Enter a Certificate of a Pharmaceutical Product (CPP) Application Step-by-Step Instructions

April, 2016

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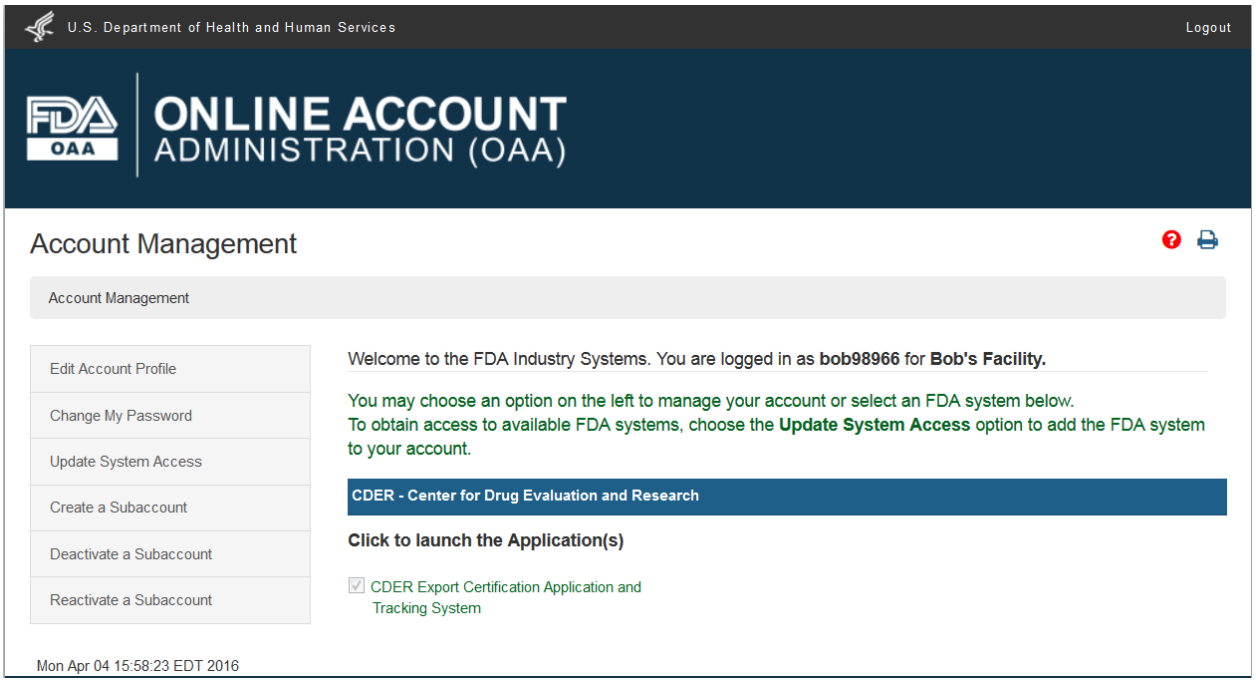
Enter a Certificate of a Pharmaceutical Product (CPP) Application

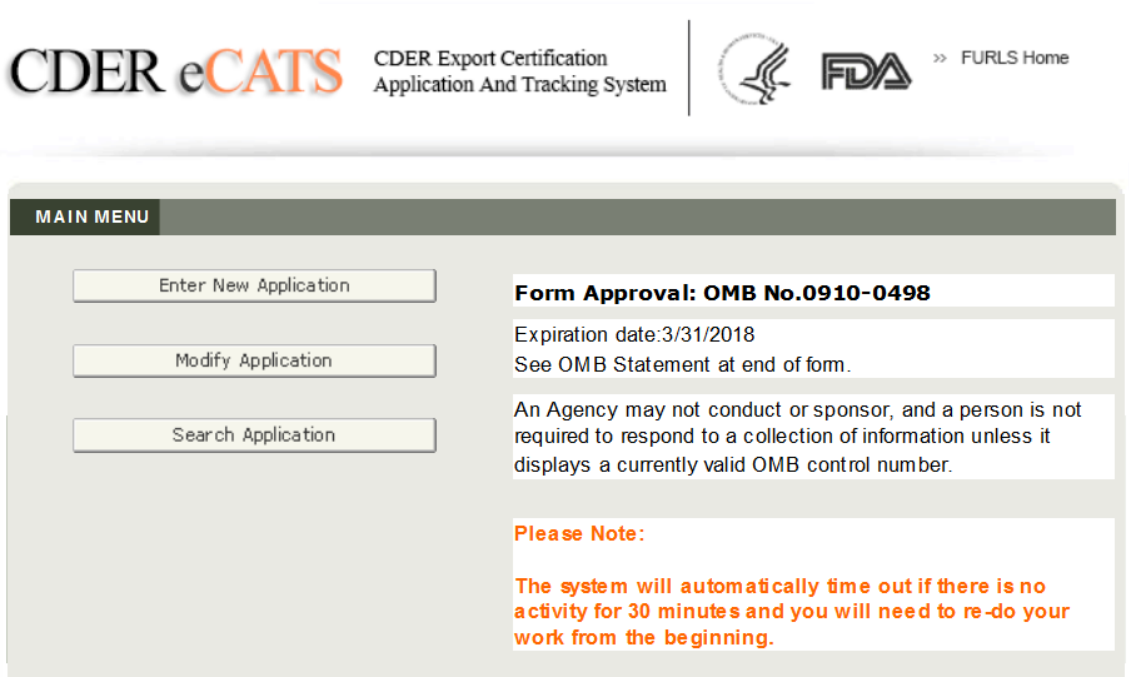
After you have logged into the FDA Industry Systems, select **CDER Export Certification Application & Tracking System** from the list of systems available on the FURLS Home Page as shown in **Figure 1** below.

Figure 1: FDA Industry Systems Page



Once you have selected **CDER Export Certification Application & Tracking System**, the system will navigate you to the CDER eCATS Main Menu page as shown in **Figure 2** below.

Figure 2: CDER eCATS Main Menu

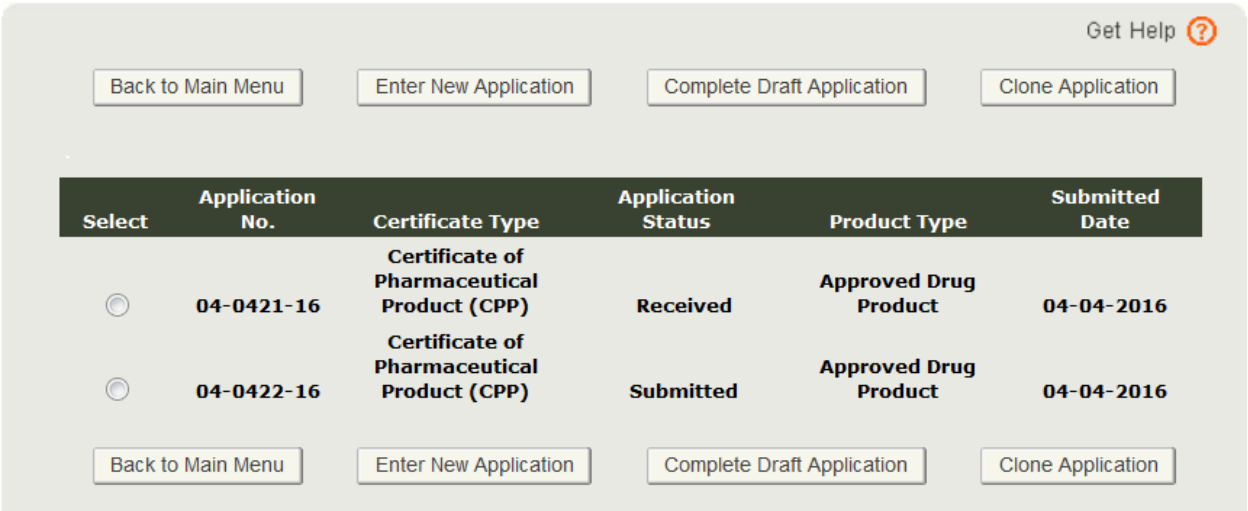


To begin the application process, select 'Enter New Application' from the list of options. You may select 'Modify Application' (when applicable) or 'Search Application' from the main menu.

After you select the 'Enter New Application' option, the system will display all applications that you have saved or submitted as shown in **Figure 3** below.

NOTE: If this is your first application, you will be directed the General/Contact Information page shown in **Figure 4a**.

Figure 3: Account Applications



Applications that are saved but not submitted will be in 'Draft' status until you submit the application.

- If you wish to continue working on an application that has been saved, select the desired application radio button and click on 'Complete Draft Application'.

- If you wish to copy an existing application, select the desired application radio button and click on 'Clone Application'. Please refer to 'Create an application based on the existing application' section under the Modify Application of this document for more details.

- If you wish to create a new application, click on 'Enter New Application'.

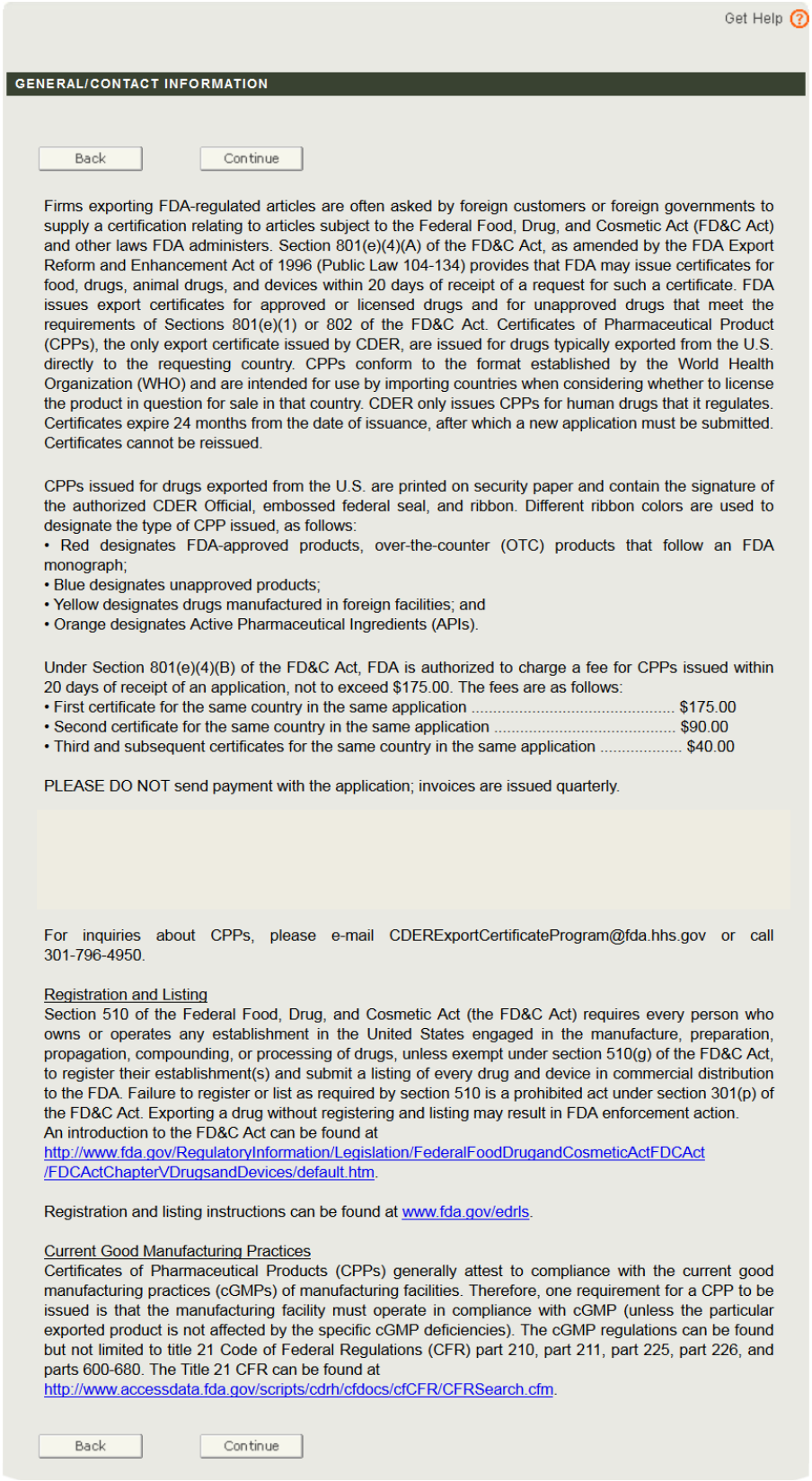
Click on 'Enter New Application' to create a new application.

General/Contact Information

Prior to creating a new application, please read and review the general information and guidelines regarding exporting drug products as shown in **Figure 4a and Figure 4b** below. If you have any questions, please refer to the links provided. Click on 'Continue' to begin the application process.

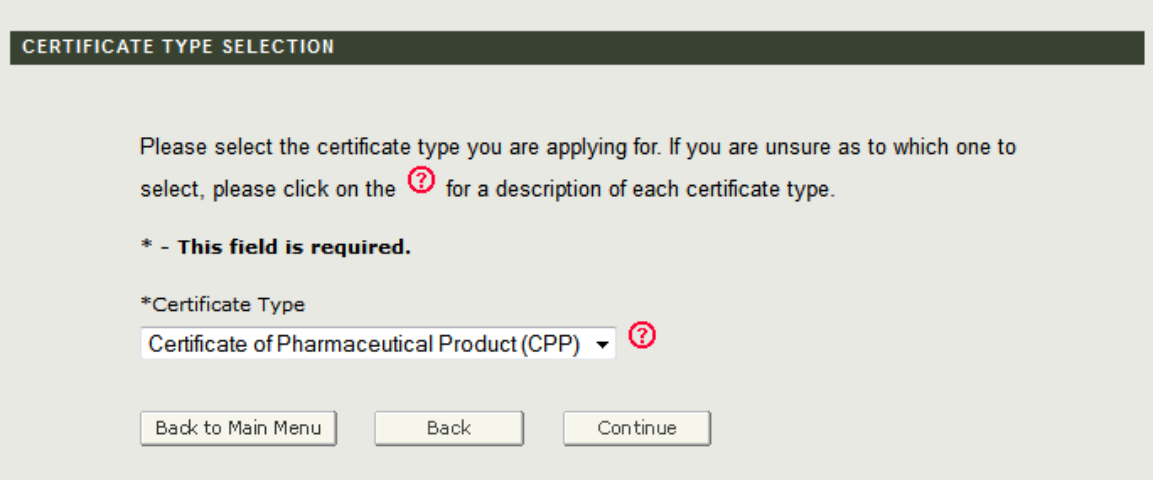
Figure 4a: General/Contact Information

Figure 4b: General/Contact Information (cont.)



The Center for Drug Evaluation and Research (CDER) issues the Certificate of Pharmaceutical Product. Please select 'Certificate of Pharmaceutical Product' from the Certificate Type dropdown list as shown in **Figure 5** below.

Figure 5: Certificate Types



Select Certificate of a Pharmaceutical Product (CPP)

Description of Certificate Types:

CPP	Certificate to a Pharmaceutical Product, World Health Organization (Labeling required)
Pilot Certificate of Pharmaceutical Product	Certificate to a Pharmaceutical Product that are exported from one foreign country to another
Simple Notification	Simple Notification (Requires persons exporting a drug or device under section 802(b)(1) of the Act to provide a "simple notification identifying the drug or device when the exporter first begins to export such drug or device" to any country listed in section 802(b)(1) of the Act. If the product is to be exported to an unlisted country, section 802(g) of the Act requires the exporter to provide a simple notification "identifying the drug or device and the country to which such drug or device is being exported.)

To view the definitions of the product types for which you can request an Export Certificate in CDER eCATS, click on the red question icon located next to the certificate type list. The system will display in a new window with a description of each certificate type as shown in **Figure 6** below**.**

Figure 6: Certificate Type Description

Certificate to a Pharmaceutical Product (CPP)

An export certificate is a document prepared by FDA certifying that the food, drug, animal drug, or device being exported meets the applicable requirements of the Federal Food, Drug, and Cosmetic Act. In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States or meet specific U.S. regulations, for example current Good Manufacturing Practice (cGMP) regulations. At the current time CDER only issues one type of export certificate, the Certificate of a Pharmaceutical Product (CPP). CPPs issued conform to the format established by the World Health Organization (WHO) and are intended for use by the importing country when considering whether to license the product in question for sale in that country.

Foreign Exported Certificate of a Pharmaceutical Product (CPP)

CDER's Export Certificate Program currently issues CPPs for FDA-approved products that are exported from one foreign country to another. This program began as a pilot in February 2005, and continues to date. CDER implemented the program to accommodate industry's request to provide foreign importing countries with FDA-issued CPP for FDA-approved products, even though the product is not manufactured and exported from the United States. Foreign Exported CPPs will be issued on security paper and signed by the CDER approving official. The CPP will not contain attachments, a ribbon, or embossed federal seal. The criteria for applying for a foreign exported CPP:

1. The product is approved by the FDA under a New Drug Application, an Abbreviated New Drug Application, or a Biologics Licensing Application regulated by CDER;
2. The product is not approved by the exporting country, and it is not possible for the manufacturer to obtain the necessary CPP from a country other than the United States;
3. The product is manufactured according to the requirements of its FDA approval;
4. A signed cover letter with the application requesting the Foreign Exported CPP should state that the above requirements are met and include the following statement:
   "We certify that [product name] is manufactured in [name of foreign country of manufacture] according to the requirements of its approval in the United States and will be exported from [name of foreign country of manufacture] to [name of importing country]. We further certify that [product name] is not authorized for marketing in [name of foreign country of manufacture] and that the necessary Certificate of Pharmaceutical Product cannot be obtained from that country or any other country;"
5. The product meets all other requirements for issuance of a CPP.
   Please share notice of this procedural change with others in your firm who have a reason to know and with the foreign governmental authorities with whom you do the business.

NOTE: At this time the Certificate of a Pharmaceutical Product is the only certificate type that can be requested online. For the Simple Notification, please fill out and send the appropriate application form to the following address:

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
10903 New Hampshire Avenue, Building 51, Room 4249
Silver Spring, MD 20993-0002

CDERExportCertificateProgram@fda.hhs.gov

Navigation

At the top of every page during the Enter New Application process, a status bar will track your progress through each step of the online application process as shown in **Figure 7** below.

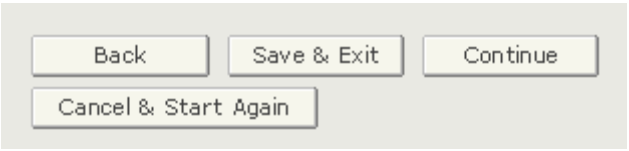
Figure 7: Navigation Bar

A 'Get Help' icon, located at the top right of each step, will provide page specific help. For an overview of all help files available, please refer to the FDA Industry Systems Index of Help Pages at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm

The 'FURLS Home' link, located at the top right corner of each page, will take you to the FURLS Home Page. The 'CDER eCATS Home' link, located below the 'FURLS Home' link, will take you to the CDER eCATS Main Menu Page (Refer to **Figure 1 and Figure 2**). To log out of the system, select 'FURLS Home' and click on logout.

At the top and bottom of each screen are navigation buttons as shown in **Figure 8** below.

Figure 8: General Navigation Buttons



- **Back** - Go back one screen and continue entering application information. Information entered on the current screen will NOT be saved.
- **Save & Exit** - Information entered up to this point will be saved. The system will provide you with an application number and your application will be in a 'Draft' status in the system for 30 days. After 30 days the application will be deleted from the system. When you log into the CDER eCATS system, any applications that are in a 'Draft' status will be displayed after selecting the 'Enter New Application' option from the main menu.
- **Continue** - Go to the next screen and continue entering the application form.
- **Cancel & Start Again** - The system will return you to the screen where you enter your selected the Certificate Type. Any information you have entered will NOT be saved.

Step 1 - Applicant Information

The applicant is the owner of the account from which the application is filed, and the person requesting the export certificate. The applicant is responsible for completing and signing the application form.

