Proceed to Step 4.

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



Step 4: Click on "Annual Registration" link in the DRLM menu.

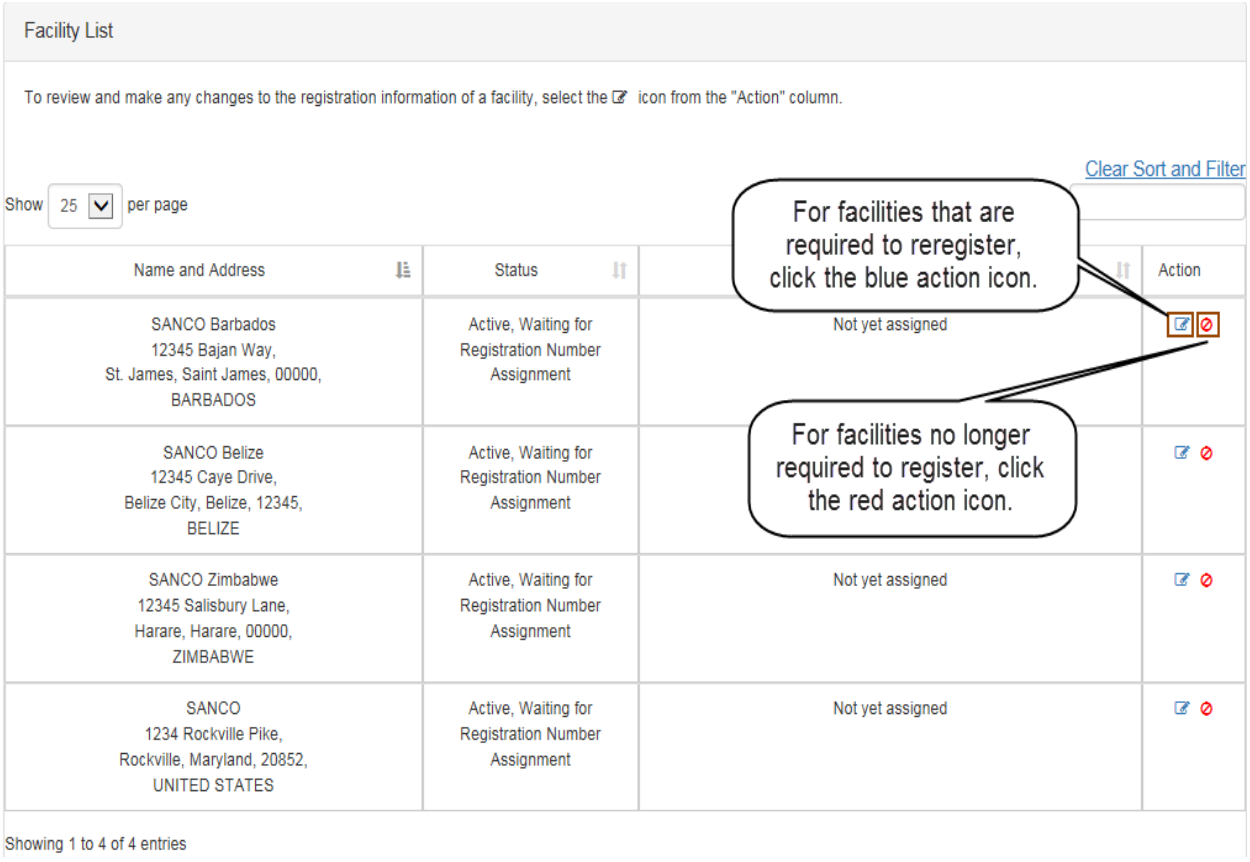
Proceed to Step 5.



Step 5: You will see a list of all of your facilities that need to complete the annual registration. For each facility, that has activities that require registration, click on the blue action icon.

Proceed to Step 8.

If a facility no longer has activities that require registration, click on the red action icon to deactivate the registration. Proceed to step 6.

