

Welcome

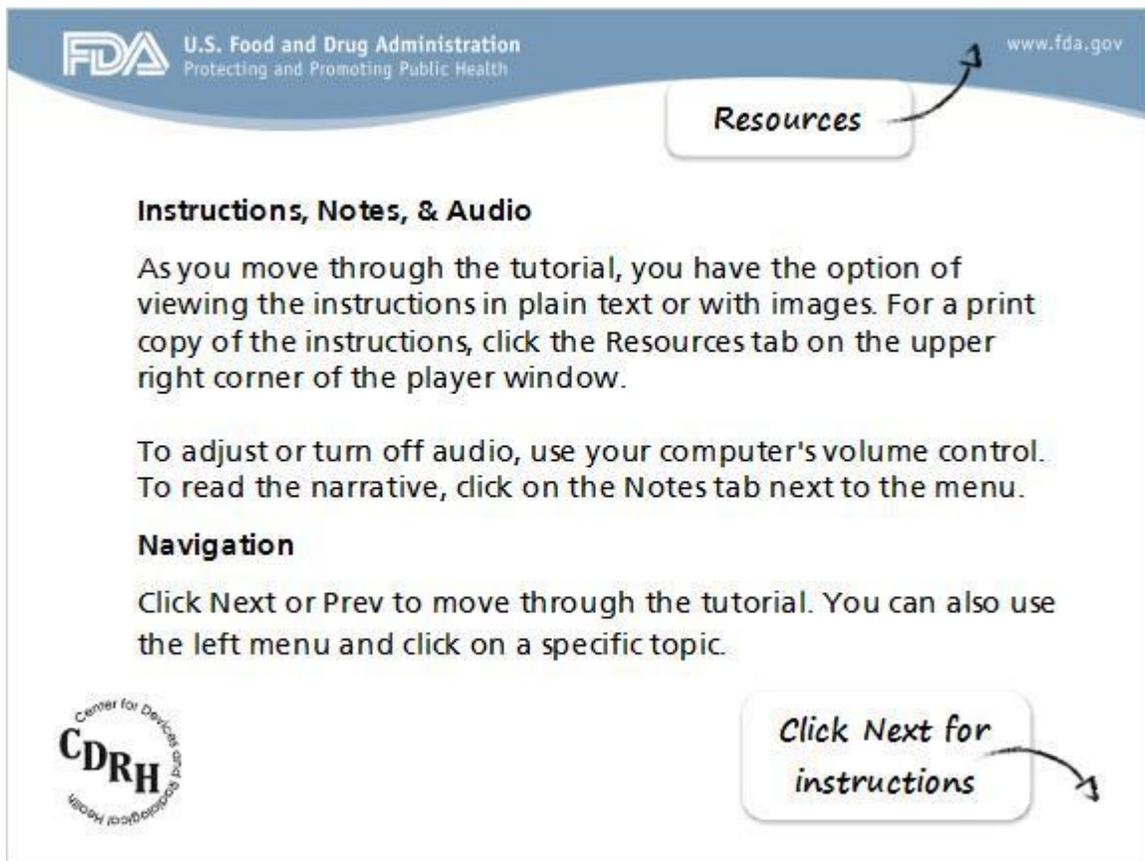


The screenshot shows a web page header with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Public Health" on the left, and the website address "www.fda.gov" on the right. The main content area features a large, bold title "FURLS Device Registration and Listing Module Annual Registration" centered on the page. Below the title, the text "U.S. Food and Drug Administration Center for Devices and Radiological Health" is centered. Further down, the text "Division of Small Manufacturers, International and Consumer Assistance (DSMICA)" is centered. In the bottom left corner, there is a circular logo for the Center for Devices and Radiological Health (CDRH). In the bottom right corner, there is a button labeled "Click Next" with a curved arrow pointing to the right.

Notes:

This tutorial will show you how to complete the annual registration of a medical device facility.