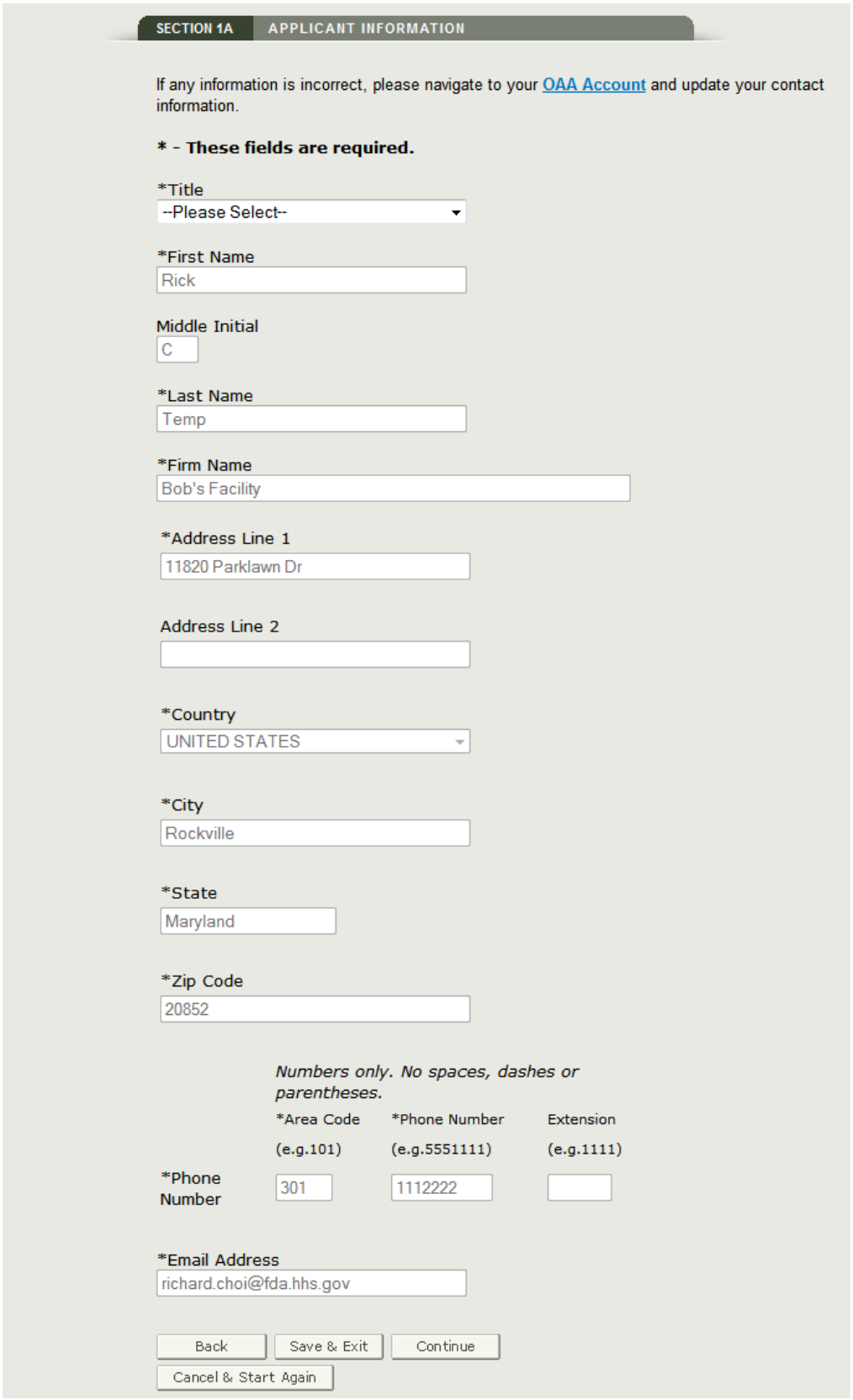
Most of the fields in section one are automatically populated based on the information from your Online Administration Account (OAA) and cannot be edited in CDER eCATS. If the information is incorrect, you can click on the '**OAA Account**' hyperlink and login into your OAA.

You can also click on the 'FURLS Home' link, located in the top right corner and select 'Edit Account Profile' on the left-hand side and update your account profile accordingly. Once you have updated your account, navigate back to CDER eCATS and verify your changes.

Fields marked with an asterisk (*) are mandatory.

Once you have completed this section, click on Continue. See **Figure 9** below.

Figure 9: Applicant Information



SECTION 1A APPLICANT INFORMATION

If any information is incorrect, please navigate to your OAA Account and update your contact information.

* - **These fields are required.**

*Title
--Please Select--

*First Name
Rick

Middle Initial
C

*Last Name
Temp

*Firm Name
Bob's Facility

*Address Line 1
11820 Parklawn Dr

Address Line 2

*Country
UNITED STATES

*City
Rockville

*State
Maryland

*Zip Code
20852

Numbers only. No spaces, dashes or parentheses.

	*Area Code (e.g.101)	*Phone Number (e.g.5551111)	Extension (e.g.1111)
*Phone Number	301	1112222	

*Email Address
richard.choi@fda.hhs.gov

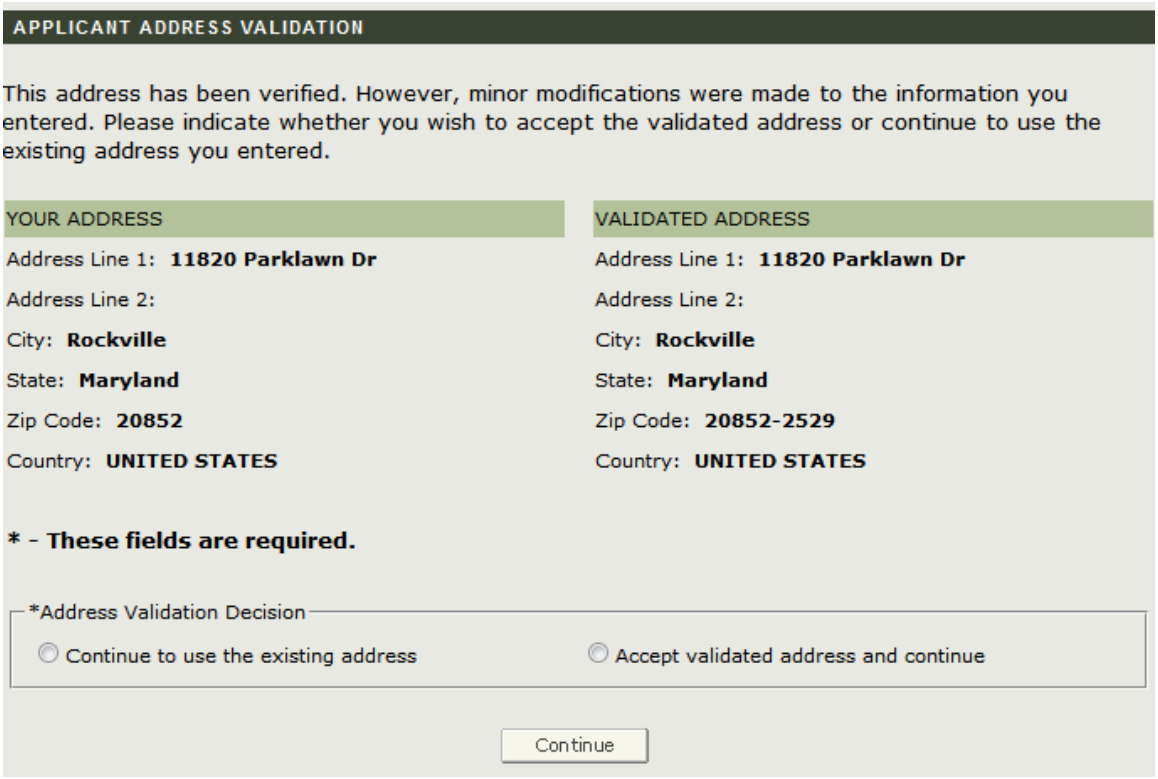
Back | Save & Exit | Continue

Cancel & Start Again

Address Validation

The system will perform an address validation. The system will display the 'Validated Address' if there are minor differences to the requestor address. If the address is incorrect, you will need to exit the application and make the necessary updates to your Online Account Administration. If you wish to use the address without any changes, select 'Continue to use the existing address' radio button and click on Continue. Otherwise, select the 'Accept validated address and continue' radio button and click on Continue to proceed to Step 2. See **Figure 10** below.

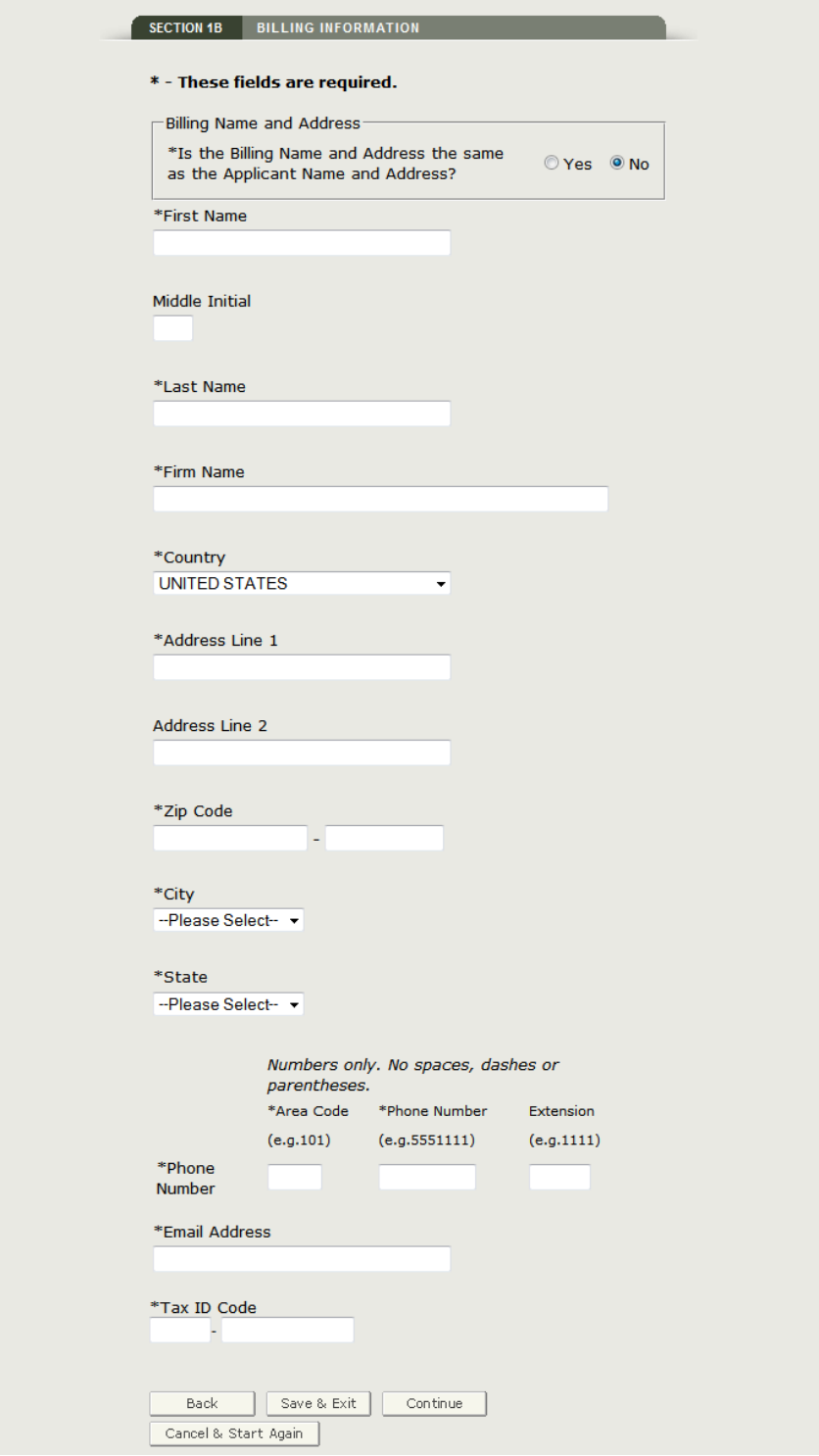
Figure 10: **Address Validation**



Billing Address

You will need to verify if the billing name and address is the same as the applicant name and address. If it is NOT the same as the applicant name and address, select 'No' and enter the billing name and address information. Also, you must provide the Tax ID Code or you will not be able to continue with the application process as shown in **Figure 11** below.

Figure 11: **Billing Address**



Once you have completed this section, click on ‘Continue’.

NOTE: The system will perform an address validation check if you entered a new billing address. The system will display the ‘Validated Address’ if there are minor differences to the billing

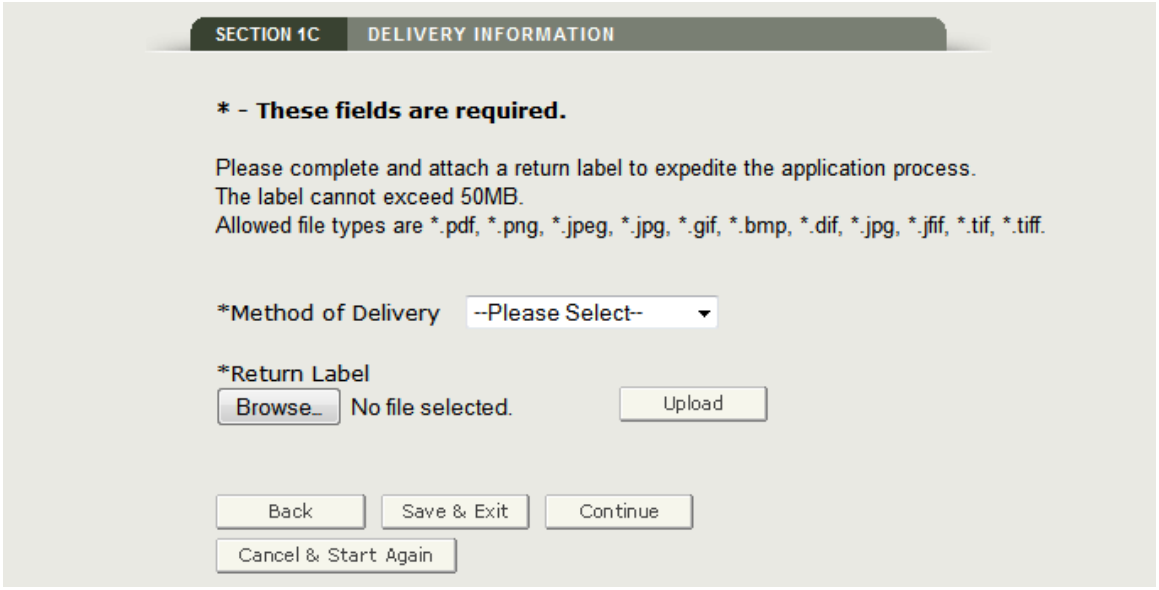
address. If the address is incorrect, you will need to update the billing address from the previous screen. Otherwise, select the 'Accept validated address and continue' radio button and click on 'Continue'.

Method of Delivery

You can select the method of delivery from a dropdown list shown in **Figure 12** below. You must select either FedEx or UPS. Once you have made your carrier selection, you must also completely fill out (both sender and receiver sections of the return label) and attach the return label file as part of the application.

NOTE: Please enter FDA information in the sender section and your contact name and address in the receiver section of the return label.

Figure 12: **Method of Delivery**



Step 2:

Section 2A - General Product Information

Please select 'Yes' or 'No' if the drug product is licensed to be placed on the market in the United States as shown in **Figure 13** below.

NOTE: Click on the '**licensed or approved**' hyperlink to view the definition.

Select the product type from the following dropdown list also shown in **Figure 13**:

- Approved Drug Product
- Over-the-Counter (OTC)
- Active Pharmaceutical Ingredient (API)
- Unapproved Drug Product

NOTE: Click on the icon to view the definition for each product type.

Figure 13: **General Product Information**

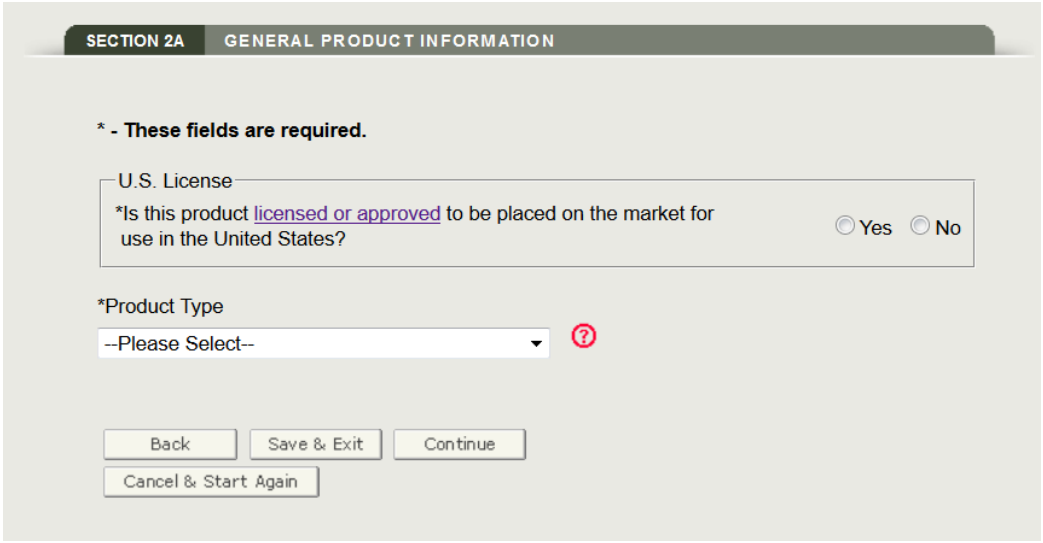


Figure 14: Product Type Description

Product Types

FDA's Center for Drug Evaluation and Research (CDER) issues certificates of pharmaceutical products (CPPs) for the following types of human drug items:

Approved Drugs and Licensed Biological Products

Approved new drugs (regulated by CDER) have been evaluated and reviewed by CDER for safety and effectiveness and may be marketed in the United States. Approved drugs are subject to the following types of drug applications: NDA (new drug applications); ANDA (abbreviated new drug application); and certain licensed biological products regulated by CDER under BLAs (biologic license applications).

Nonprescription ("Over the Counter (OTC)") Drugs

An OTC drug can be brought to the market if it is the subject of an approved NDA or ANDA or if it conforms to a final or pending OTC monograph. Each OTC drug monograph is a kind of "recipe book" covering acceptable ingredients, doses, formulations, labeling, and, in some cases, testing parameters. Products conforming to a monograph are not considered approved drugs but they may be marketed without FDA pre-approval. FDA defines OTC drugs as safe and effective for use by the general public without a doctor's prescription.

The OTC monographs can be found at the following website:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/default.htm

Active Pharmaceutical Ingredients (API)

An active pharmaceutical ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Unapproved New Drugs

Unapproved New Drugs have not been approved or evaluated by CDER for safety and effectiveness and cannot be marketed in the United States. Exportation of these drugs is permitted only in accordance with the requirements found in sections 801 and 802 of the Food Drug and Cosmetic Act. In addition, when export is permitted, pursuant to 21 CFR 1.101(d), a simple notification is required when first exporting your unapproved new drug.