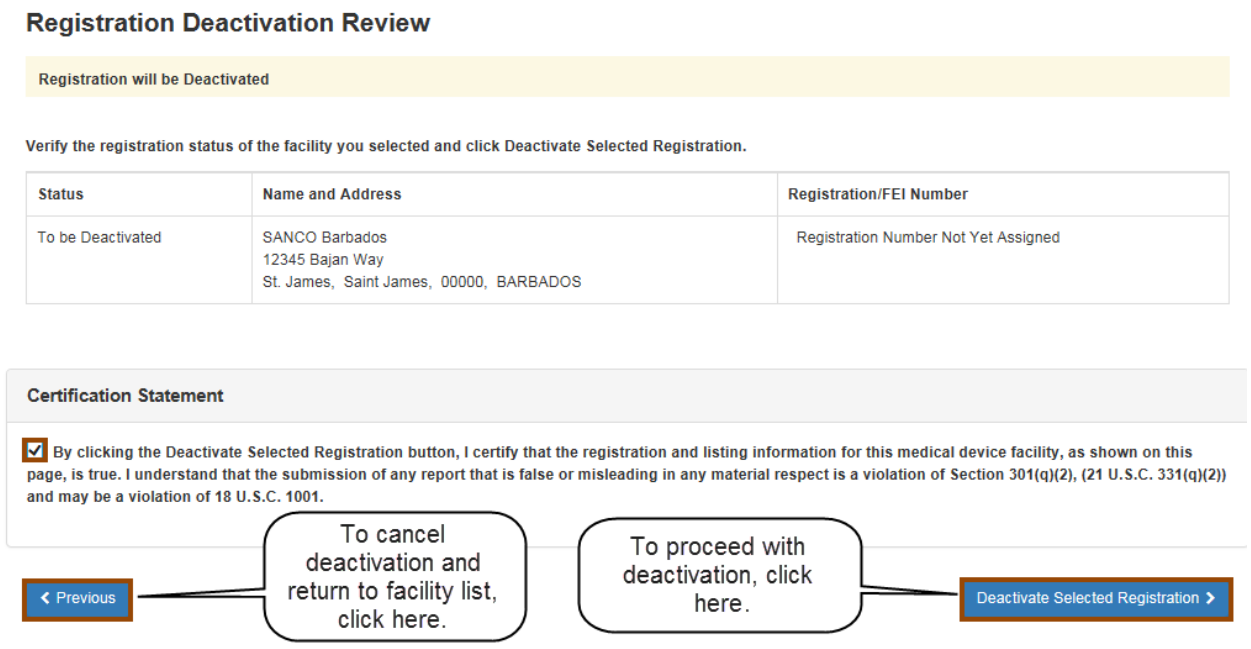


Step 6: Review the facility information to confirm that you have selected the correct registration for deactivation. If correct, click the certification statement box and then click “Deactivate Selected Registration”.

Proceed to step 7.

If you have not selected the correct registration for deactivation, click on “previous” to return to the facility selection page and return to Step 5.

Return to Step 5.



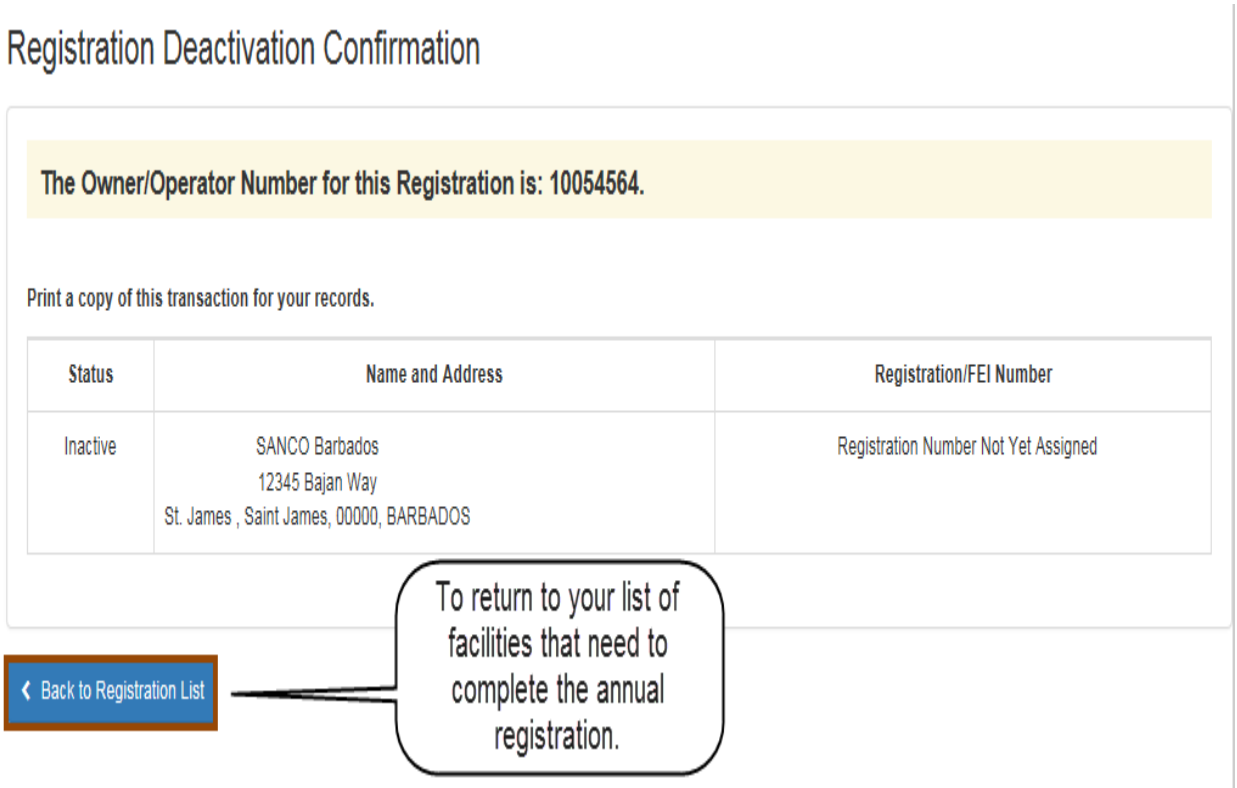
Step 7: You will now see a registration deactivation confirmation screen.

Note: If you want to have a copy of the deactivation confirmation for your records, print a copy now. You will not be able to return to this confirmation page later.

If you have other annual registrations to complete, click on “Back to Registration List”.

Return to Step 5.

If you do not have any other annual registrations to complete, you may select other actions from the DRLM menu or you may return to the Account Management page to log out of FURLS.



Step 8: Review each section of the Registration Review page for accuracy.

Below is an example of a domestic facility Registration Review page. Each section will be discussed on the following pages.