Navigation



The screenshot shows a slide from a tutorial. At the top left is the FDA logo with the text "U.S. Food and Drug Administration Protecting and Promoting Public Health". At the top right is the URL "www.fda.gov". In the upper right corner, there is a button labeled "Resources" with a hand-drawn arrow pointing to it. Below this, the text reads: "Instructions, Notes, & Audio" followed by "As you move through the tutorial, you have the option of viewing the instructions in plain text or with images. For a print copy of the instructions, click the Resources tab on the upper right corner of the player window." The next paragraph says: "To adjust or turn off audio, use your computer's volume control. To read the narrative, click on the Notes tab next to the menu." Below that is the section "Navigation" with the text: "Click Next or Prev to move through the tutorial. You can also use the left menu and click on a specific topic." In the bottom left corner is the CDRH logo (Center for Devices and Radiological Health). In the bottom right corner, there is a button labeled "Click Next for instructions" with a hand-drawn arrow pointing to it.

Notes:

You have the option of viewing the instructions in text or with images in this tutorial. You can also print the instructions by clicking Resources located in the upper corner of the slide.

Instructions



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

Follow these steps to access FURLS or click next to see instructions with images:

1. Click www.access.fda.gov/oa to open the FURLS website in a new browser window.
2. Enter your account ID and password, review the statement, click the radio button next to "I Understand," and "Login" to open the Account Management page.
3. Click "Device Registration & Listing" to open the Important Messages page.
4. When you have your Payment Identification Number (PIN) and Payment Confirmation Number (PCN), click Continue. If you don't have your PIN & PCN, you will need to pay the annual fee on the DFUF Website. It will take at least 48 hours to receive your PCN. Then return to the FURLS website to complete your annual registration.
5. Click "Annual Registration" to open the View Registrations page.
6. Click the radio button next to the facility you wish to re-register, then click "Re-register selected establishment" to open the Review Registration Information page.
7. Review the information to ensure accuracy. Edit as needed, then click "Continue" to open the Review Registration Information page. If no edits are needed, scroll down to Certification Statement.
8. Review the Certification Statement and click the checkbox and then "Submit." If an error message pops up, click the checkbox next to the statement before resubmitting.
9. Enter the PIN & PCN and click Submit.
10. Return to the "Main Menu" to re-register another facility or "Account Management" to log out.

Click Next to view instructions with images 

Notes:

You can start here with the text instructions, or click next to view instructions with images.

Login

The image shows a screenshot of the FDA Industry Systems login page. The page header includes the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Public Health". The main heading is "FDA Industry Systems". There are three callout boxes with instructions:

- 1. Click www.access.fda.gov/oaa to open the FURLS website.** (Points to the top navigation area)
- 2. Enter the Account ID & password for the facility that is being registered...** (Points to the "LOGIN" form fields)
- ... then review the statement and click radio button next to "I Understand" & Login.** (Points to the "I Understand" radio button and the "LOGIN" button)

The login form includes fields for "Account ID" and "Password", a "LOGIN" button, and a "NEW USER" section with links for "Create New Account", "See IF Instructions", "See Tutorials", and "Help Desk". There is also a "SYSTEM STATUS" and "HELP DESK" link at the top.