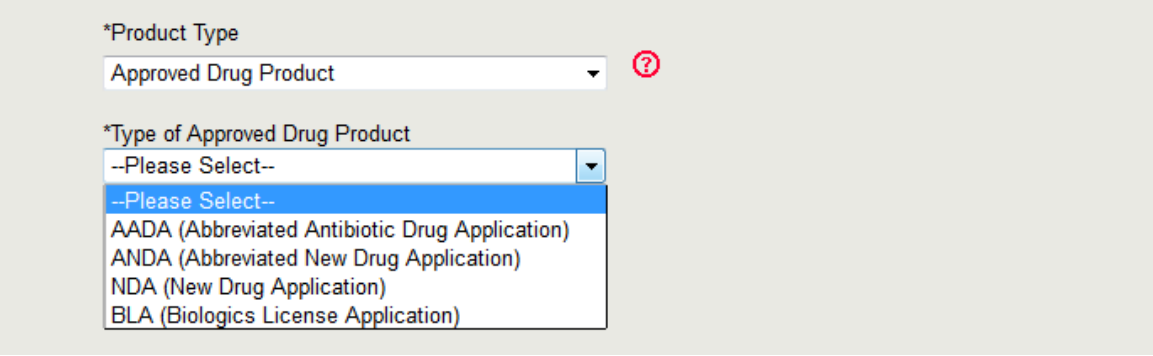
Approved Drug Product Flow

If you select Approved Drug Product, the system displays the 'Type of Approved Drug Product' dropdown list.

Please select from the following as shown in **Figure 14** below:

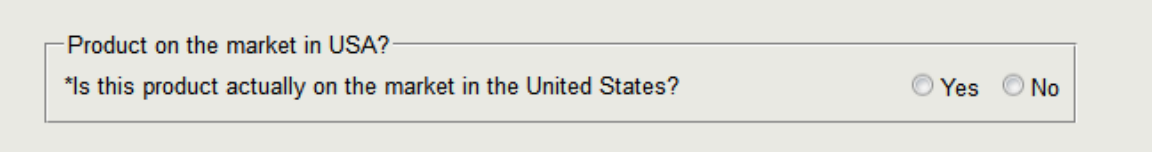
- AADA (Abbreviated Antibiotic Drug Application)
- ANDA (Abbreviated New Drug Application)
- NDA (New Drug Application)
- BLA (Biologics License Application)

Figure 15: Type of Approved Drug Product List



Select 'Yes' or 'No' if the approved drug product is actually on the market in the United States as shown in **Figure 16** below.

Figure 16: Actually marketed in the U.S.

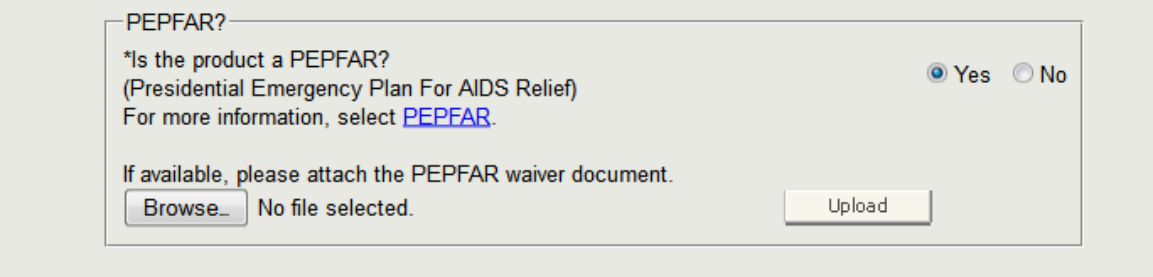


Select 'Yes' or 'No' if the approved drug product is a PEPFAR also shown in **Figure 16** below.

NOTE: PEPFAR does not apply for a BLA. Click on the '**PEPFAR**' hyperlink to view the definition of PEPFAR.

If the approved drug product is a PEPFAR, you have the option to attach the PEPFAR waiver document as shown **Figure 17** below.

Figure 17: PEPFAR Waiver Document

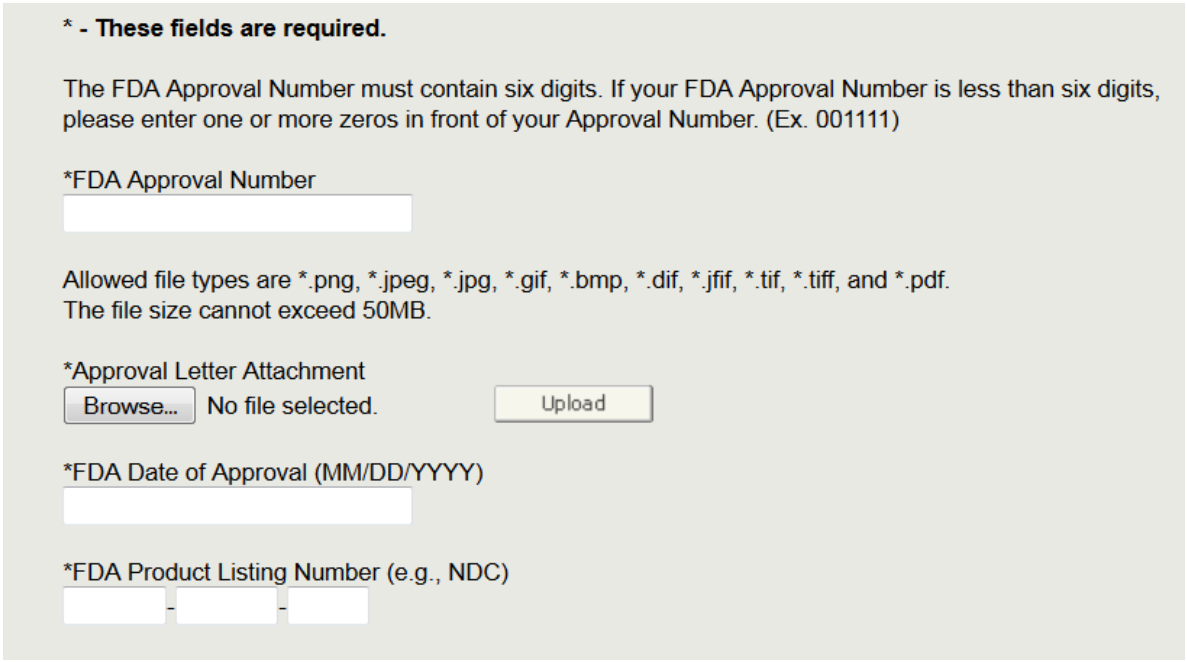


Click on 'Continue' to navigate to Section 2B.

Section 2B - Product Specific Information - Approved Drug
Applies to AADA, ANDA, or NDA

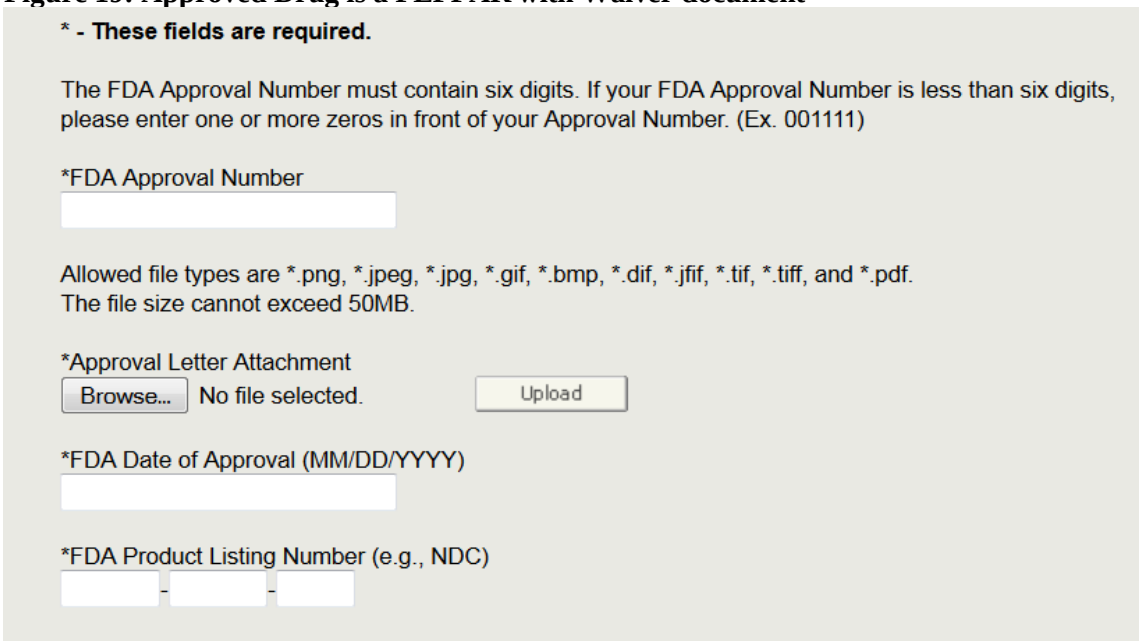
1. If the approved drug product is **NOT** a PEPFAR
   OR
2. If the approved drug product is a PEPFAR, and you did NOT upload a waiver document, enter / upload the following information as shown in **Figure 18** below:
   - *FDA Approval Number
   - *Approval Letter Attachment
   - *FDA Date of Approval (MM/DD/YYYY)
   - *FDA Product Listing Number

Figure 18: Approved Drug not a PEPFAR



3. If the approved drug product is a PEPFAR, and you uploaded a waiver document, you have the option to enter / upload the following information as shown in **Figure 19** below:
    - FDA Approval Number or Tentative Approval Number
    - Approval Letter or Tentative Approval Letter
    - FDA Date of Approval (MM/DD/YYYY)
    - FDA Product Listing Number

Figure 19: Approved Drug is a PEPFAR with Waiver document

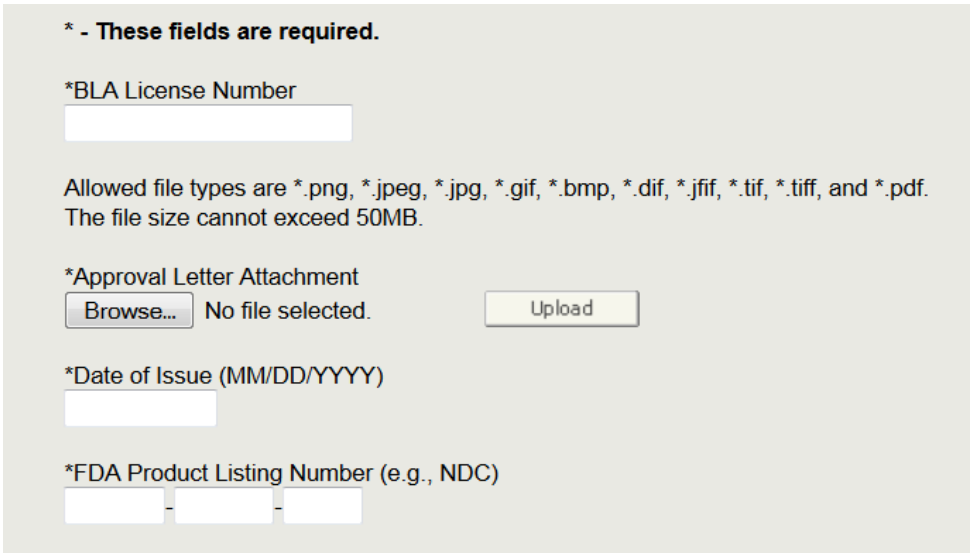


Applies to BLA

If the approved drug product is a **BLA**, enter / upload the following information as shown in **Figure 20** below:

- *BLA License Number
- *Approval Letter Attachment
- *Date of Issue (MM/DD/YYYY)
- * FDA Product Listing Number

Figure 20: PEPFAR Waiver Document



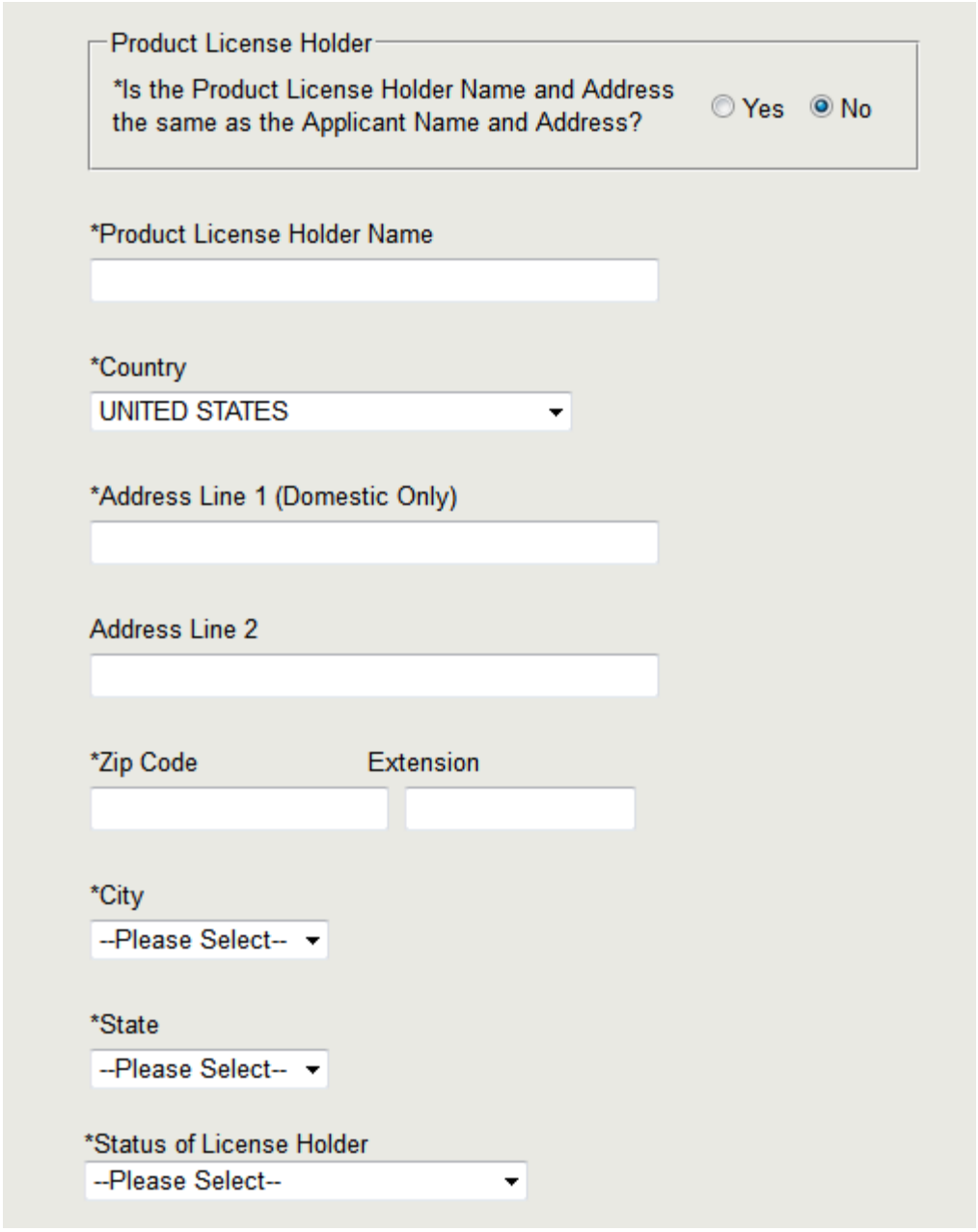
WARNING: Any FDA Approval Number entered in Section 2B must be a valid FDA Approval Number or you will not be able to continue with the application process.

Section 2C - Product License Holder Information – Approve Drug

Applies to all product types including AADA, ANDA, NDA, and BLA

You will need to verify if the Product License Holder name and address is the same as the applicant name and address. If it is NOT the same as the applicant name and address, select 'No' and enter the License Holder name and address information. Also, you must select a Status of License Holder option from the dropdown list as shown in **Figure 21** below.

Figure 21: Product License Holder Name and Address



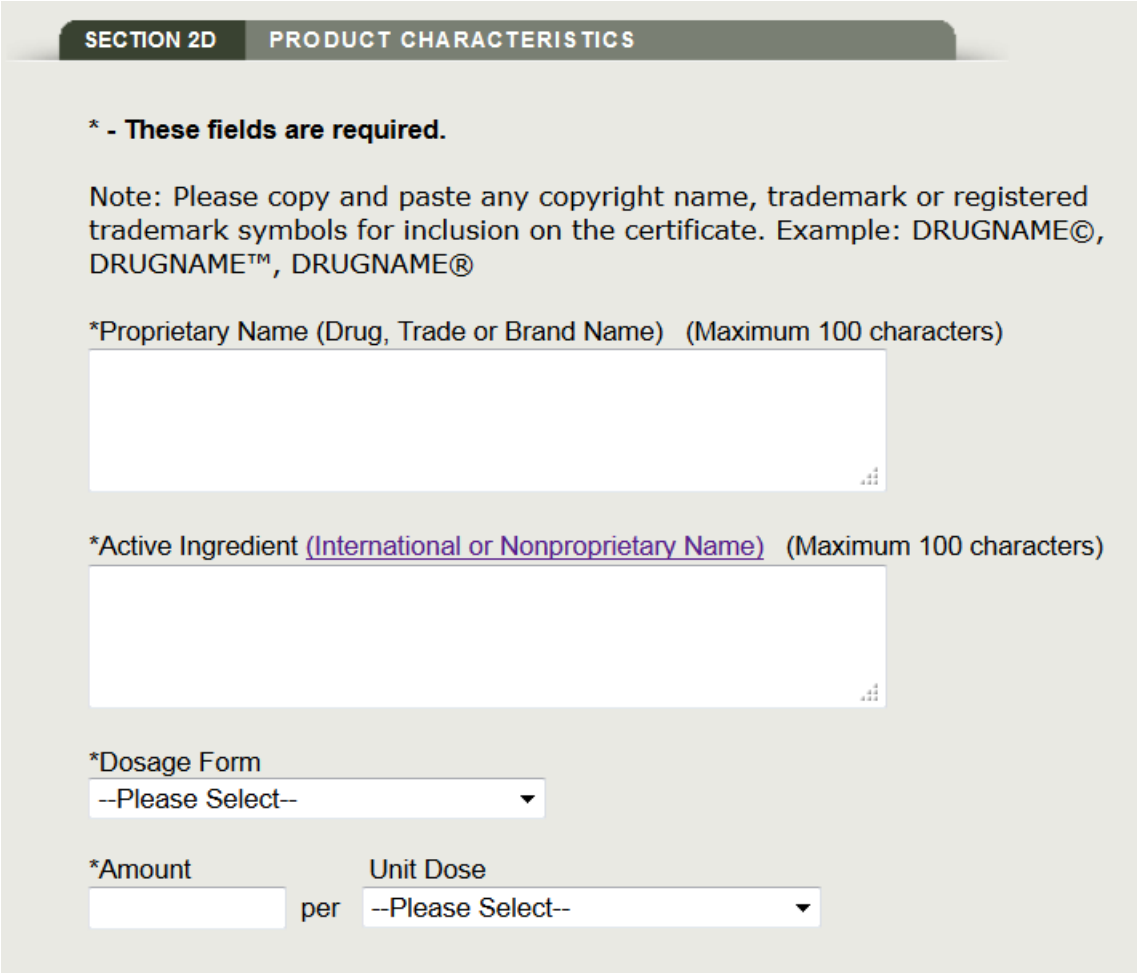
Click on ‘Continue’ to navigate to Section 2D.

Section 2D - Product Characteristics – Approved Drug
Applies to all Product Types including AADA, ANDA, NDA, and BLA

Enter the following product characteristics information as shown in **Figure 22** below:

- *Proprietary Name
- *Active Ingredient
- *Dosage Form
- *Amount
- *Unit Dose

Figure 22: Product Characteristics



Click on ‘Continue’ to navigate to Section 3A.

Navigate to Step 3

Over-the-Counter (OTC) Flow

If you select Over-the-Counter (OTC), select 'Yes' or 'No' if the approved drug product is actually on the market in the United States as shown in **Figure 23** below.

Figure 23: Actually marketed in the U.S.