Note: if you are not registered as Initial Importer, you will not see the Imported Products and Manufacturers section of the screen

Registration Review

Facility: SANCO, Rockville, Maryland, UNITED STATES

- Review the information that you provided for your facility.
- Make changes to your facility, listing or imported products information by clicking the Edit button at the top of the corresponding section.
- Make changes to Owner/Operator or Official Correspondent information by clicking on FURLS HOME at the top right corner of your screen.

Facility Information

Edit

Registration Number:	
Initial Importer:	Y
Facility Name:	SANCO
Address:	1234 Rockville Pike, Rockville, Maryland, 20852, UNITED STATES
DUNS Number:	
Foreign Trade Zone:	N
Facility URL:	
Other Business Trade Name(s):	

Owner/Operator Information

Owner/Operator Number:	10054564
Contact Name:	Istvan Nagy
Company:	SANCO
Address:	1234 Rockville Pike Rockville, MARYLAND, 20852, UNITED STATES
Telephone:	301 - 7701234
Fax:	-
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

Official Correspondent Information

Contact Name:	Istvan Nagy
Company:	SANCO
Address:	1234 Rockville Pike Rockville, MARYLAND, 20852, UNITED STATES
Telephone:	301 - 7701234
Fax:	-
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

Device Listings

Edit

Listing Number	Premarket Submission Number/Type	Product Code (s)	Device Name(s)	Activities
D271630	Preamendment	ECX	Cylinder, compressed gas, and valve	Repackager/Relabeler

Imported Products and Manufacturers

Edit

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
COLAB DESIGN PTY LTD	Unit 5, 15-17 Gibbes Street, Chatswood, Sydney, New South Wales, 2067, AUSTRALIA	HQY	Sunglasses (non-prescription including photosensitive)	

Certification Statement

☐ I have reviewed the registration information for the establishment and listing information for the medical devices shown on this page, made any corrections, additions or deletions as may be necessary, and certify that this information is true and correct. I understand that the submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C 1001.

‹ Previous Submit ›

Below is an example of a foreign facility Registration Review page. Each section will be discussed on the following pages.

Facility Information

Registration Number:	
Initial Importer:	N
Facility Name	SANCO Barbados
Address:	12345 Bajan Way St. James , Saint James , 00000 , BARBADOS
DUNS Number:	
Foreign Trade Zone	N
Facility URL:	
Other Business Trade Name(s)	

Owner/Operator Information

Owner/Operator Number:	10054564
Contact Name:	Istvan Nagy
Company:	SANCO
Address:	1234 Rockville Pike Rockville , MARYLAND , 20852 , UNITED STATES
Telephone:	301 - 7701234
Fax:	
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

Official Correspondent Information

Contact Name:	Istvan Nagy
Company:	SANCO
Address:	1234 Rockville Pike , Rockville , MARYLAND , 20852 , UNITED STATES
Telephone:	301-7701234
Fax:	
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

United States Agent Information

Contact Name:	Istvan Nagy
Contact Title	Mr
Business Name	SANCO
Address	1234 Rockville Pike Rockville , Maryland , 20852 , UNITED STATES
Phone:	301 - 7704321
Fax	
DUNS Number	
E-mail Address	steve.nagy@fda.hhs.gov

Device Listings

Edit

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	
D271630	Preamendment	ECX	Cylinder, compressed gas, and valve	Repackager/Relabeler	SANCO
D271623	Exempt	BXL	ALGESIMETER, MANUAL	Repackager/Relabeler	SANCO

Certification Statement

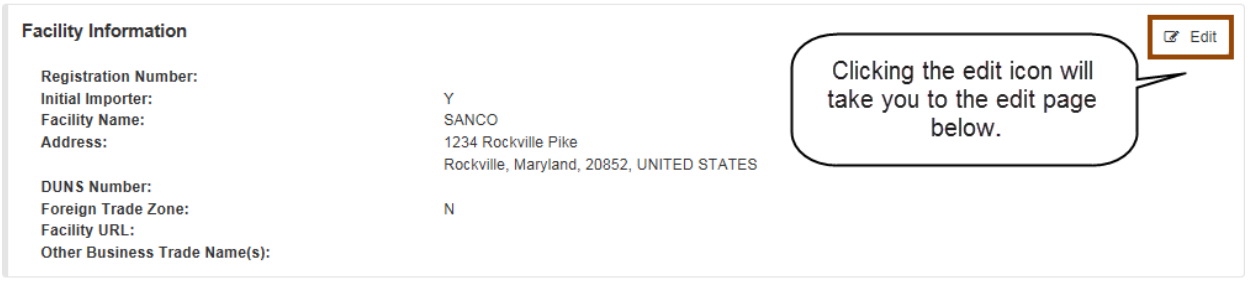
☐ **By clicking the Reactivate Registration button, I certify that the registration and listing information for this medical device facility, as shown on this page, is true. I understand that the submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.**