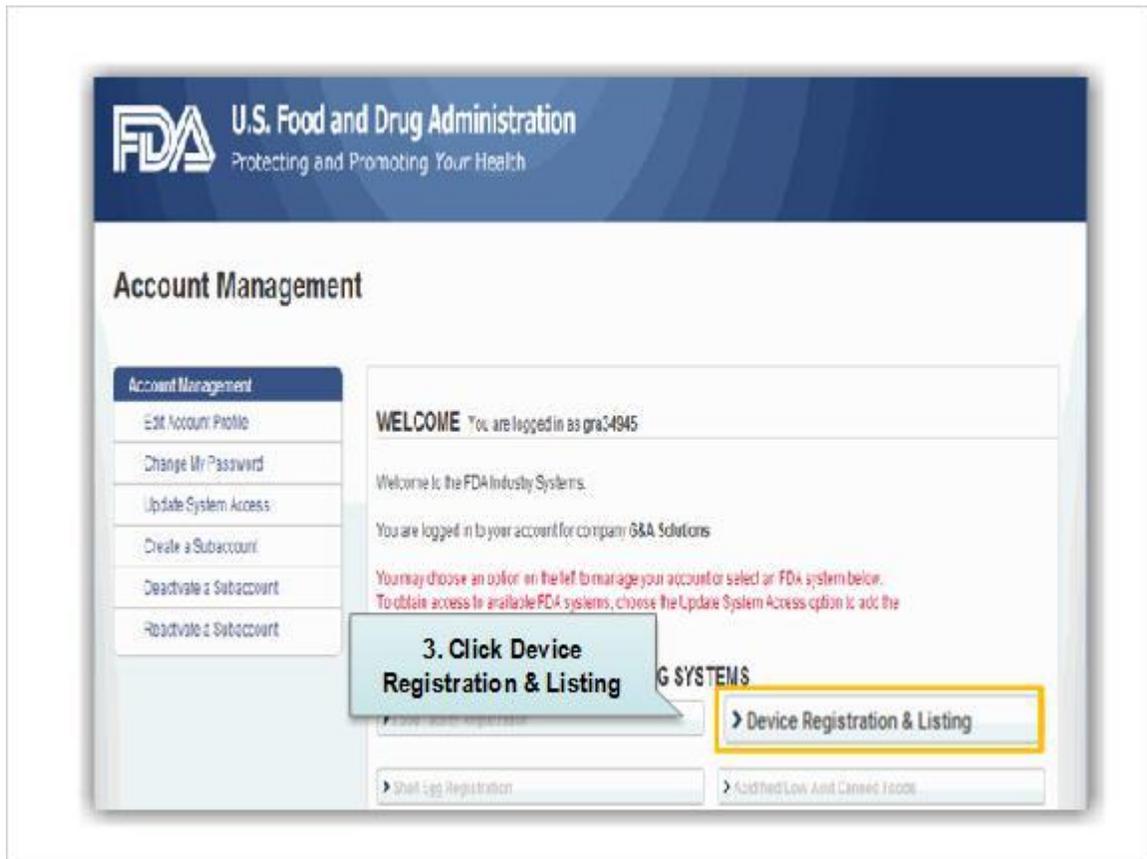
Notes:

For best results, review these instructions with the FURLS website open in another browser window.

1. Go to www.access.fda.gov/oaa to open the FURLS login page.

2. Enter your Account ID & password for the facility that is being registered, then click the radio button next to "I understand" and "Login."

Login



Notes:

3. On the Account Management page, click "Device Registration & Listing" to open the Important Messages page.

Login

DRLM
Device Registration & Listing Module

FURLS HOME
DRLM HOME

IMPORTANT MESSAGES

NEW: The CDRLH Learn Device Establishment Registration and Listing Course has been updated with the current registration and listing requirements. Please visit this website <http://www.fda.gov/Training/CDRLHLearn/ucm162015.htm> to view the course.

The FDA Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. This law includes the Medical Device User Fee Act (MDUFA III) as well as other medical device provisions. In Fiscal Year 2013, an annual registration fee will be required for all businesses or organizations that manufacture, import, or distribute medical devices in the United States. The fee for FY 2013 is \$2,000 for small businesses and \$5,000 for all other groups. For more information, please visit <http://www.fda.gov/MedicalDevices/RegulationandGuidance/Overview/MDUFAIII/default.htm>. You must pay the fee before registering a new establishment or updating your existing registration(s) and/or listing(s) for FY 2013. If you have not paid the fee, please **visit this website**. For assistance with paying the fee, please send an email to device.registration@fda.hhs.gov. FDA primarily communicates with firms by email. To verify that we have the correct email for your account, please click on the FURLS Home link at the top of this page. Then click on the Edit Account Profile button on the left hand side of your screen. If you have already paid the fee for each establishment you are registering or re-registering, please click the Continue button below to proceed to the next step. If you have not yet paid the fee, you will need to click "visit this website" to open the DFUF Website. After you have received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN), return to the FURLS website to complete your annual registration. Note that it takes at least 48 hours to receive an email with the PCN.