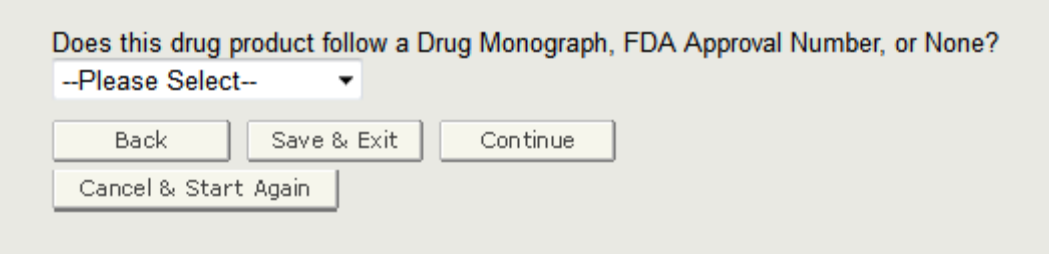
Click 'Continue' to navigate to Section 2B.

Section 2B - Product Specific Information - OTC

For OTC, select from the following dropdown list which method the drug follows as shown in **Figure 24** below:

- Drug Monograph
- FDA Approval Number
- None

Figure 24: OTC Type



If the drug follows a Drug Monograph, enter the following information as shown in **Figure 25** below:

- *Monograph
- * FDA Product Listing Number
- *What is the Applicant Status?
- *Why is marketing authorization lacking?

NOTE: Click on the icon for more information on Monograph.

If the drug does not follow a Drug Monograph or FDA Approval Number, you will not be able to continue with the application process. Please return to the Section 2B and select the Unapproved Drug Product Type.

Figure 25: Follows Drug Monograph

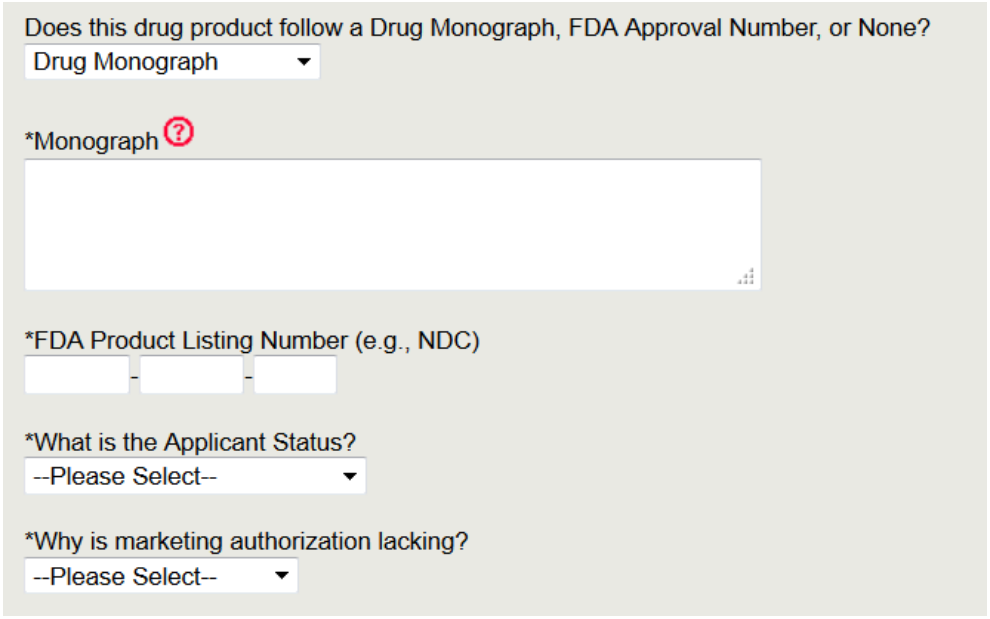
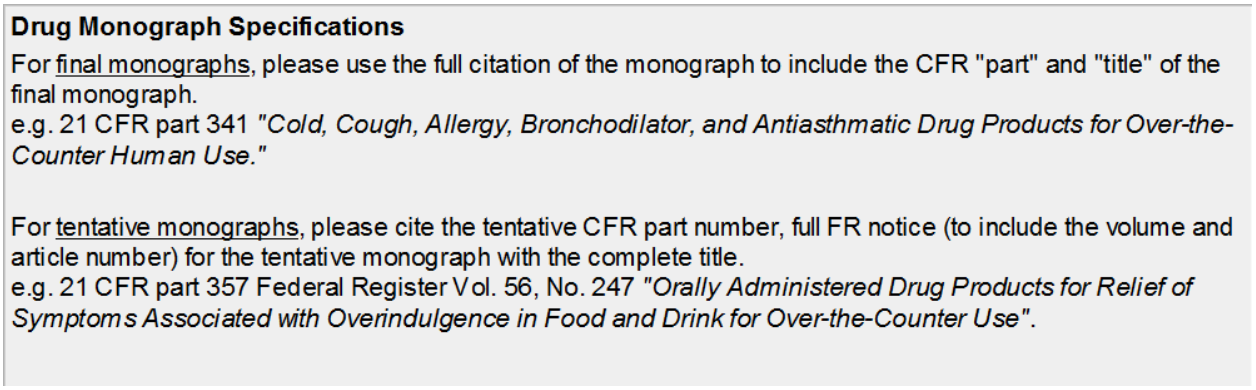


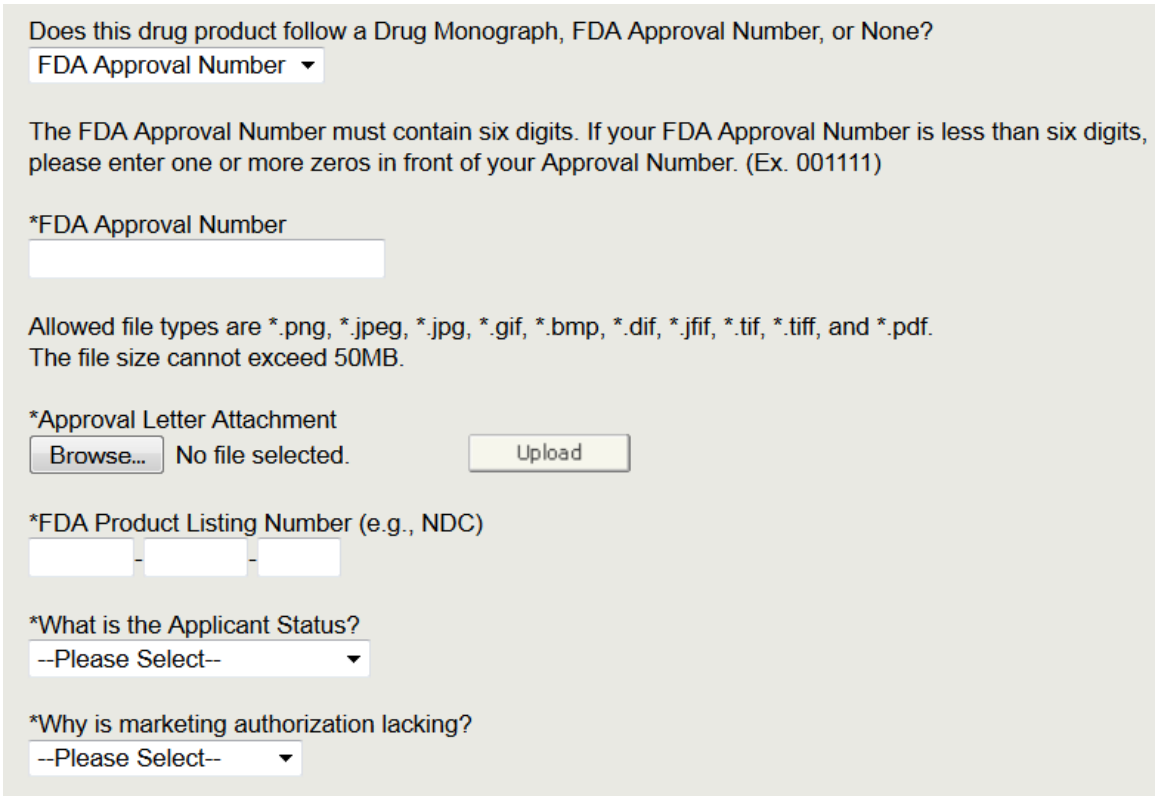
Figure 26: Drug Monograph Specifications



If the drug follows an FDA Approval Number, enter/upload the following information as shown in **Figure 27** below:

- *FDA Approval Number
- *Approval Letter Attachment
- * FDA Product Listing Number
- *What is the Applicant Status?
- *Why is marketing authorization lacking?

Figure 27: Follow FDA Approval Number



WARNING: The FDA Approval Number entered in section 2B for an OTC must be a valid FDA Approval Number or you will not be able to continue with the application process.

Click 'Continue' to navigate to Section 2D.

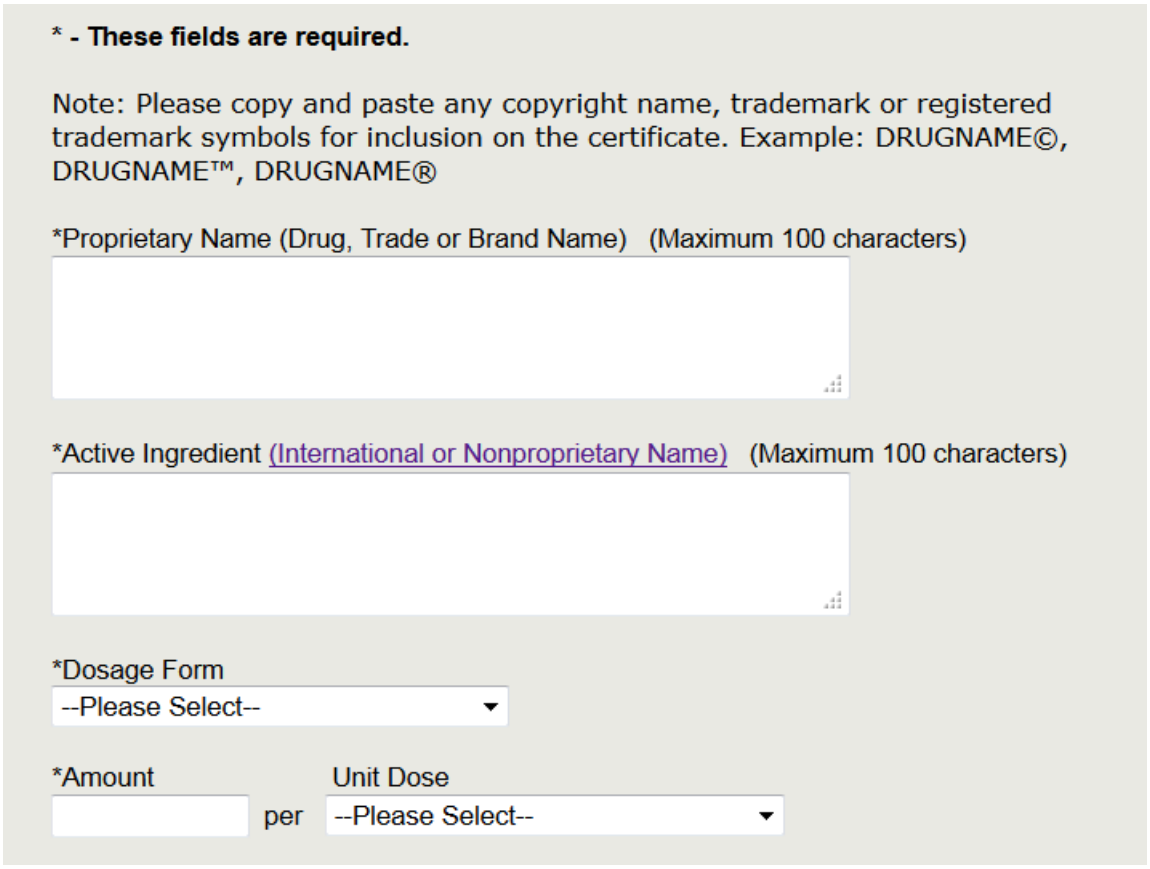
NOTE: Section 2C does not apply for an OTC product type.

Section 2D - Product Characteristics - OTC

Enter the following product characteristics information as shown in **Figure 26** below:

- *Proprietary Name License Number
- *Active Ingredient
- *Dosage Form
- *Amount
- *Unit Dose

Figure 28: Product Characteristics



Click on ‘Continue’ to navigate to Section 3A.

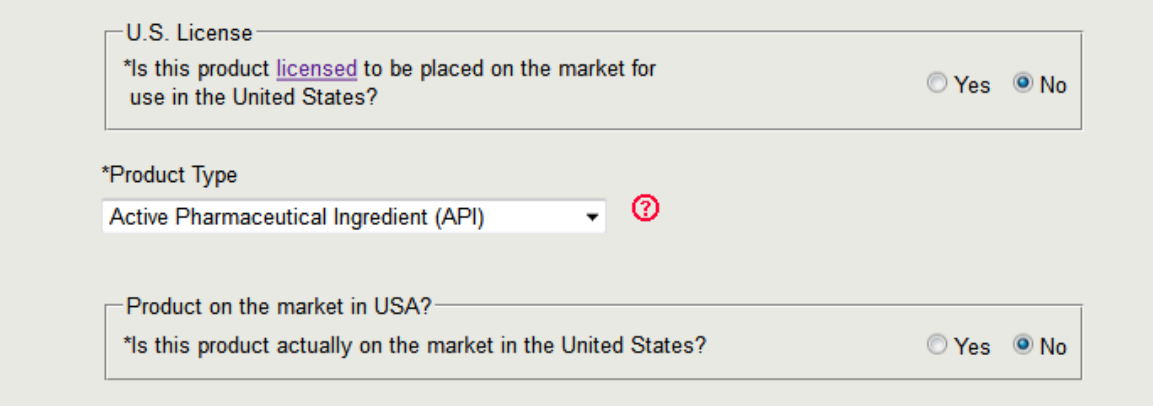
Navigate to Step 3

Active Pharmaceutical Ingredient (API) Flow

If you select Active Pharmaceutical Ingredient (API), you must select 'No' for both the following questions as shown in **Figure 29** below:

Is the product licensed or approved to be placed on the market in the United States?
Is the product actually on the market in the United States?

Figure 29: Active Pharmaceutical Ingredient



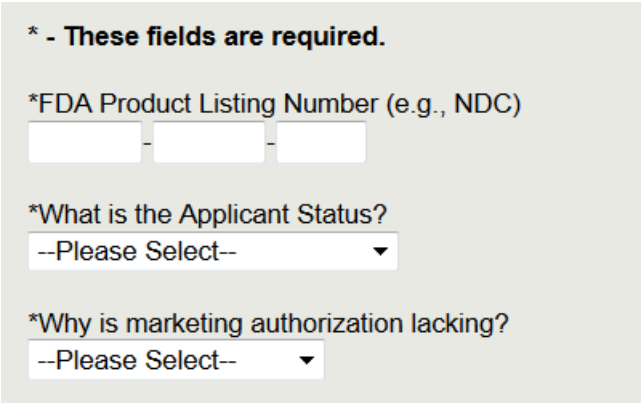
Click on 'Continue' to navigate to Section 2B.

Section 2B - Product Specific Information - API

For API, enter the following information as shown in **Figure 30** below:

- *FDA Product Listing Number
- *What is the Applicant Status?
- *Why is marketing authorization lacking?

Figure 30: Product Specific Information – API



Click 'Continue' to navigate to Section 2D.

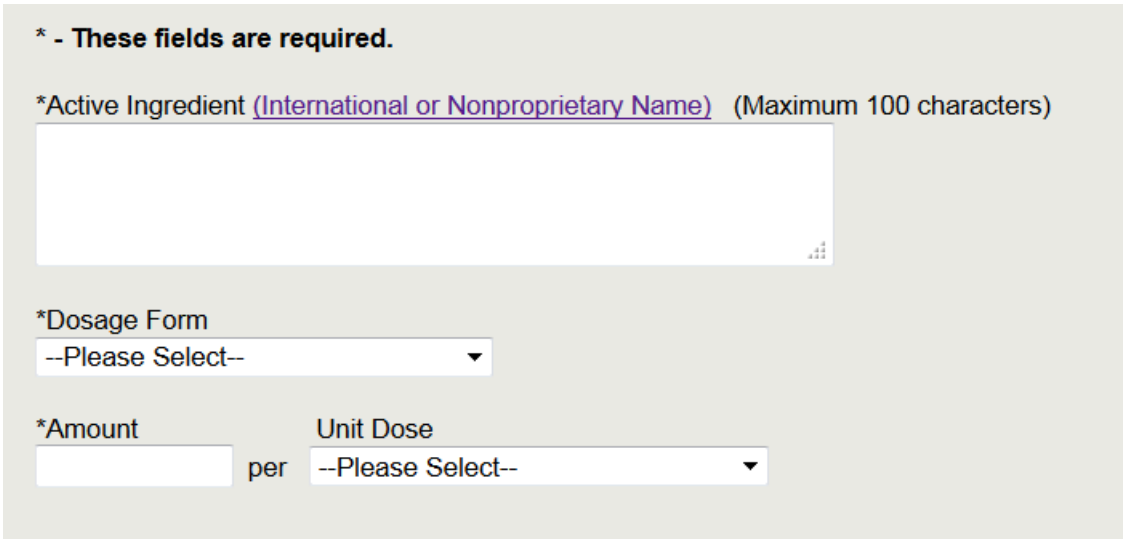
NOTE: Section 2C does not apply for an API product type.

Section 2D - Product Characteristics - API

Enter the following product characteristics information as shown in **Figure 31** below:

- *Active Ingredient (International or Non-Proprietary Name)
- *Dosage Form
- *Amount
- *Unit Dose

Figure 31: Product Characteristics – API



Click on ‘Continue’ to navigate to Section 3B.

Section 3A does not apply to the API product type.

Unapproved Drug Product Flow

If you select Unapproved Drug Product, you must select 'No' for the U.S. License field.

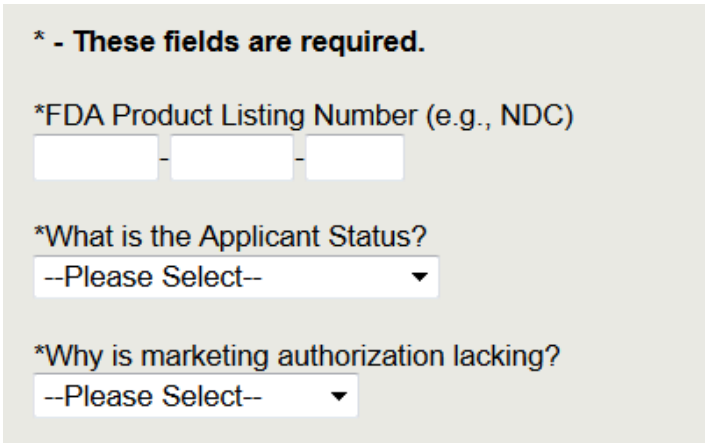
Click on 'Continue' to navigate to Section 2B.

Section 2B - Product Specific Information – Unapproved Drug

For Unapproved Drug Product, enter the following information as shown in **Figure 32** below:

- *FDA Product Listing Number
- *What is the Applicant Status?
- *Why is marketing authorization lacking?

Figure 32: Product Specific Information – Unapproved Drug



Click 'Continue' to navigate to Section 2D.