‹ Back to View Registrations

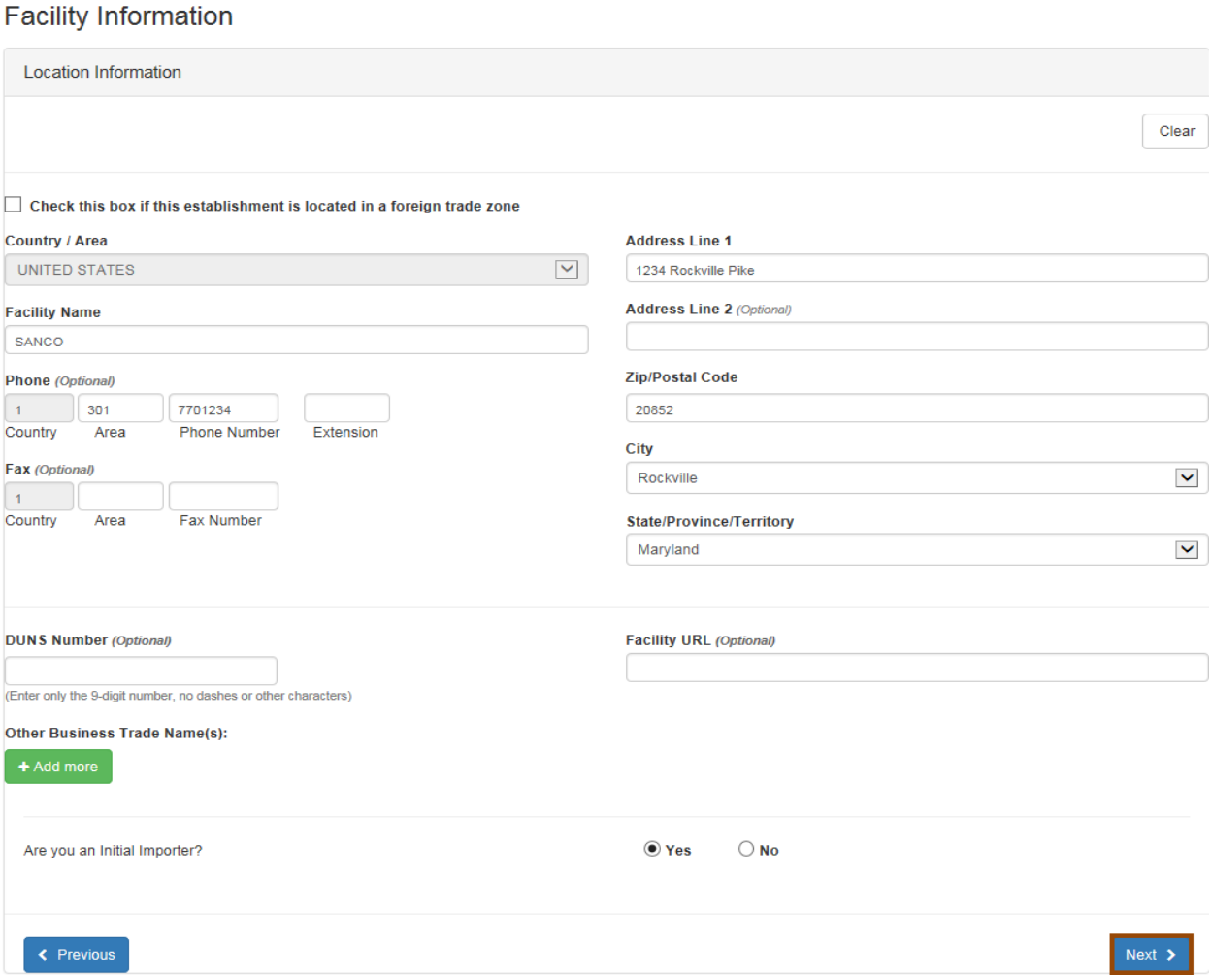
Reactivate Registration ›

Section 1: Facility Information (for domestic and foreign)

If you need to edit facility information, click on the edit icon to go to the edit page.



Edit page:



After making edits, click on “next” to return to the Registration Review page to complete the review of the registration and listing information.

Section 2: Owner/Operator Information & Official Correspondent Information

If you need to update either the owner/operator or official correspondent information, you must click on the FURLS Home link, located at the top right corner of your screen. Clicking on the FURLS Home link will take you out of the annual registration process.

Owner/Operator Information

Owner/Operator Number:	10054564
Contact Name:	Istvan Nagy
Company:	SANCO
Address:	1234 Rockville Pike Rockville, MARYLAND, 20852, UNITED STATES
Telephone:	301 - 7701234
Fax:	-
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

Official Correspondent Information

Contact Name:	Istvan Nagy
Company:	SANCO
Address:	1234 Rockville Pike Rockville, MARYLAND, 20852, UNITED STATES
Telephone:	301 - 7701234
Fax:	-
E-mail:	steve.nagy@fda.hhs.gov
DUNS Number:	

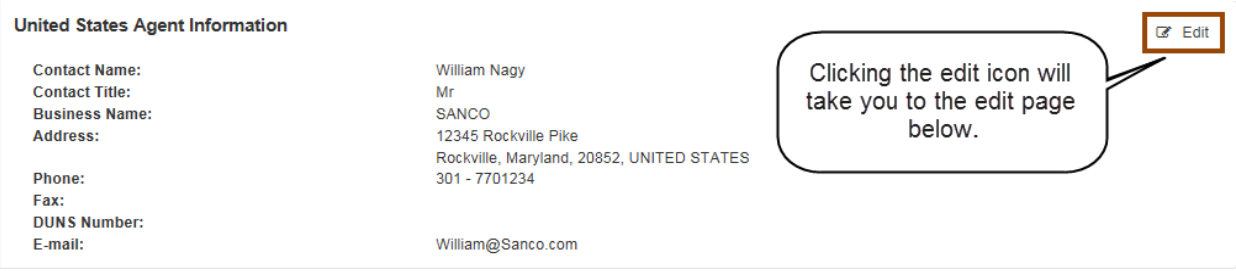
Instructions for updating the owner/operator and official correspondent information is available here: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm#11)

After making updates, return to Step 2 to complete the Annual Registration process.