4. When you have your PIN & PCN, click Continue to go to the DRLM Main Menu.

> CONTINUE

Notes:

If you have not paid the annual registration fee, you will not be able to complete the annual registration. You will need to click "visit this website" to open the DFUF Website. After you have received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN), return to the FURLS website to complete your annual registration. Note that it takes at least 48 hours to receive an email with the PCN.

4. When you have your PIN & PCN, click "Continue" to open the DRLM Main Menu.

DRLM Main Menu

5. Click Annual Registration to open the View Registrations page.

6. Click the radio button for the facility to be re-registered...

...then click Re-register Selected Establishment.

Notes:

5. On the DRLM Main Menu page click "Annual Registration" to open the DRLM View Registration page.

6. On the View Registrations page, click on the radio button next to the facility to re-register, then click Re-register Selected Establishment to open the Review Registration Information page.

Note: If the facility that you want to select is visible but the radio button is grayed out, you will need to contact the owner/operator contact person and ask to be assigned as the official correspondent. If the facility is missing from the page, return to the DRLM main menu and click "view your registration and listing information" to ensure the annual registration was completed. If the facility is not listed, contact the CDRH Registration and Listing Helpdesk.

Editing

The screenshot shows the 'Annual Re-Registration Review Registration Information' page. On the left, there are five black buttons with white text: 'Facility Information', 'Owner/Operator & Official Correspondent', 'US Agent Information', 'Device Listings', and 'Imported Products & Mfrs'. The main content area has a title 'Annual Re-Registration Review Registration Information' and a 'Get Help' icon. A callout box says '7. Review information for accuracy on the Review Registration Information page.' Another callout points to the buttons: 'Click on each section to learn about editing options.' A third callout points to an 'EDIT' button: 'Click EDIT to make changes in the various sections.' The page also contains an 'Important Notice' and a list of instructions for editing.

Annual Re-Registration
Review Registration Information

7. Review information for accuracy on the Review Registration Information page.

Click on each section to learn about editing options.

Click EDIT to make changes in the various sections.

Important Notice: You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.

- Make changes to your facility or listing information by clicking the Edit button at the top of the corresponding section.
- Make changes to Owner/Operator or Official Correspondent information by clicking Submit, then select "Return to Account Management" on the next page.

> EDIT

Notes:

7. You have a number of editing options to update information. To learn more about editing each section, click on the topic buttons.

Click "EDIT" on each section to edit the specified information.

Click "Continue" when you are done editing to go back to the Review Registration Information page and scroll down to the Certification Statement.

Facility Information

The screenshot displays a web interface for managing facility information. On the left, there is a vertical navigation menu with five buttons: "Facility Information", "Owner/Operator & Official Correspondent", "US Agent Information", "Device Listings", and "Imported Products & Mfrs". The main content area is divided into two sections. The top section, titled "Facility", shows a summary of the facility's details: Registration Number (N), Initial Importer (Grady East), Facility Name (7001 Zongchun Road), Address (Shanghai, Shanghai, 201101, CHINA), DUNS Number, and Foreign Trade Zone (M). A yellow box highlights an "EDIT" button in the top right corner of this section. A light blue callout box with a speech bubble icon contains the text: "To correct facility information, click EDIT to open Update Facility Information." The bottom section is titled "Update Facility Information" and contains a form with the following fields: "Choose Country/Area where Facility is Located:" (dropdown menu set to CHINA), "Facility Name:" (text input: Grady East Manufacturing), "Address Line 1:" (text input: 7001 Zongchun Road), "Address Line 2:" (text input: B Building, Suite 512), "Postal Code:" (text input: 201101), "City:" (text input: Shanghai), "Foreign State:" (text input: Shanghai), "Phone:" (Country Code: 86, Area/City Code, Phone Number, Extension), and "Fax:" (Country Code: 86, Area/City Code, Fax Number). A red note at the top of the form states: "Fields marked with an asterisk (*) are required."