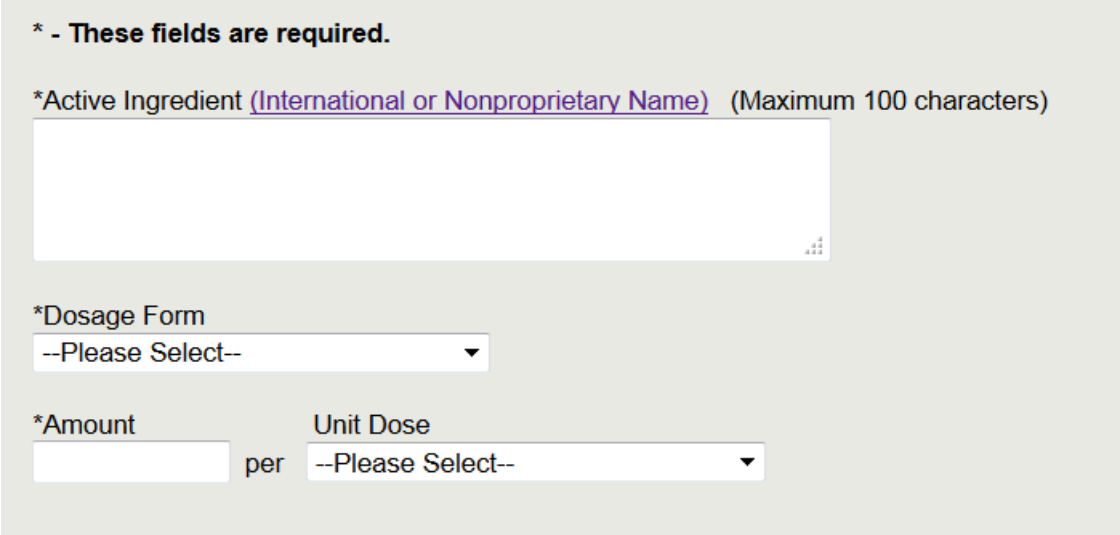
NOTE: Section 2C does not apply for an Unapproved Drug product type.

Section 2D - Product Characteristics – Unapproved Drug

Enter the following product characteristics information as shown in **Figure 33** below:

- *Active Ingredient
- *Dosage Form
- *Amount
- *Unit Dose

Figure 33: Product Characteristics – Unapproved Drug



Click on ‘Continue’ to navigate to Section 3A.

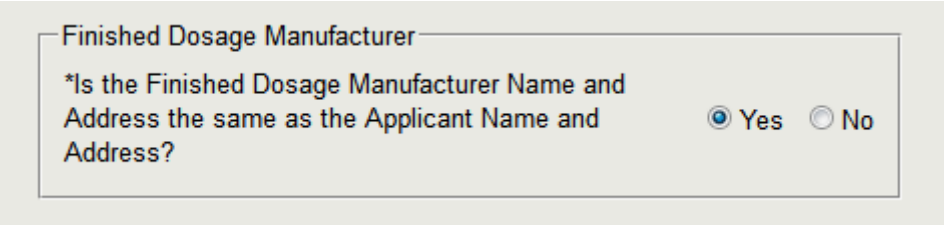
Navigate to Step 3

Step 3:

Section 3A – Finished Dosage Manufacturer

Select ‘Yes’ or ‘No’ if the Finished Dosage Manufacturer Name and Address is the same as the Applicant Name and Address as shown in **Figure 34** below.

Figure 34: Finished Dosage Manufacturer same as Applicant

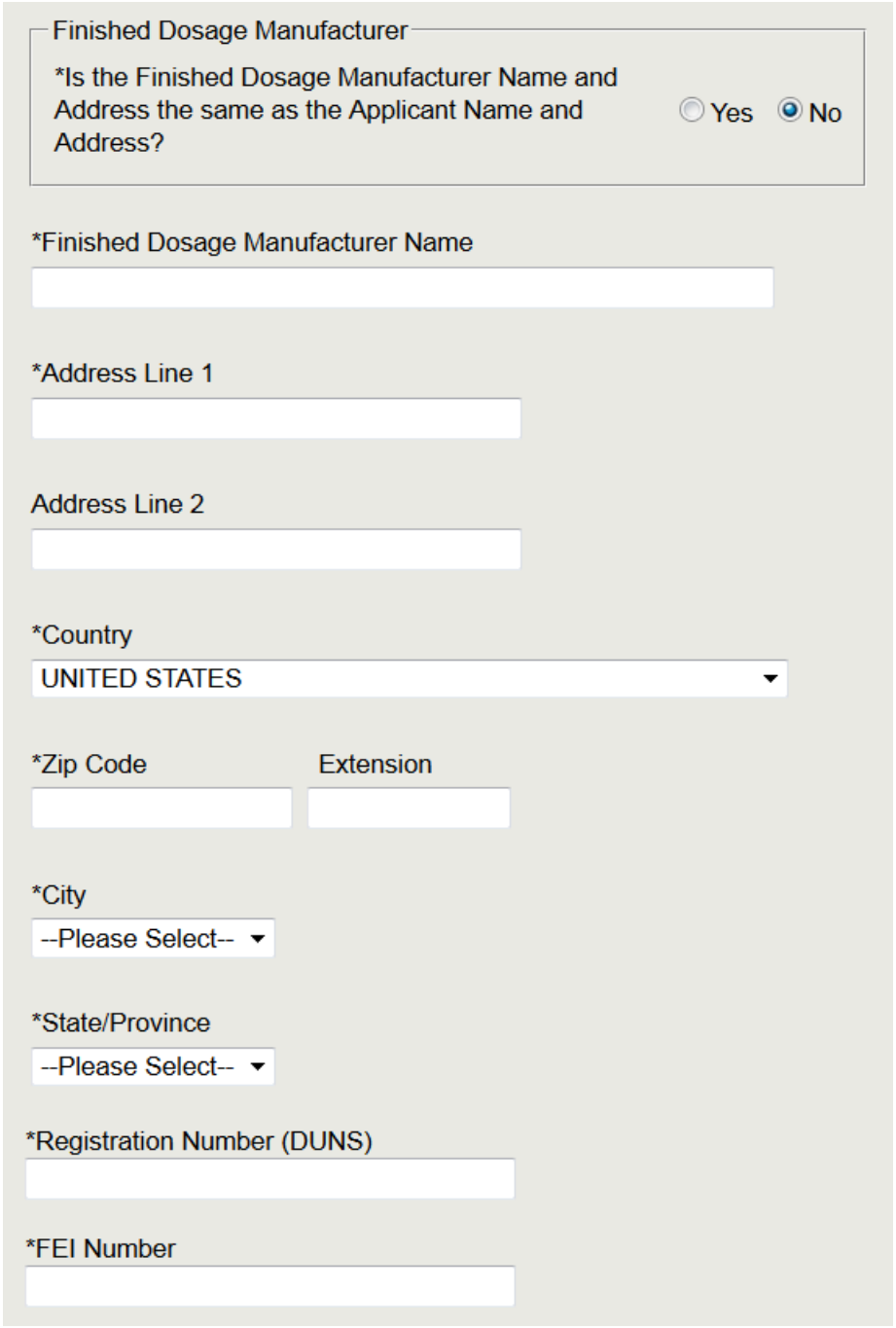


NOTE: Section 3A does not apply to the product type API.

If you select ‘No’, enter the following Finished Dosage Manufacturer information as shown in **Figure 35** below:

- *Finished Dosage Manufacturer Name
- *Address Line 1
- *Country
- *Zip Code
- *City
- *State/Province
- *Registration Number (DUNS)
- *FEI/CFN Number

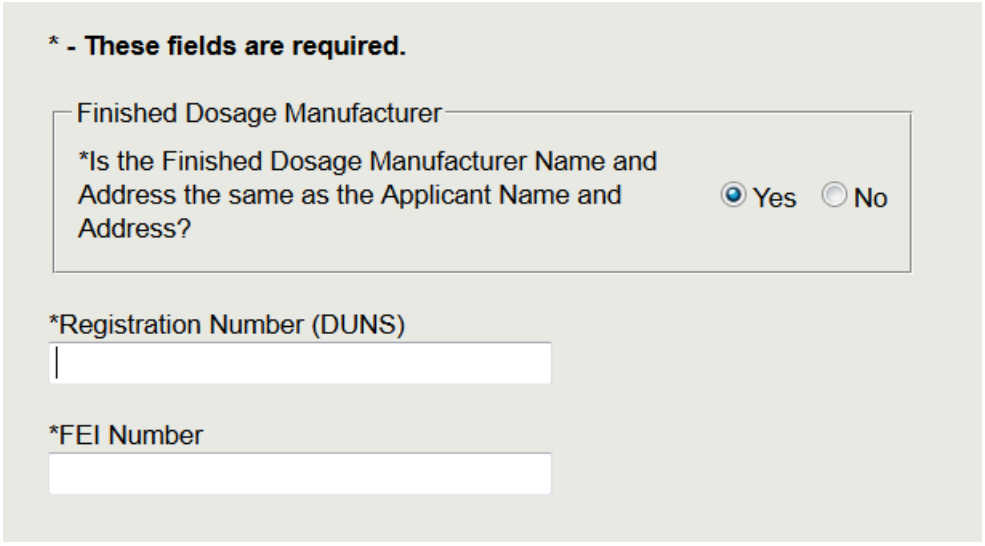
Figure 35: Facility Information with DUNS and FEI



If you select 'Yes', enter the following Finished Dosage Manufacturer information as shown in **Figure 36** below:

- *Registration Number (DUNS)
- *FEI Number

Figure 36: DUNS and FEI

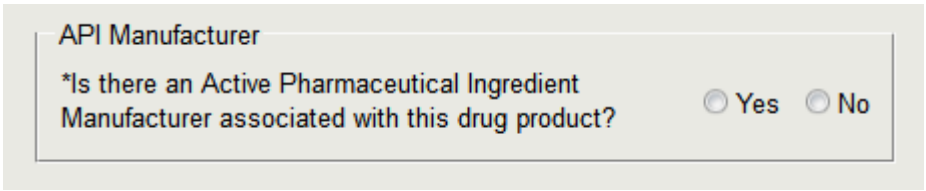


Click on 'Continue' to navigate to Section 3B.

Section 3B – Active Pharmaceutical Ingredient Manufacturer

Select 'Yes' or 'No' if there is an Active Pharmaceutical Ingredient Manufacturer associated with the drug product as shown in **Figure 37** below. **This applies to all product types except API.**

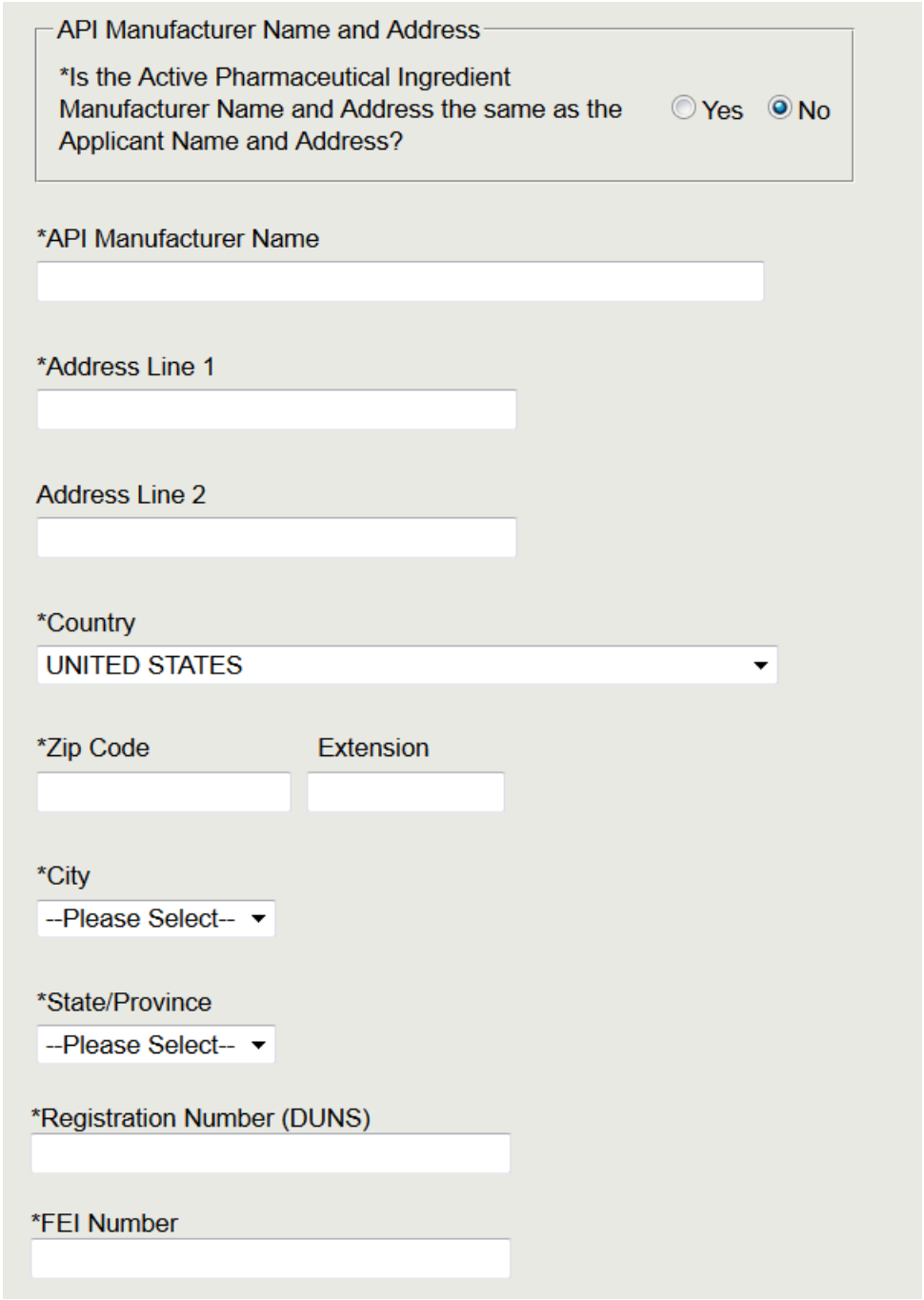
Figure 37: API Manufacturer Association



NOTE: If your product type is an Active Pharmaceutical Ingredient (API), you will NOT be prompted to answer whether there is an API associated with the drug product as shown in **Figure 37** above, but must fill out Section 3B.

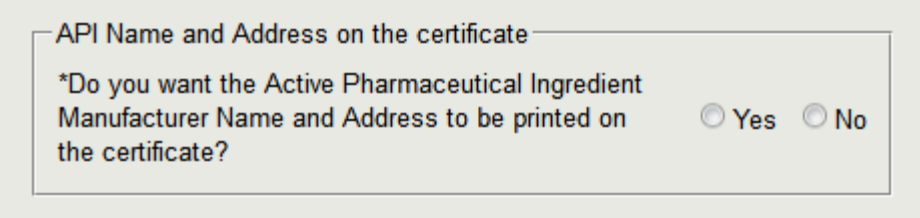
If you answered 'Yes' to the above prompt, or if your product type is an API, the system displays the following to be filled out in section 3B as shown in **Figure 38** below:

Figure 38: API Manufacturer Contact Information



For all products types except API, select ‘Yes’ or ‘No’ if you would like to print the Active Pharmaceutical Ingredient Manufacturer name and address on the certificate as shown in **Figure 39** below.

Figure 39: API Manufacturer Name and Address Printed on the Certificate

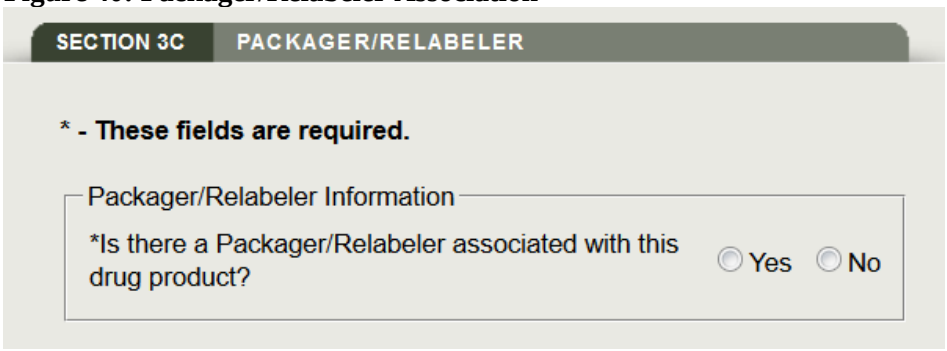


Click on ‘Continue’ to navigate to Section 3C.

Section 3C – Packager / Relabeler

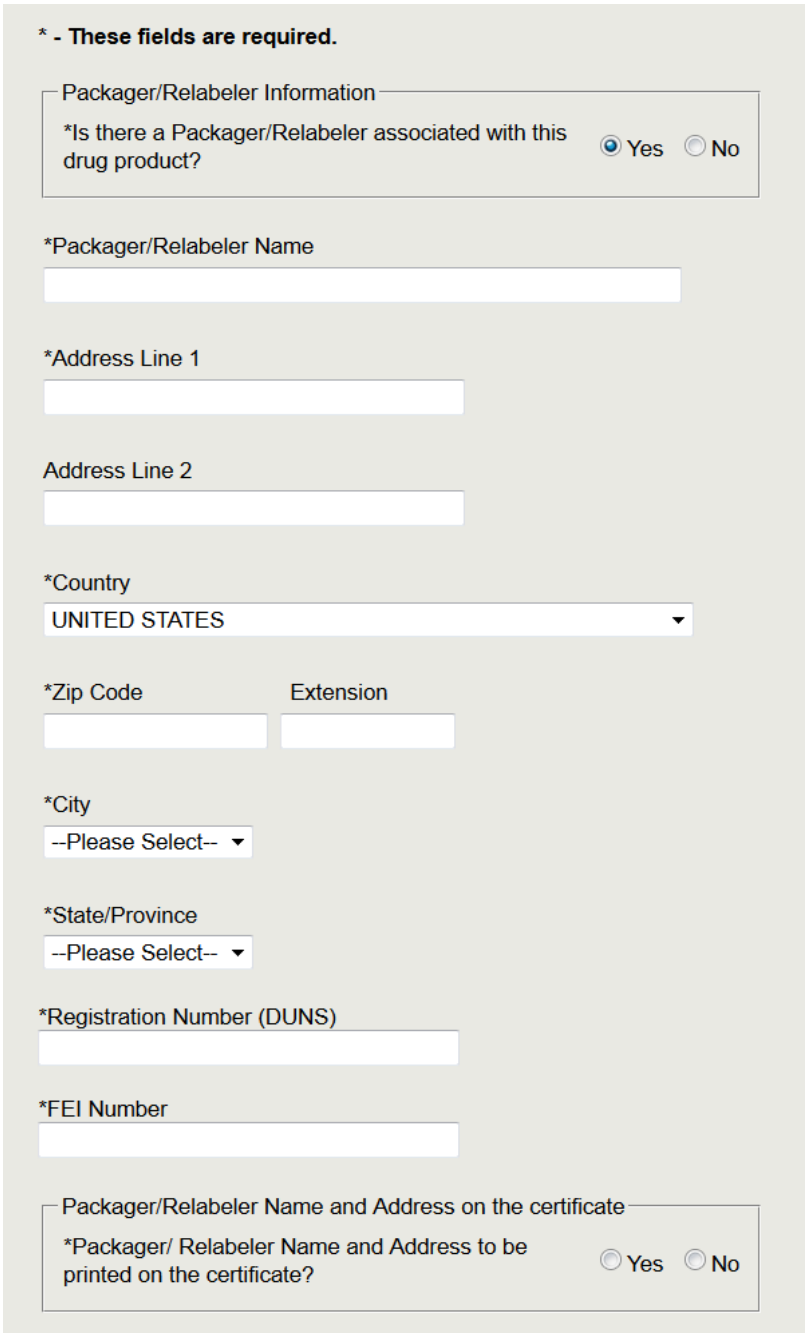
Select ‘Yes’ or ‘No’ if there is an Repackager associated with the drug product as shown in **Figure 40** below.