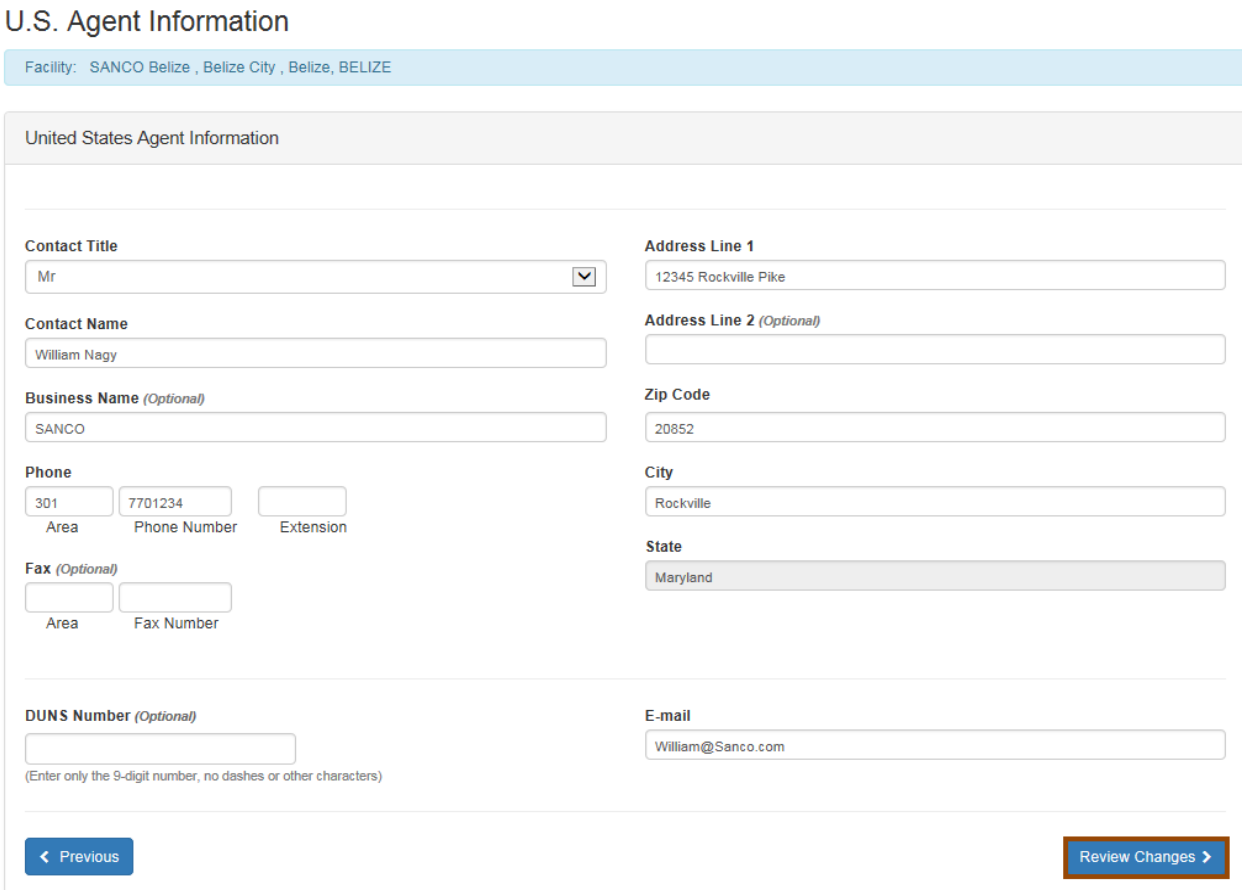
If you do not need to update either the owner/operator or official correspondent information, proceed to the next section below, U.S. Agent information (foreign establishments only). Otherwise, proceed to section 4 to edit Device Listings.

Section 3: U.S. Agent Information (Foreign Registrations Only)

If you need to edit the U.S. Agent information, click on the edit icon to go to the edit page.



Edit page:

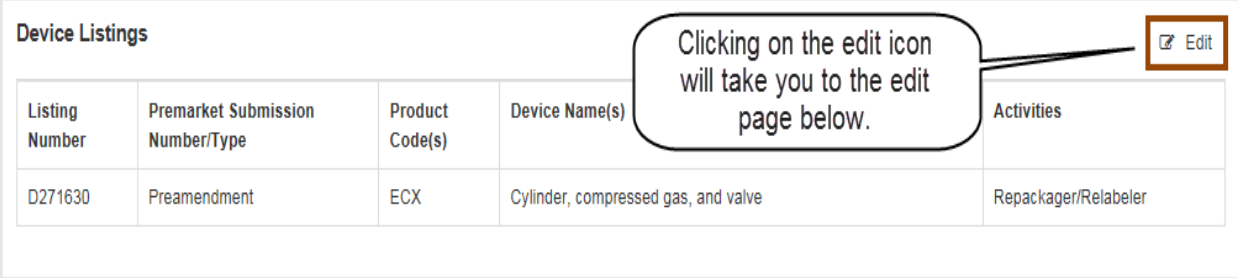


After making edits, click on “Review Changes” to return to the Registration Review page to complete the review of the registration and listing information.