Notes:

Facility Information: Click "EDIT" to update facility information. However, if the country/area needs editing, you will need to contact the CDRH Registration & Listing Helpdesk.

Owner/Operator and Official Correspondent

The screenshot displays a web interface with a left-hand navigation menu and a main content area. The navigation menu includes five buttons: "Facility Information", "Owner/Operator & Official Correspondent", "US Agent Information", "Device Listings", and "Imported Products & Mfrs". The "Owner/Operator & Official Correspondent" button is highlighted. The main content area shows a "Review Registration Information page" with two forms: "Owner/Operator Information" and "Official Correspondent Information". A light blue callout box at the top right contains instructions: "Instructions for how to edit the owner/operator and official correspondent information is available [here](#). After editing you will need to start the registration process from step # 3." The "Owner/Operator Information" form contains the following details:

Contact Name:	Patricia Grady
Company:	G&A SOLUTIONS
Address:	po box 5304 Springfield , VIRGINIA , 22150 , UNITED STATES
Telephone:	1- 571 - 5775077
Fax:	

The "Official Correspondent Information" form contains the following details:

Contact Name:	Patricia Grady
Company:	G&A SOLUTIONS
Address:	po box 5304 Springfield , VIRGINIA , 22150 , UNITED STATES
Telephone:	1 571 - 5775077
Fax:	
E-mail:	patricia.grady@fda.hhs.gov
DUNS Number:	123456789

Notes:

Owner/Operator Information & Official Correspondent Information: Instructions for how to edit this information is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm#11>. After editing, you will need to start the registration process from step #3.

US Agent

United States Agent Information **> EDIT**

Contact Name: Steven Nagy
Contact Title: Mr
Business Name: SANCO
Address: 12345 Rockville Pike
Rockville, Maryland, 20852, UNITED STATES
Phone: 301 - 7701234
Fax:

Annual Re-Registration
Update U.S. Agent Information Get Help

FACILITY: GRADY EAST MANUFACTURING, SHANGHAI, SHANGHAI, CHINA

Fields marked with an asterisk (*) are required.

Contact Name:* Steven Nagy
Contact Title: Mr
Business Name: SANCO
Address: 12345 Rockville Pike
Address: 12345 Rockville Pike
Zip: 20852
City:* Rockville

< BACK **> Review Changes**

Click EDIT to open the Update US Agent Information page.

Click Review Changes when you are done.

Notes:

US Agent Information: Click "EDIT" to change information on the Update US Agent Information page. When you are done, click "Review Changes" to make sure your changes are correct.

Device Listings

The screenshot shows a software interface for managing device listings. On the left is a vertical navigation menu with five items: Facility Information, Owner/Operator & Official Correspondent, US Agent Information, Device Listings (highlighted), and Imported Products & Mfrs. The main content area is titled 'Device Listings' and features a table with columns: Listing Number, Premarket Submission Number/Type, Product Codes, and Device Name. A callout box points to a '> ADD, EDIT OR DELETE' button above the table. Below the table, the facility name is displayed: 'FACILITY: GRADY EAST MANUFACTURING, SHANGHAI, SHANGHAI, CHINA'. A second table below shows a listing with a radio button selected. A callout points to this radio button with the text: '..then, click radio button to select device.' To the right of this table, another callout points to buttons labeled '> REMOVE this PRODUCT from FACILITY'S LISTINGS', '> EDIT SELECTED LISTING', and '> ADD NEW PRODUCT' with the text: 'To REMOVE, ADD, or EDIT device, click on appropriate button.' At the bottom of the interface are buttons for '< Go to OWNER OPERATOR LIST', '< CANCEL - RETURN to MAIN MENU', and '> CONTINUE'.