Figure 40: Packager/Relabeler Association



If you answered ‘Yes’ to the above prompt, the system displays the following to be filled out in section 3C as shown in **Figure 41** below:

Figure 41: Packager/Relabeler Information

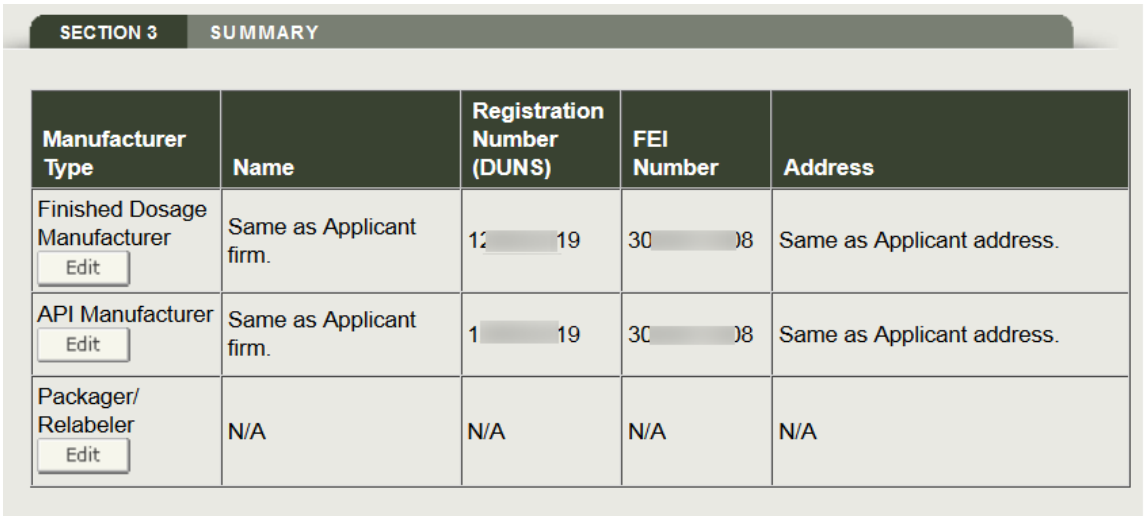


Click on ‘Continue’

Section 3 – Summary Page of Manufacturers

Prior to navigating to step 4 of the application, the system displays a summary of all manufacturers entered in the application. Please review each manufacturer entered and, if necessary, click on the 'Edit' button next to the facility you wish to update any information as shown in **Figure 42** below.

Figure 42: Summary Page – Manufacturers



Click on 'Continue'

Navigate to Step 4.

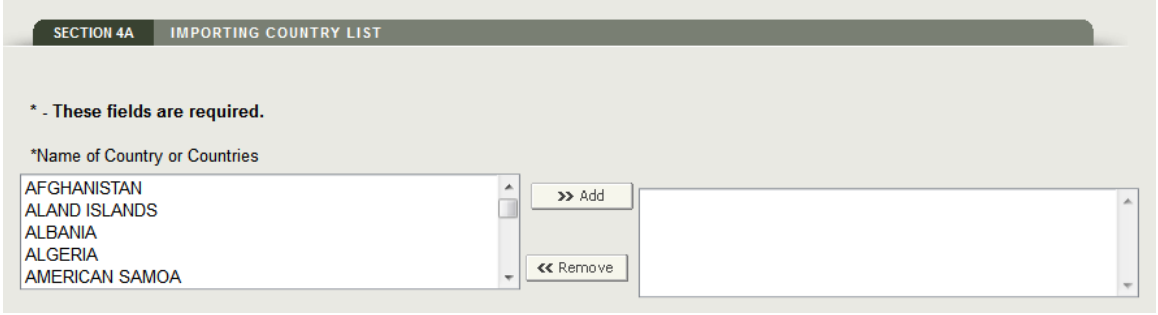
Step 4

Section 4A – Importing Country List

***NAME OF COUNTRY or COUNTRIES** - Select one or more countries to indicate the product destination as shown in **Figure 43** below.

NOTE: Another method to select a country (other than scrolling down the list) is to first click on a country from the country list and then type in the first few letters of the desired country name. The system will jump to the country that begins with the letters typed. You also have the option to hold down the 'CTRL' button and select multiple countries.

Figure 43: List of Countries



Click on 'Continue' to navigate to Section 4B.

Section 4B – Number of Certificates

The system displays the selected country or countries (from section 4A). You will be able to request additional certificate copies by country as shown in **Figure 44** below. The system also calculates the user fee based on the number of additional certificates requested. For more information on fee calculation, click on the ⓘ icon.

NOTE: The total number of certificates cannot exceed 50 per application.

Figure 44: **Number of Certificates Requested by Country**

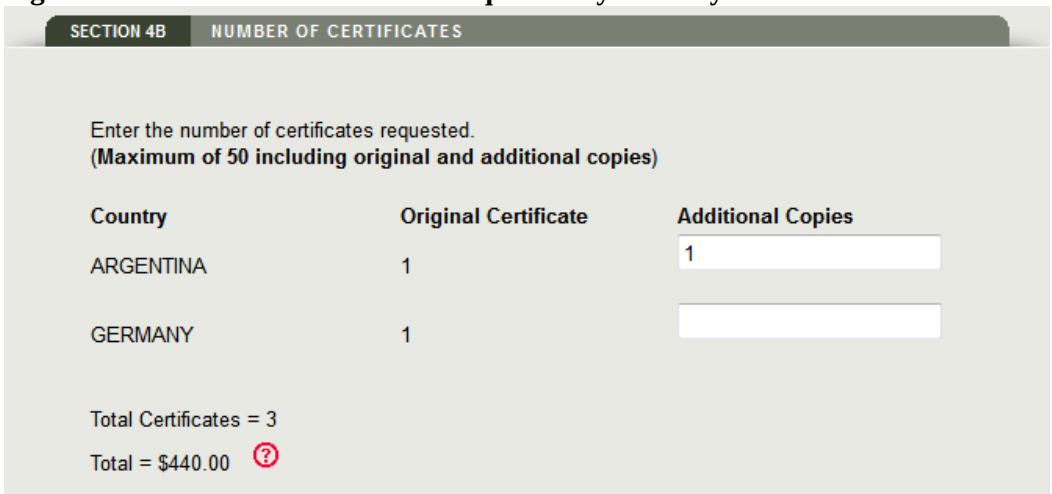
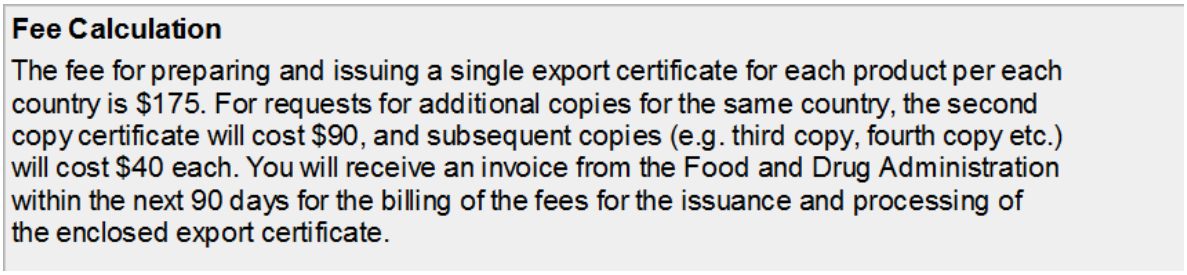


Figure 45: **Fee Calculation**



Click on ‘Continue’

Navigate to Step 5

Step 5

Section 5A – Drug Labels

In this section, you must provide labels for your drug product. The following labels are required for each application based on the product type selected:

Approved Drugs

- Package or Container Label
- Outer Packager Label
- Package Insert

For Over the Counter (OTC)

- Package or Container Label
- Outer Package Label

For an Active Pharmaceutical Ingredient (API)

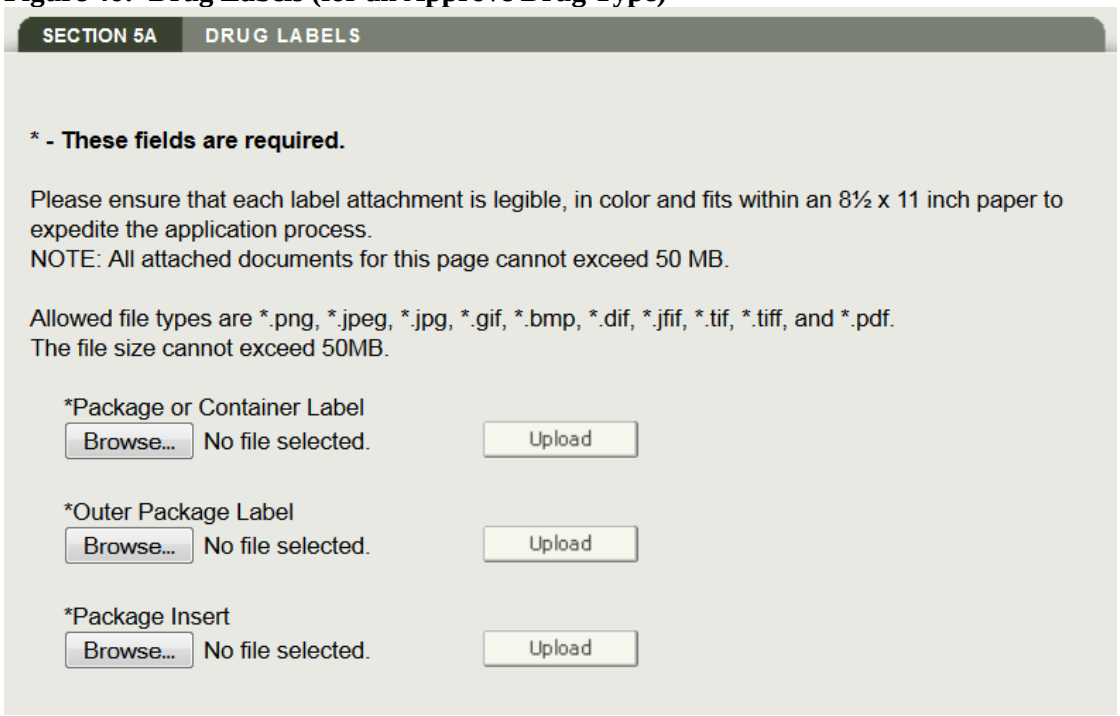
- Package or Container Label

For an Unapproved Drug

- Outer Package Label
- Formulation Page

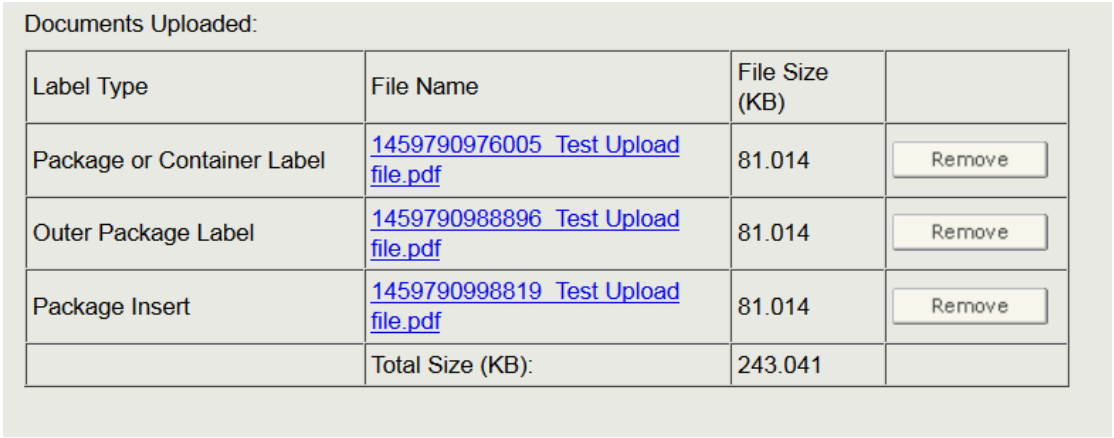
Figure 46 below shows the labels required for an Approve Drug Type.

Figure 46: Drug Labels (for an Approve Drug Type)



Once you have attached each drug label, the system displays each attachment as a hyperlink. You can click on the hyperlink to view the label. You also have the ability to remove any attachment and reattach a label as shown in **Figure 47** below.

Figure 47: Drug Label Hyperlinks



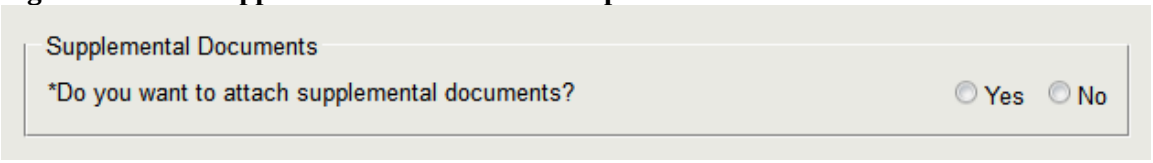
NOTE: The total files attached on this page cannot exceed 50 (MB) Megabytes.

Click on 'Continue' to navigate to Section 5B.

Section 5B – Supplemental Documents

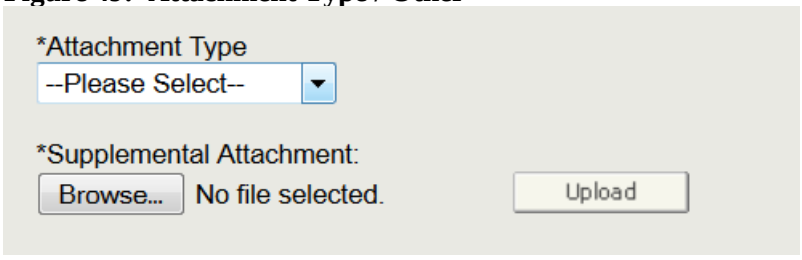
In this section, you have the option to attach additional supporting documents for your application. To add additional documents, click on the 'Yes' radio button as shown in **Figure 48** below. Otherwise, click 'No' and proceed to Section 5D.

Figure 48: Add Supplemental Documents Prompt



If you select 'Yes', please select an option from the 'Attachment Type' dropdown list. If you select 'Other', you must provide a description of the attachment in the freeform text field shown in **Figure 49** below.

Figure 49: Attachment Type / Other



Once you have attached the document, the system displays the following two prompts as shown in **Figure 50** below.

Figure 50: Associate document with country and print on certificate prompt

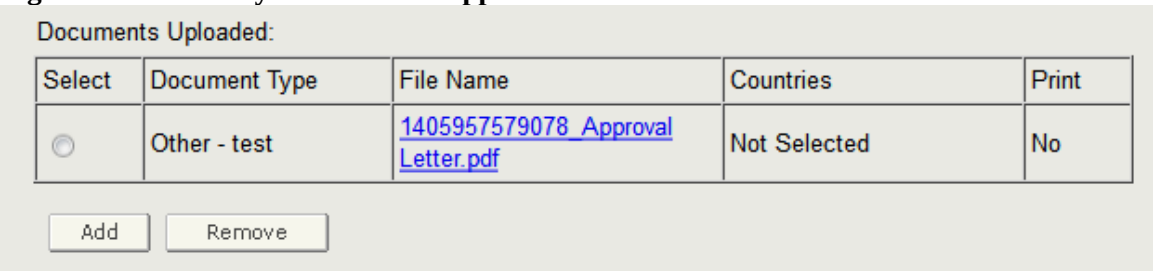
If you select 'Yes' to associate one or more countries to this attachments, the system displays all countries selected in Section 4A. Please select one or more countries.

Click on Continue to navigate to Section 5C.

Section 5C – Summary of Attached Supplemental Documents

The system displays the attachment as a hyperlink. You can click on the hyperlink to view the document. You also have the ability to remove any attachment or add additional documents as shown in **Figure 51** below.

Figure 51: Summary of Attached Supplement Documents

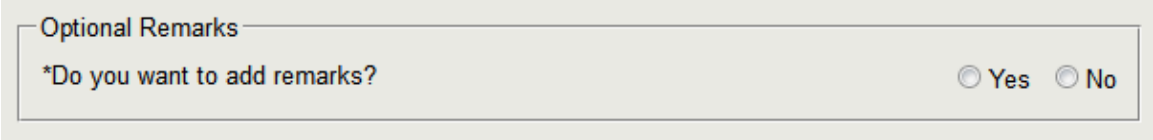


Click on 'Continue' to navigate to Section 5D.

Section 5D – Remarks

In this section, you have the option to attach additional one or more remarks. To add a remark, click on the 'Yes' radio button as shown in **Figure 52** below. Otherwise, click 'No' and proceed to Step 6.

Figure 52: Add a Remark Prompt



Select 'Yes' or 'No' and click on Continue.

Section 5E – Remarks Entry

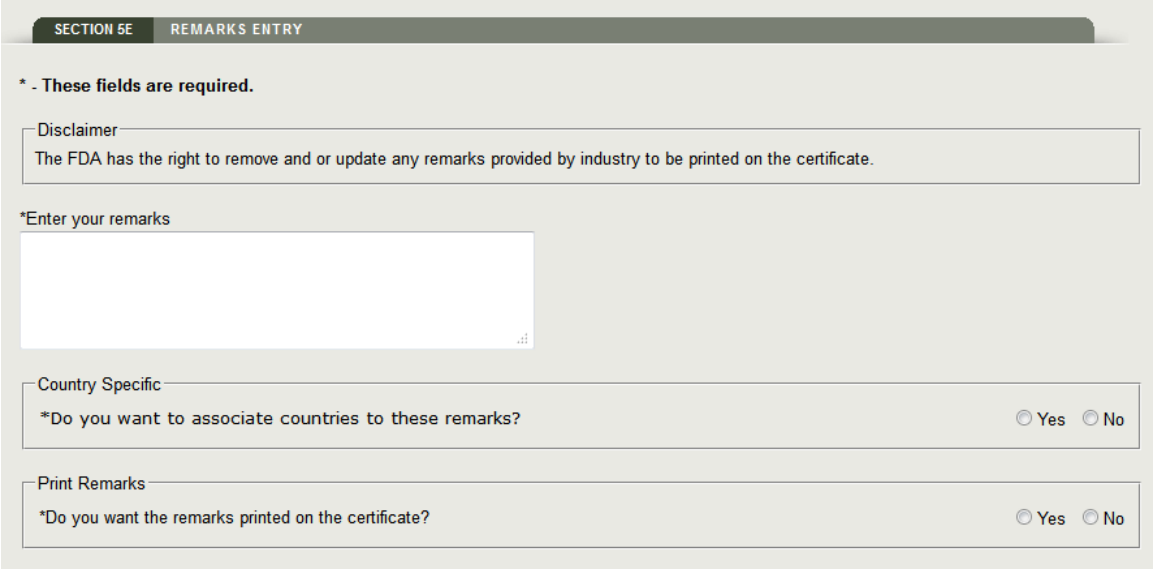
If you select 'Yes', please enter your remark in the freeform text field.

You will also be prompted to associate one or more countries to this remark. If you select 'Yes' to associate one or more countries to this remark, the system displays all countries selected in Section 4A. Please select one or more countries.

If you select 'Yes' to print the remark on the certificate, the system will print this remark in the 'Remarks' section of the certificate.

For Section 5E, refer to **Figure 53** below:

Figure 53: Remarks Entry



Click on Continue.

The system displays a summary of the remark entered. You have the ability to remove any remark or add additional remarks to the application as shown in **Figure 54** below.

Figure 54: Summary of Remarks

Click on 'Continue'

Navigate to Step 6.