IMPORTANT NOTE: A new feature is being added to FURLS/DRLM beginning with the Fiscal Year (FY) 2018 registration cycle. Each U.S. Agent will receive an email that notifies her/him of the need to verify that she/he agrees to act in this capacity for your registered establishment once the facility registration is complete. The email will provide instructions on how to access and verify the information in FURLS/DRLM. If she/he fails to verify, then FDA will inform the establishment's Official Correspondent and Owner/Operator contact person that a new U.S. Agent must be identified. Failure to provide valid U.S. Agent information will result in the deactivation of your registration. Carefully review this section for accuracy and make any needed corrections before you submit your annual registration. You should consider notifying your U.S. agent of this new verification process, so she/he responds to the FDA email.

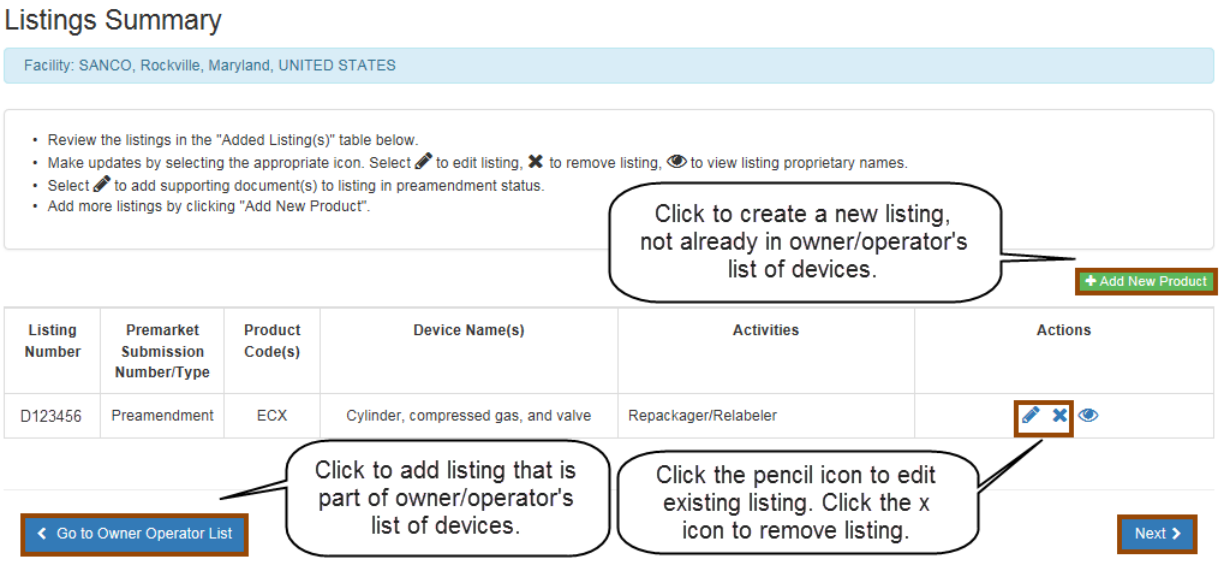
Section 4: Device Listings

If you need to edit listing information, click on the edit icon to go to the edit page.



You will have the choice of editing the existing listing or removing the existing listing. You also may add a new listing from either the existing owner/operator list or by creating a new listing.

Edit page:



After making edits, click on "Next" to return to the Registration Review page to complete the review of the registration and listing information.

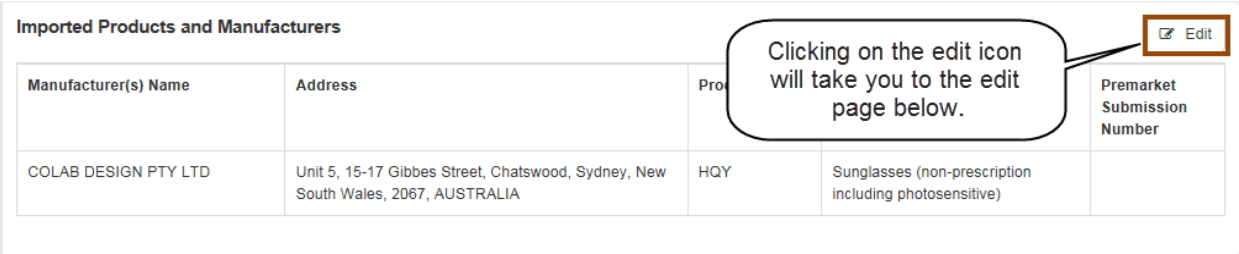
If you have finished reviewing your registration and listing information, please proceed to Section 6: Certification Statement

Important Note about creating a new listing: A new feature is being added beginning with FY 2018 registration cycle that will allow you to create two listings for a product – one

listing for products made in the United States and another listing for the products manufactured for export only. You will no longer be able to add the "U.S. Manufacturer for Export Only" establishment type to an existing listing for a product. You will now be required to create a separate listing for the export only model of the device.