Notes:

Device Listings: Click the radio button to select the device that needs updating. Then click "add, edit or delete" to add, remove or edit device information.

Imported Products

The screenshot shows a software interface for managing imported products. On the left is a vertical navigation menu with five items: Facility Information, Owner/Operator & Official Correspondent, US Agent Information, Device Listings, and Imported Products & Mfrs. The main content area is titled 'Imported Products and Manufacturers' and features a table with columns for Manufacturer(s) Name, Address, Name, and Premarket Submission Number. Two rows of data are visible, both for 'OTTO BOCK MANUFACTURING KONIGSEE GMBH'. A yellow callout box points to an '> ADD OR DELETE' button. Another callout points to the table with the text 'Click ADD OR DELETE to open the Products Imported page.' Below the table is a section titled 'PRODUCTS IMPORTED:' with a table containing columns for Product Code, Device Name, and Premarket Submission Number. A callout points to a radio button in the first row of this table with the text 'Click radio button to select product.' Below the table are three callouts: '...then click to remove products no longer imported.' pointing to a '> REMOVE THIS PRODUCT' button; '...or to add a product from previously identified mfrs.' pointing to a '< Go to LIST OF MFRS ALREADY IDENTIFIED BY OO' button; and '...or to add product from new mfr.' pointing to a '> SEARCH & ADD MFR'S PRODUCTS' button. At the bottom are two buttons: '< CANCEL - RETURN to MAIN MENU' and '> CONTINUE'.

Manufacturer(s) Name	Address	Name	Premarket Submission Number
OTTO BOCK MANUFACTURING KONIGSEE GMBH	LINDENSTRASSE 13, KONIGSEE, THURINGEN, D-07426, GERMANY	WHEELCHAIR, MECHANICAL	K052081
OTTO BOCK MANUFACTURING KONIGSEE GMBH	LINDENSTRASSE 13, KONIGSEE, Thuringen, D-07426, GERMANY	WHEELCHAIR, MECHANICAL	K951847

Product Code	Device Name	Premarket Submission Number
...	WHEELCHAIR, MECHANICAL	K052081

Notes:

Imported Products and Manufacturers: Click "ADD OR DELETE" to remove products that are no longer imported, to add a product from a list of previously identified manufacturers, or add a product from a new manufacturer."

Certificate

The screenshot shows a web form titled "Certification Statement". At the top, there is a checkbox that is checked, with a callout box pointing to it that says "8. Read statement and click the checkbox...". Below this is a text area containing an "Important Notice" about the FDA User Fee website and Payment Confirmation Number (PCN). A second callout box points to the text area, saying "If an error message pops up, check the box above." At the bottom of the form, there are three buttons: "BACK to DISPLAY REGISTRATIONS", "CANCEL - RETURN to MAIN MENU", and "SUBMIT". A third callout box points to the "SUBMIT" button, saying "...then click Submit." In the foreground, a "Windows Internet Explorer" error message box is visible, with the text "Click the Certification Statement box." and an "OK" button.

Notes:

8. On the Review Registration Information page, scroll down to the Certification Statement. Review the statement and click the checkbox and then "Submit." If you get an error message, click the checkbox next to the statement before trying to resubmit.

Payment

Annual Re-Registration

Enter Payment Confirmation Number

Enter your Payment Identification Number (PIN) and Payment Confirmation Number (PCN) for each registration shown below.

The PIN is a 8-digit number beginning with the number 5. The PCN is an 8-digit number beginning with the two character fiscal year - for 2013, the PCN begins with "13".

You must have a separate PCN for each registration. If you have not yet paid your annual registration user fee, you must visit the [FDA User Fee website](#) to complete your registration. If you have paid for your registration(s) and do not have your numbers by visiting the [FDA User Fee website](#).