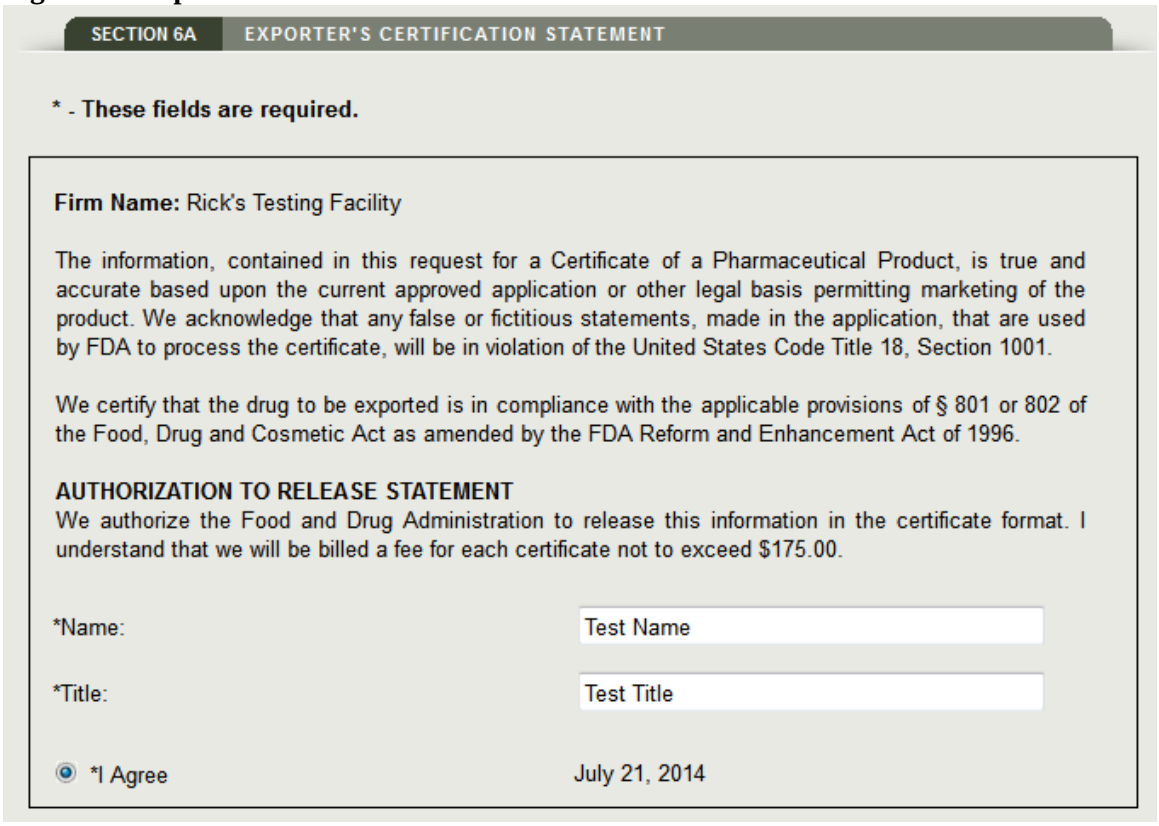
Step 6

Exporter's Certification Statement (ECS)

The Exporter's Certification Statement (ECS) acknowledges that you, the responsible official or designee, certify that the facility(s) and the product identified are to the best of your knowledge in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations.

You must click on the 'I Agree' button located at the bottom of this section, and enter your name and title. You will not be able to continue with the application until these fields have been completed as shown in **Figure 55** below.

Figure 55: **Exporter's Certification Statement**



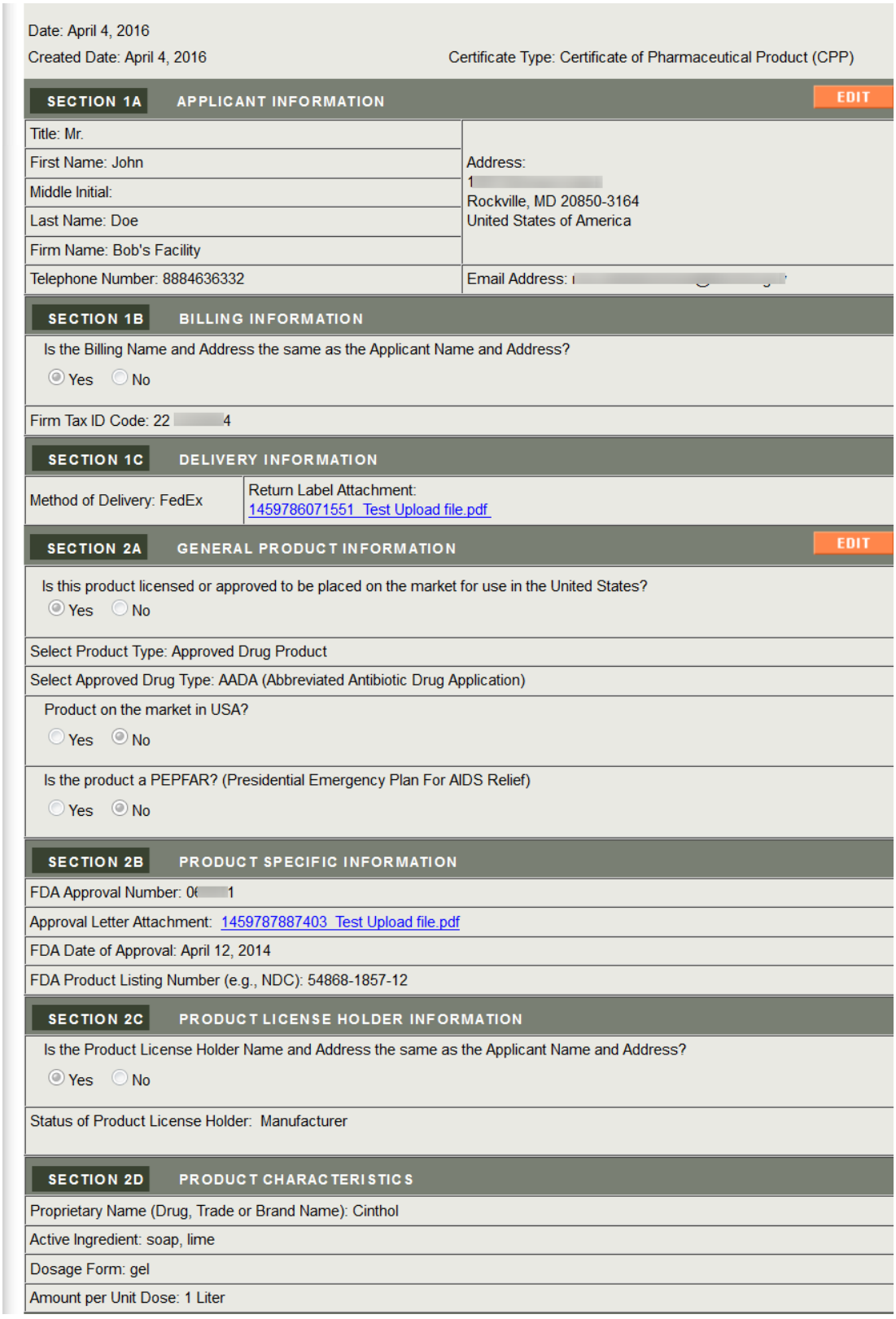
Once you have completed this step, click on the 'Continue' button to proceed to the Step 7 - Final Review Page.

Step 7

Final Review Page

The system will display the entire application broken out by section as shown in **Figure 56-58** below. You may choose to modify a section by selecting the 'Edit' button next to the step to be updated. The system will re-display the data entry screen corresponding to your chosen section. You may make changes as needed.

Figure 56: Final Review Page Section 1 and 2



Date: April 4, 2016

Created Date: April 4, 2016 Certificate Type: Certificate of Pharmaceutical Product (CPP)

SECTION 1A APPLICANT INFORMATION EDIT

Title: Mr.	
First Name: John	Address: 1 [redacted] Rockville, MD 20850-3164 United States of America
Middle Initial:	
Last Name: Doe	
Firm Name: Bob's Facility	
Telephone Number: 8884636332	Email Address: [redacted]

SECTION 1B BILLING INFORMATION

Is the Billing Name and Address the same as the Applicant Name and Address?

(•) Yes ( ) No

Firm Tax ID Code: 22 [redacted] 4

SECTION 1C DELIVERY INFORMATION

Method of Delivery: FedEx	Return Label Attachment: 1459786071551_Test Upload file.pdf

SECTION 2A GENERAL PRODUCT INFORMATION EDIT

Is this product licensed or approved to be placed on the market for use in the United States?

(•) Yes ( ) No

Select Product Type: Approved Drug Product

Select Approved Drug Type: AADA (Abbreviated Antibiotic Drug Application)

Product on the market in USA?

( ) Yes (•) No

Is the product a PEPFAR? (Presidential Emergency Plan For AIDS Relief)

( ) Yes (•) No

SECTION 2B PRODUCT SPECIFIC INFORMATION

FDA Approval Number: 0[redacted]1

Approval Letter Attachment: 1459787887403_Test Upload file.pdf

FDA Date of Approval: April 12, 2014

FDA Product Listing Number (e.g., NDC): 54868-1857-12

SECTION 2C PRODUCT LICENSE HOLDER INFORMATION

Is the Product License Holder Name and Address the same as the Applicant Name and Address?

(•) Yes ( ) No

Status of Product License Holder: Manufacturer

SECTION 2D PRODUCT CHARACTERISTICS

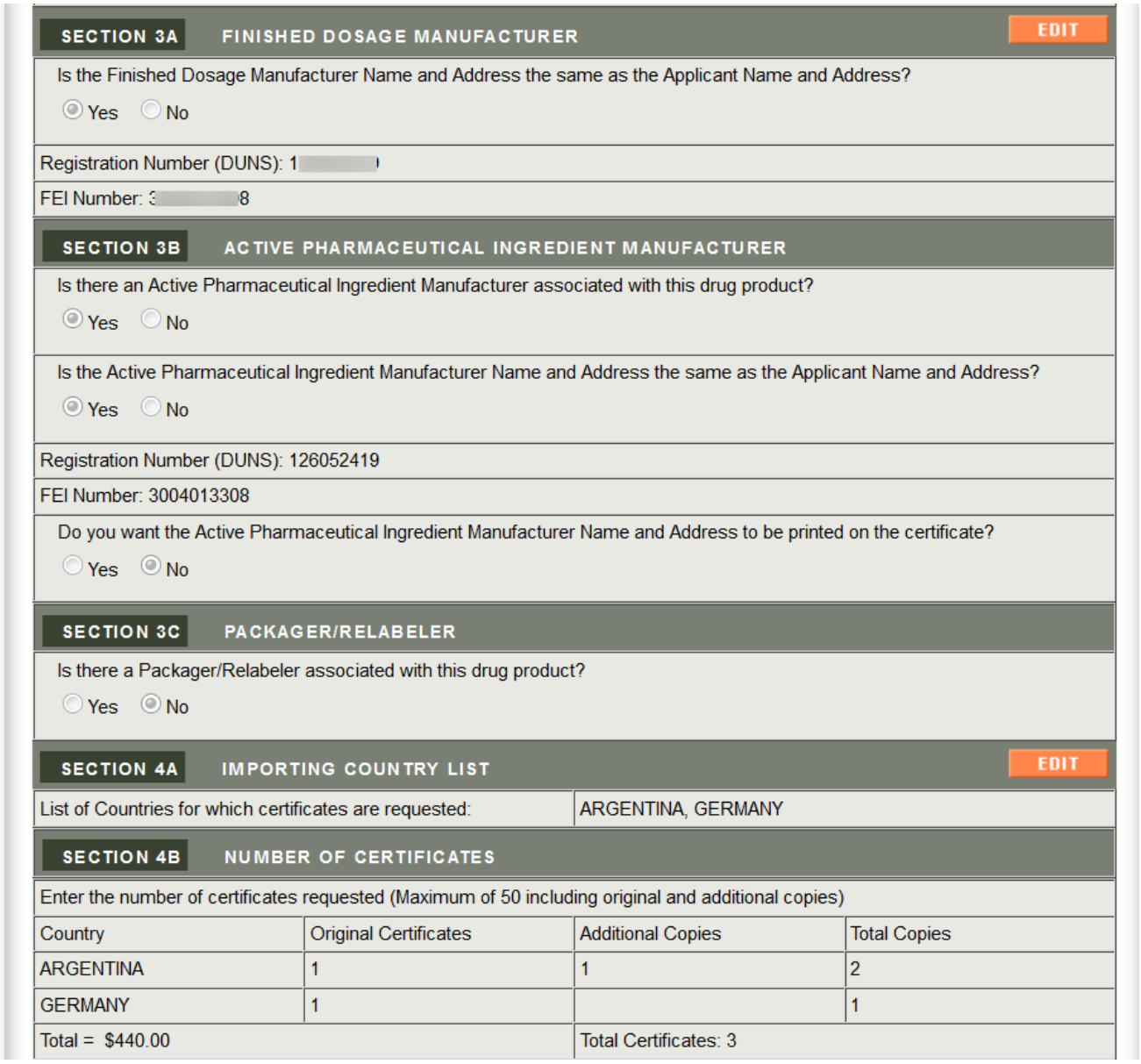
Proprietary Name (Drug, Trade or Brand Name): Cinthol

Active Ingredient: soap, lime

Dosage Form: gel

Amount per Unit Dose: 1 Liter

Figure 57: Final Review Page Section 3 and 4



SECTION 3A FINISHED DOSAGE MANUFACTURER — EDIT

Is the Finished Dosage Manufacturer Name and Address the same as the Applicant Name and Address?

(•) Yes ( ) No

Registration Number (DUNS): 1[redacted]

FEI Number: 3[redacted]8

SECTION 3B ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER

Is there an Active Pharmaceutical Ingredient Manufacturer associated with this drug product?

(•) Yes ( ) No

Is the Active Pharmaceutical Ingredient Manufacturer Name and Address the same as the Applicant Name and Address?

(•) Yes ( ) No

Registration Number (DUNS): 126052419

FEI Number: 3004013308

Do you want the Active Pharmaceutical Ingredient Manufacturer Name and Address to be printed on the certificate?

( ) Yes (•) No

SECTION 3C PACKAGER/RELABELER

Is there a Packager/Relabeler associated with this drug product?

( ) Yes (•) No

SECTION 4A IMPORTING COUNTRY LIST — EDIT

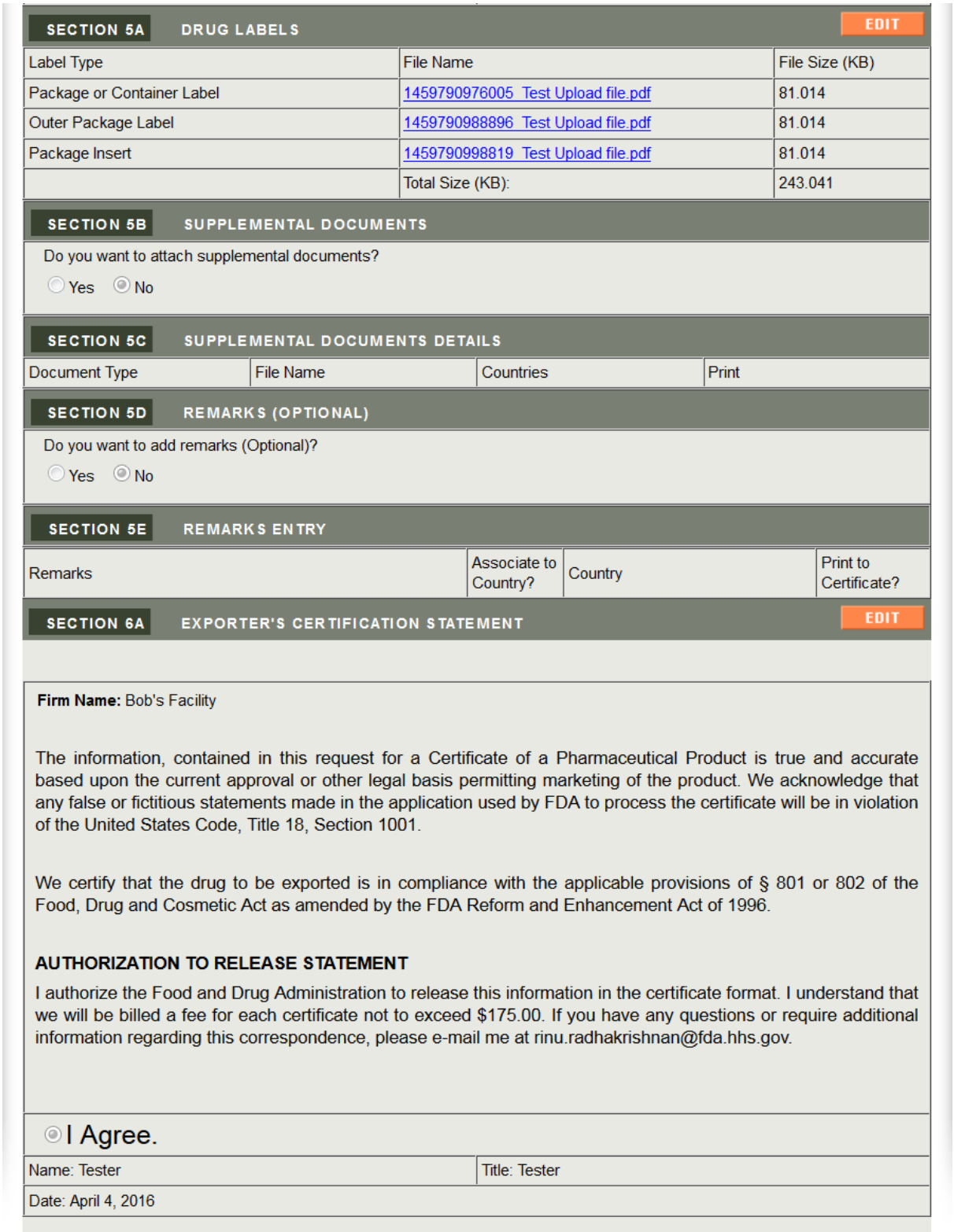
List of Countries for which certificates are requested:	ARGENTINA, GERMANY

SECTION 4B NUMBER OF CERTIFICATES

Enter the number of certificates requested (Maximum of 50 including original and additional copies)

Country	Original Certificates	Additional Copies	Total Copies
ARGENTINA	1	1	2
GERMANY	1		1
Total = $440.00		Total Certificates: 3	

Figure 58: Final Review Page Section 5 and 6



SECTION 5A DRUG LABELS EDIT

Label Type	File Name	File Size (KB)
Package or Container Label	1459790976005_Test Upload file.pdf	81.014
Outer Package Label	1459790988896_Test Upload file.pdf	81.014
Package Insert	1459790998819_Test Upload file.pdf	81.014
	Total Size (KB):	243.041

SECTION 5B SUPPLEMENTAL DOCUMENTS

Do you want to attach supplemental documents?

○ Yes ◉ No

SECTION 5C SUPPLEMENTAL DOCUMENTS DETAILS

Document Type	File Name	Countries	Print

SECTION 5D REMARKS (OPTIONAL)

Do you want to add remarks (Optional)?

○ Yes ◉ No

SECTION 5E REMARKS ENTRY

Remarks	Associate to Country?	Country	Print to Certificate?

SECTION 6A EXPORTER'S CERTIFICATION STATEMENT EDIT

Firm Name: Bob's Facility

The information, contained in this request for a Certificate of a Pharmaceutical Product is true and accurate based upon the current approval or other legal basis permitting marketing of the product. We acknowledge that any false or fictitious statements made in the application used by FDA to process the certificate will be in violation of the United States Code, Title 18, Section 1001.

We certify that the drug to be exported is in compliance with the applicable provisions of § 801 or 802 of the Food, Drug and Cosmetic Act as amended by the FDA Reform and Enhancement Act of 1996.

AUTHORIZATION TO RELEASE STATEMENT

I authorize the Food and Drug Administration to release this information in the certificate format. I understand that we will be billed a fee for each certificate not to exceed $175.00. If you have any questions or require additional information regarding this correspondence, please e-mail me at rinu.radhakrishnan@fda.hhs.gov.

◉ I Agree.