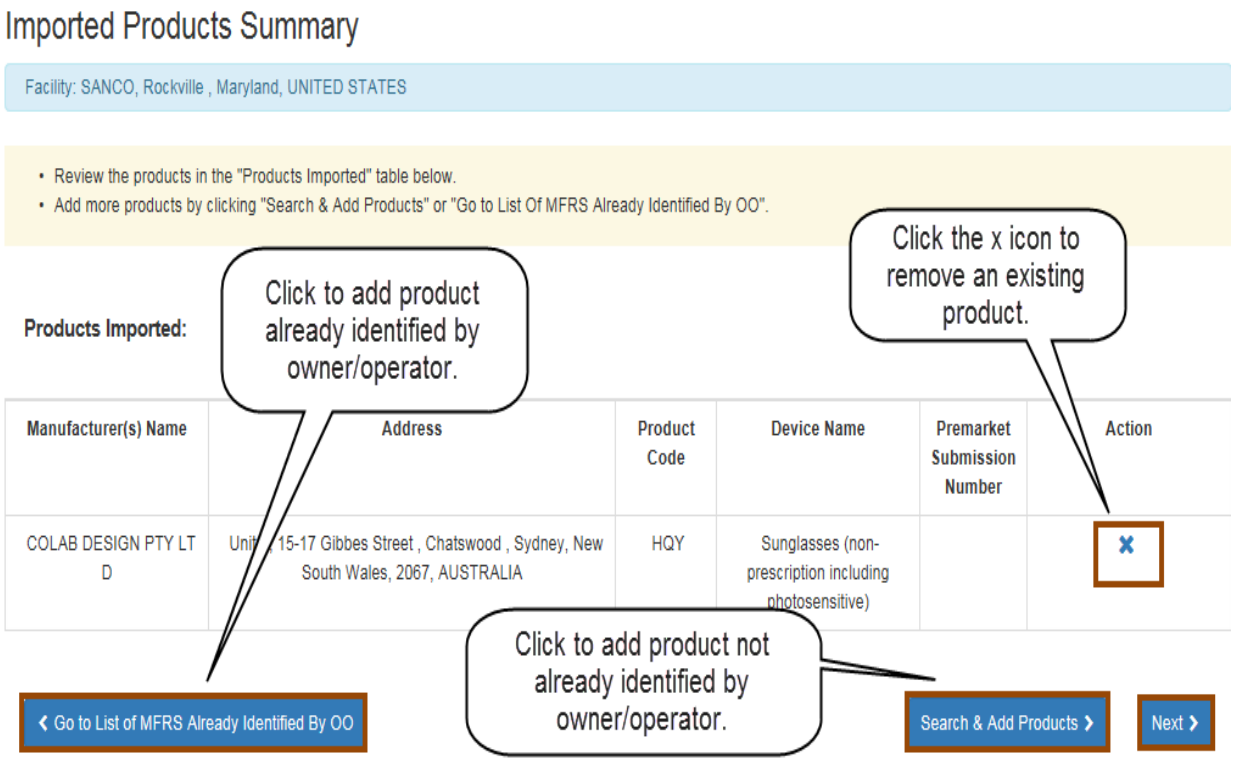
Section 5: Imported Products and Manufacturers (Initial Importers Only)

If you need to edit the imported products information, click on the edit icon to go to the edit page.



If the facility is no longer importing an identified product, you will be able to remove that product. You also may add a new imported product from either the existing owner/operator list or by identifying a new product.

Edit page:

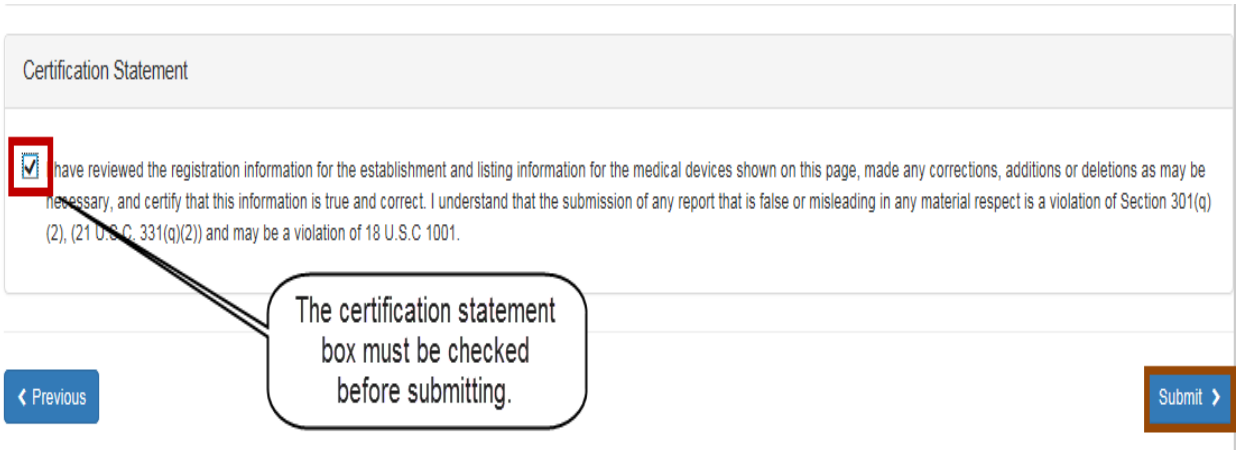


When you have finished making your edits to the Imported Products Summary page, click on "Next" to return to the Registration Review page to complete the

review of the registration and listing information.