9. Enter the PIN & PCN...

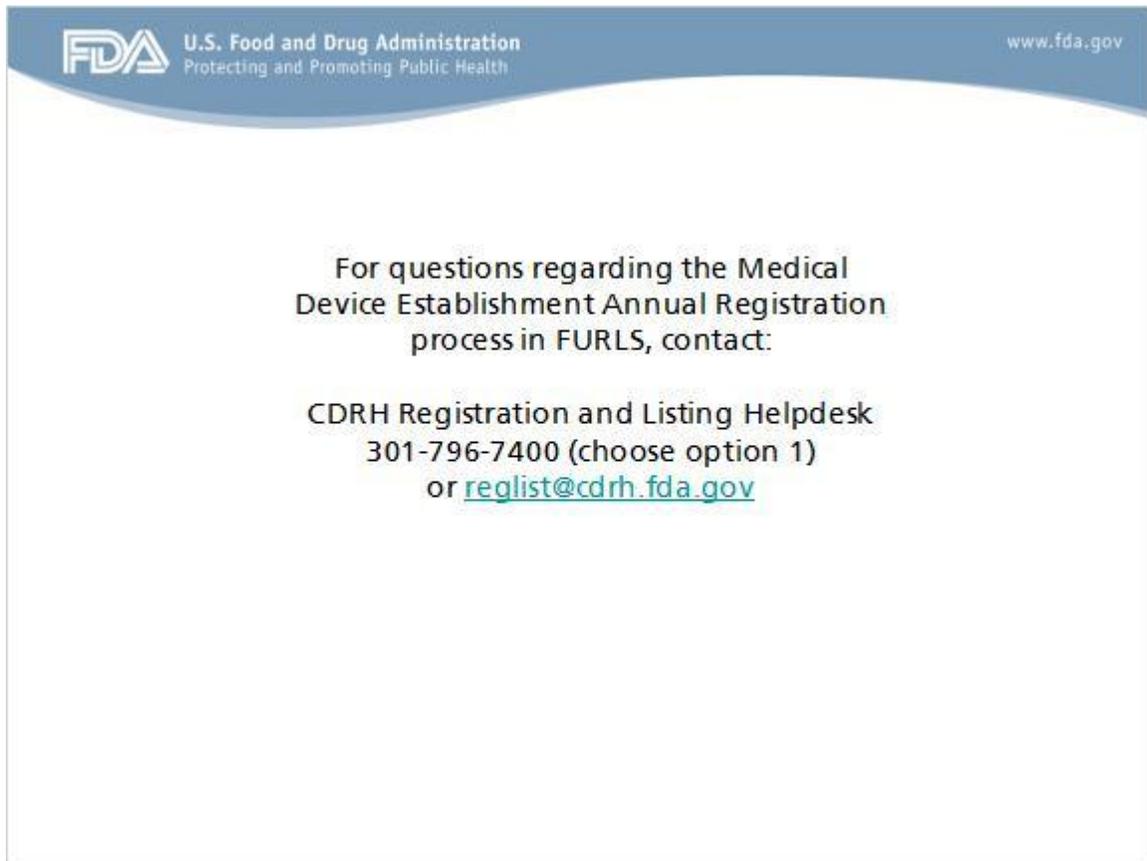
Registration Number	Address	PIN	PCN
Active, Waiting for Registration Number Assignment	Grady East Manufacturing, 7001 Zongchun Road, B Building, Suite 512, Shanghai, CHINA	<input type="text"/>	<input type="text"/>

...then click Submit

Notes:

9. On the Enter Payment Confirmation Number page, enter the PIN & PCN. Note that you must have a unique PIN & PCN to register each facility. When you click Submit, print out a copy of the annual registration for your records.

Contact Information



The image is a graphic with a blue header and a white body. The header contains the FDA logo, the text "U.S. Food and Drug Administration" and "Protecting and Promoting Public Health", and the website "www.fda.gov". The body contains the following text:

For questions regarding the Medical Device Establishment Annual Registration process in FURLS, contact:

CDRH Registration and Listing Helpdesk
301-796-7400 (choose option 1)
or reglist@cdh.fda.gov

Notes:

Please contact us if you have any questions about the re-registration process.