Section 6: Certification Statement (for domestic and foreign)

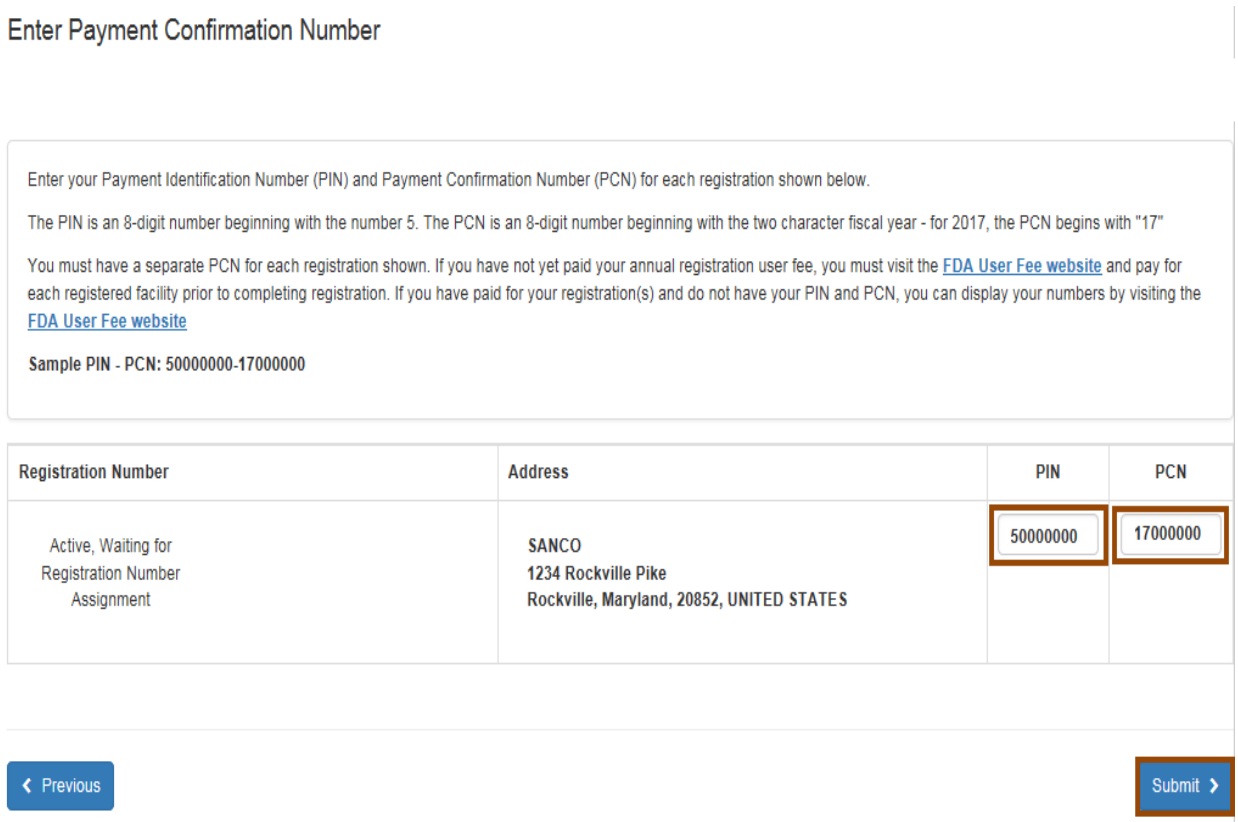
If all information is accurate, check the certification statement box, found at the bottom of the Registration Review page, and then click “Submit”.



Proceed to Step 9.

Step 9: On the Enter Payment Confirmation Number page, enter the 8-digit Payment ID Number (PIN) and 8-digit Payment Confirmation Number (PCN) previously received and click “Submit.”

Proceed to Step 10.



Step 10: The Annual Registration Successful page displays the registration information you have entered.

Annual Registration Successful

Facility: SANCO, Rockville, Maryland, UNITED STATES

You have successfully updated your registration and listing information for 2017.

Your registration will be valid through December 31, 2017.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2017.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 10054564.

Facility Information

Registration Number:	
Initial Importer:	**Y**
Facility Name:	**SANCO**
Address:	**1234 Rockville Pike** **Rockville, Maryland, 20852, UNITED STATES**
DUNS Number:	
Foreign Trade Zone:	**N**
Facility URL:	
Other Business Trade Name(s):	

Owner/Operator Information

Owner/Operator Number:	**10054564**
Contact Name:	**Istvan Nagy**
Company:	**SANCO**
Address:	**1234 Rockville Pike** **Rockville, MARYLAND, 20852, UNITED STATES**
Telephone:	**301 - 7701234**
Fax:	-
E-mail:	**steve.nagy@fda.hhs.gov**
DUNS Number:	

Official Correspondent Information

Contact Name:	**Istvan Nagy**
Company:	**SANCO**
Address:	**1234 Rockville Pike** **Rockville, MARYLAND, 20852, UNITED STATES**
Telephone:	**301 - 7701234**
Fax:	-
E-mail:	**steve.nagy@fda.hhs.gov**
DUNS Number:	

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities
D123456	Preamendment	ECX	Cylinder, compressed gas, and valve	Repackager/Relabeler

Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
COLAB DESIGN PTY LTD	Unit 5, 15-17 Gibbes Street, Chatswood, Sydney, New South Wales, 2067, AUSTRALIA	HQY	Sunglasses (non-prescription including photosensitive)	

Congratulations! This screen means the annual registration has been completed.

A Confirmation email will be sent to the official correspondent with similar information as indicated below:

Dear Istvan Nagy:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2017:

Registration Number:
Owner Operator Number: 10054564
SANCO
1234 Rockville Pike
ROCKVILLE, MD 20852
UNITED STATES

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to reglist@cdrh.fda.gov and include the registration number you believe is assigned to your establishment. We will review and determine if a duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2017. Registration for 2018 will be conducted between October 1 and December 31, 2017.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

You may select another action from the DRLM menu or you may return to the Account Management page to log out of FURLS.