Name: Tester	Title: Tester
Date: April 4, 2016	

Print the Application

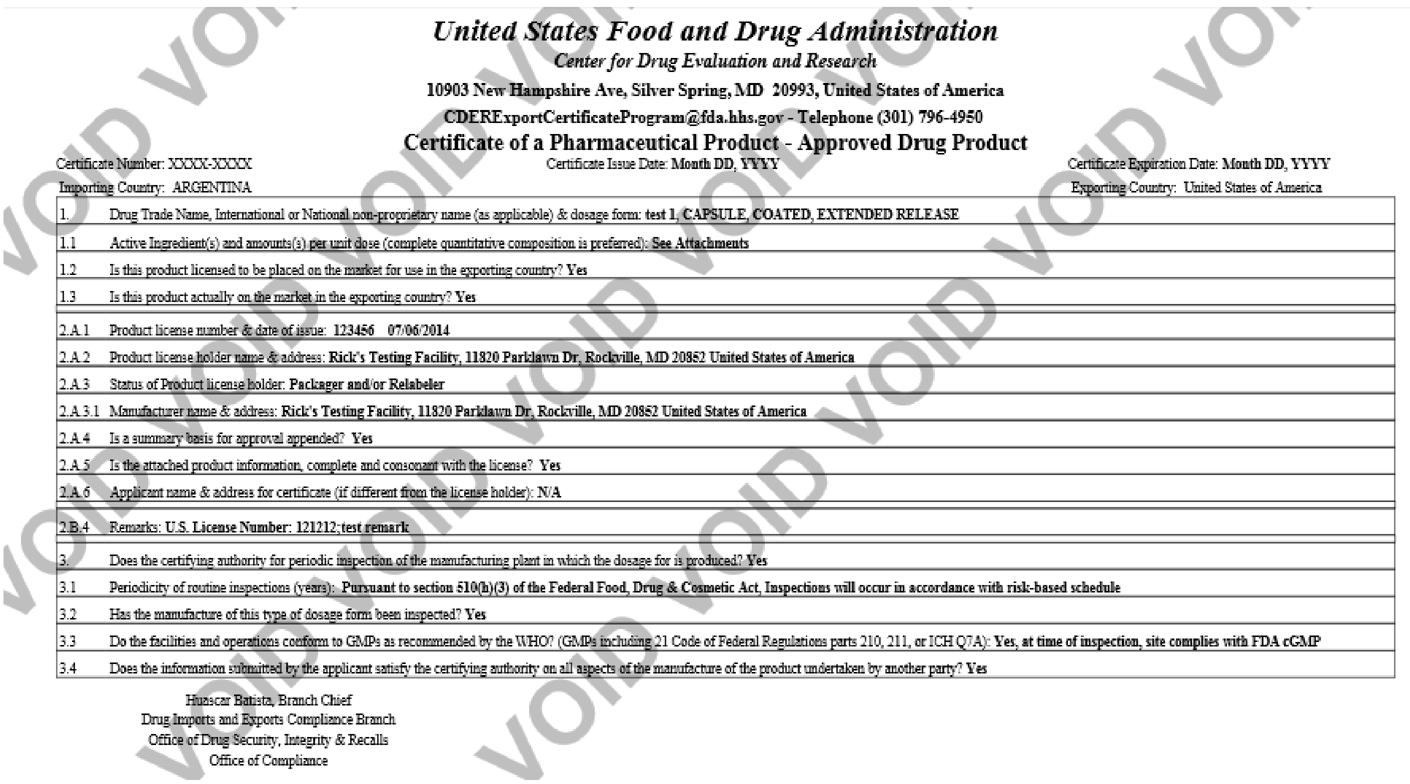
You may choose to print your application prior to submission. Select the ‘Print’ button located at the bottom of the final review page. A new browser window will open which will allow you to print the application.

Preview Certificate

You may choose to preview the certificate prior to submission Select the ‘Preview Certificate’ button located at the bottom of the final review page. This will allow you to view the certificate (assuming the FDA approves your application). You will be able to view how the certificate will look and, if necessary, make modifications to your application prior to submitting if it is not the expected output.

Below is an example of previewing a certificate as shown in **Figure 59** below.

Figure 59: Preview Certificate



United States Food and Drug Administration

Center for Drug Evaluation and Research

10903 New Hampshire Ave, Silver Spring, MD 20993, United States of America

CDERExportCertificateProgram@fda.hhs.gov - Telephone (301) 796-4950

Certificate of a Pharmaceutical Product - Approved Drug Product

Certificate Number: XXXX-XXXX   Certificate Issue Date: **Month DD, YYYY**   Certificate Expiration Date: **Month DD, YYYY**

Importing Country: ARGENTINA   Exporting Country: United States of America

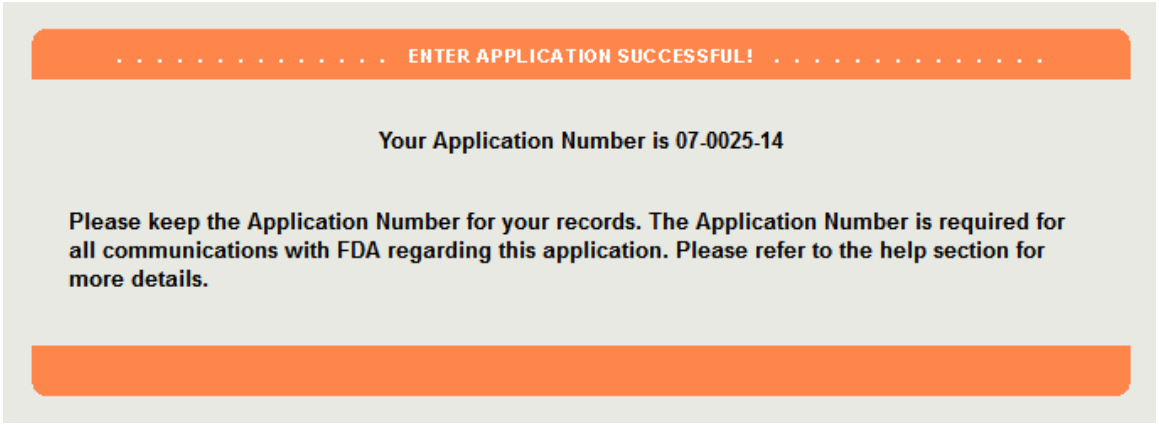
1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **test 1, CAPSULE, COATED, EXTENDED RELEASE**
1.1	Active Ingredient(s) and amounts(s) per unit dose (complete quantitative composition is preferred): **See Attachments**
1.2	Is this product licensed to be placed on the market for use in the exporting country? **Yes**
1.3	Is this product actually on the market in the exporting country? **Yes**
2.A.1	Product license number & date of issue: **123456 07/06/2014**
2.A.2	Product license holder name & address: **Rick's Testing Facility, 11820 Parklawn Dr, Rockville, MD 20852 United States of America**
2.A.3	Status of Product license holder: **Packager and/or Relabeler**
2.A.3.1	Manufacturer name & address: **Rick's Testing Facility, 11820 Parklawn Dr, Rockville, MD 20852 United States of America**
2.A.4	Is a summary basis for approval appended? **Yes**
2.A.5	Is the attached product information, complete and consonant with the license? **Yes**
2.A.6	Applicant name & address for certificate (if different from the license holder): **N/A**
2.B.4	Remarks: **U.S. License Number: 121212;test remark**
3.	Does the certifying authority for periodic inspection of the manufacturing plant in which the dosage for is produced? **Yes**
3.1	Periodicity of routine inspections (years): **Pursuant to section 510(h)(3) of the Federal Food, Drug & Cosmetic Act, Inspections will occur in accordance with risk-based schedule**
3.2	Has the manufacture of this type of dosage form been inspected? **Yes**
3.3	Do the facilities and operations conform to GMPs as recommended by the WHO? (GMPs including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A): **Yes, at time of inspection, site complies with FDA cGMP**
3.4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? **Yes**

Huascar Batista, Branch Chief
Drug Imports and Exports Compliance Branch
Office of Drug Security, Integrity & Recalls
Office of Compliance

Submitting the Application

When your application is ready for submission, click on the 'Submit' button also located at the bottom of the final review page. The system will display a message that your application was successfully submitted as shown in **Figure 60** below. The system will provide you with an application number. Please save this number for future reference. The application number will be required to check the status of your application. You will also receive an email confirmation that your application has been successfully received along with the application number.

Figure 60: Submission Page



Modify Application Step-by-Step Instructions

April, 2016

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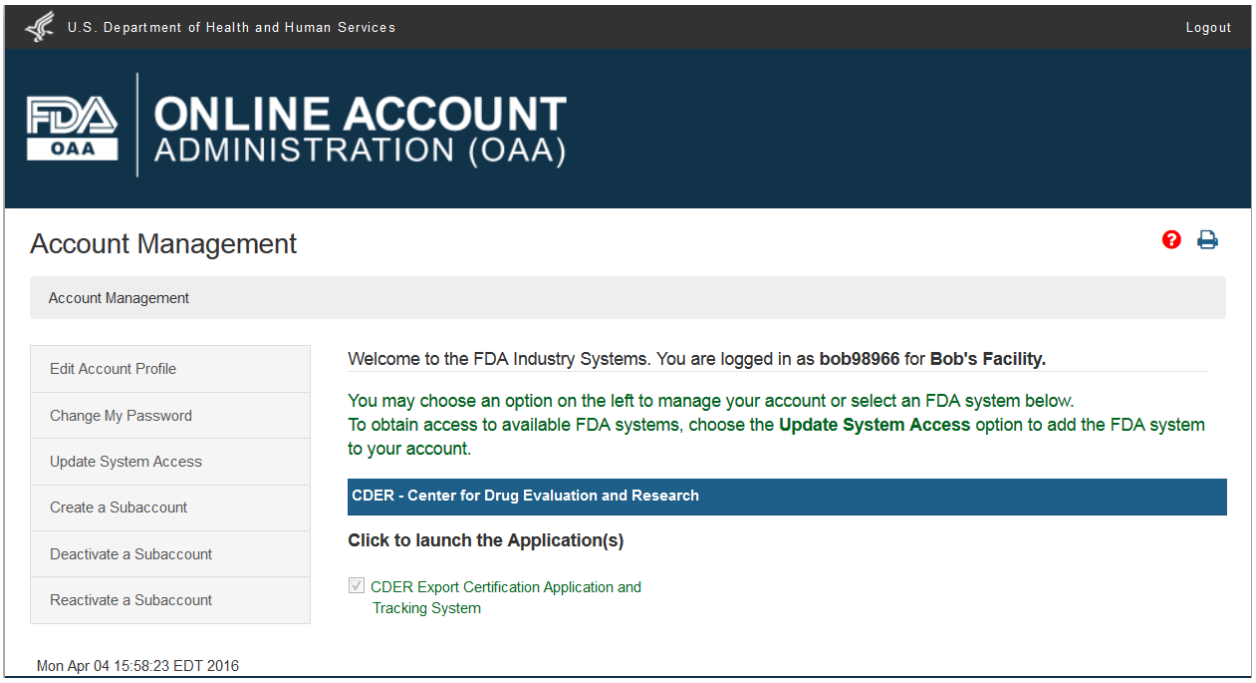
Modify a field or fields based on a notification received

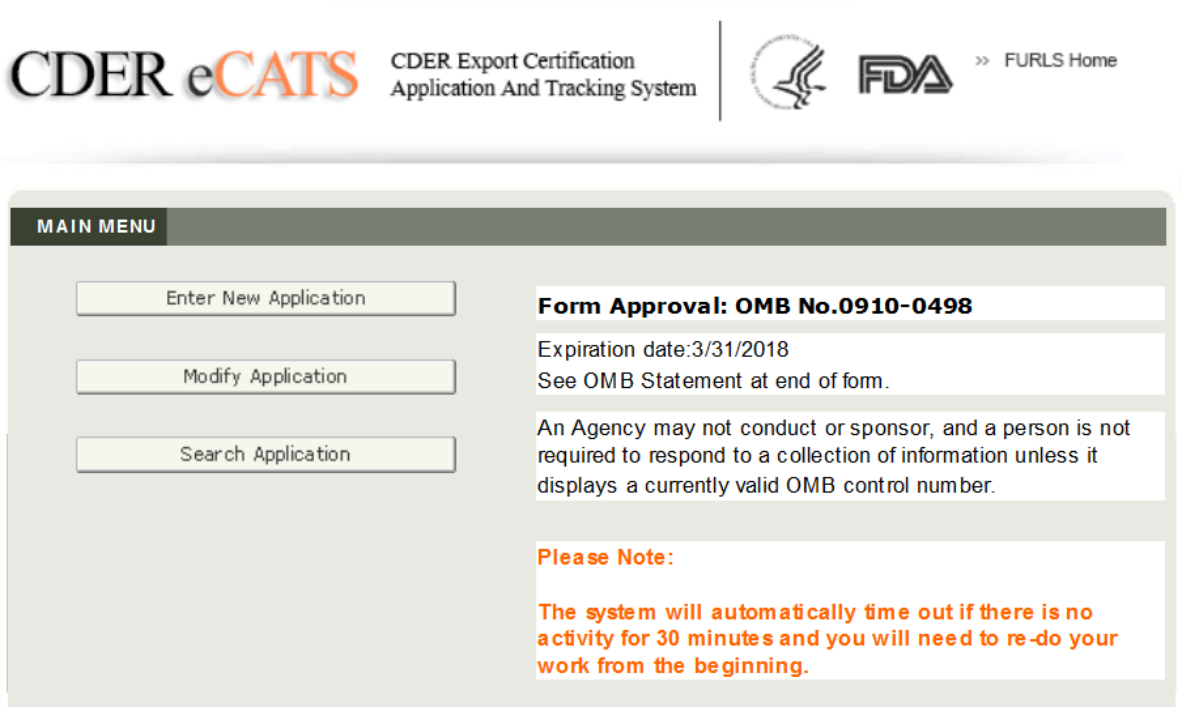
After you have logged in to FDA Industry Systems, choose ‘CDER eCATS’ from the list of systems available on the FURLS Home Page as shown in **Figure 1** below.

Figure 1: FDA Industry Systems Page



To modify an application, choose ‘Modify Application’ from the list of options on the CDER eCATS Main Menu Page as shown in Figure **2** below.

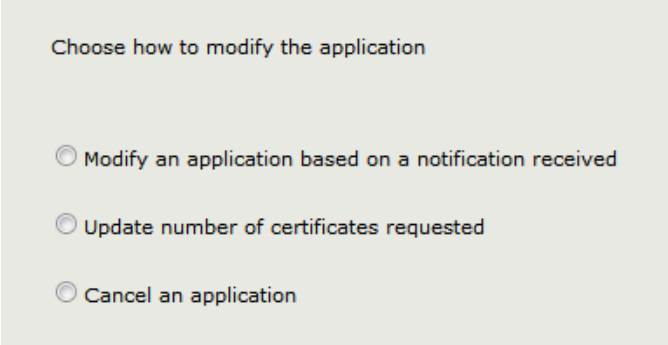
Figure 2: CDER eCATS Main Menu



Modify Application - Update ECS document

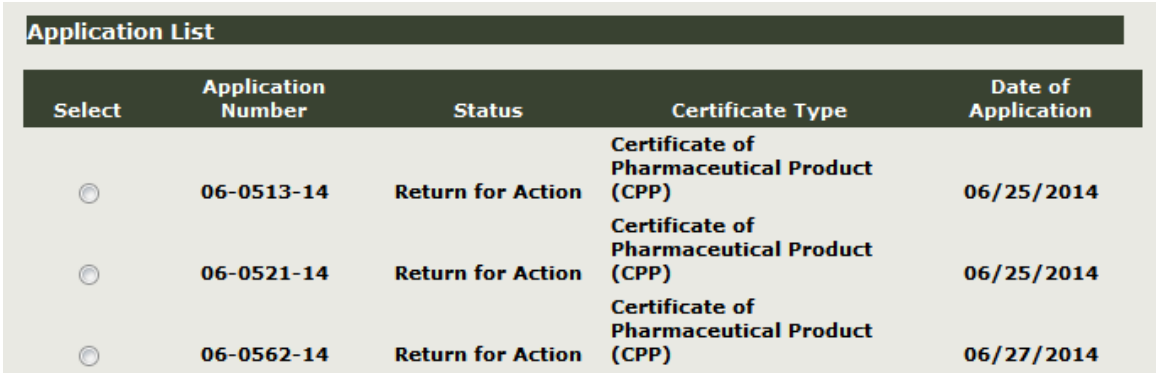
The application has been returned for action because there is an issue with the application. You will need to select the Modify Application option from the main menu and then select 'Modify a field or fields based on a notification received' option as shown in **Figure 3** below.

Figure 3: Modify Application Options



The system will display all applications that can be modified as shown in **Figure 4** below.

Figure 4: Applications that can be modified

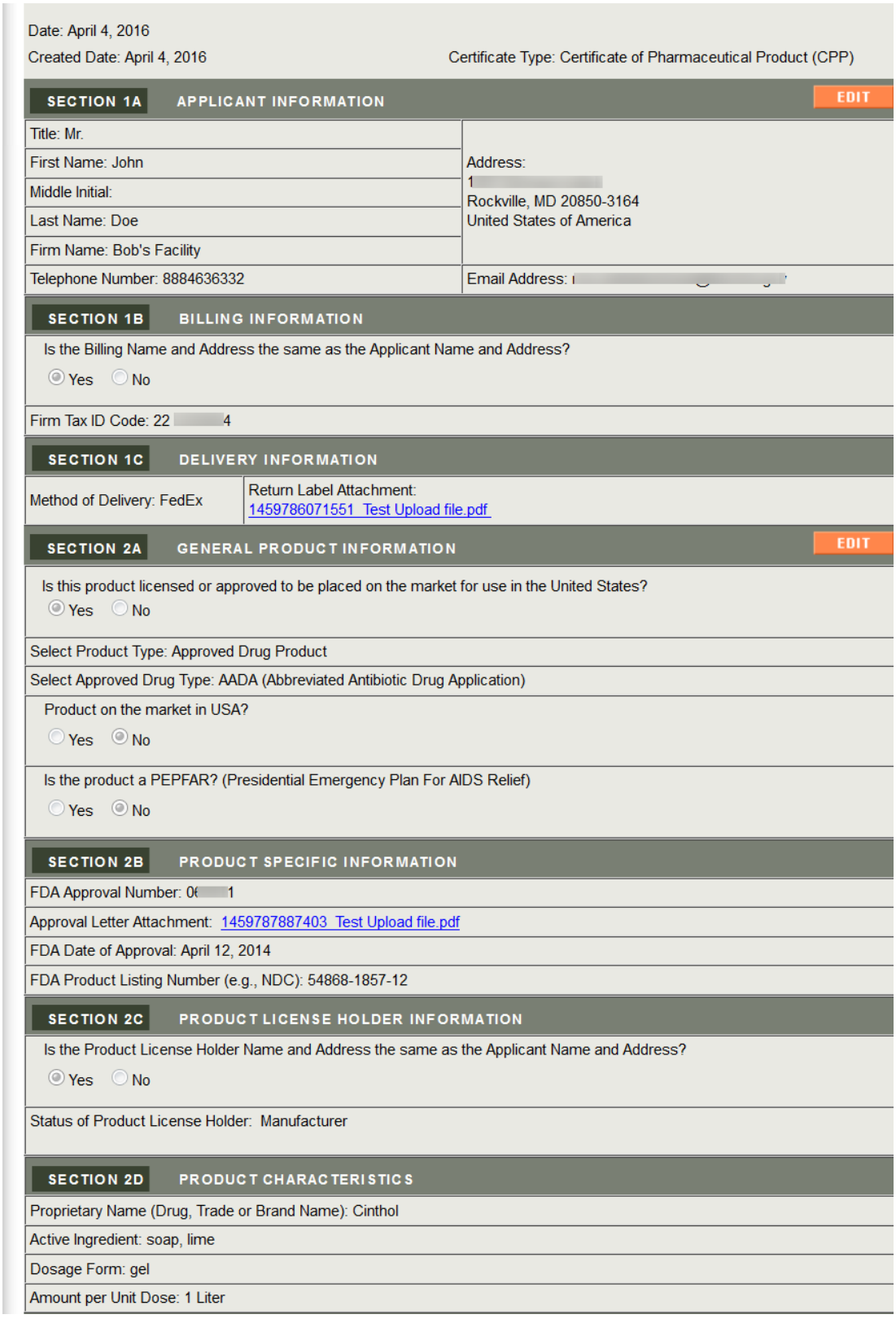


Application List

Select	Application Number	Status	Certificate Type	Date of Application
○	06-0513-14	Return for Action	Certificate of Pharmaceutical Product (CPP)	06/25/2014
○	06-0521-14	Return for Action	Certificate of Pharmaceutical Product (CPP)	06/25/2014
○	06-0562-14	Return for Action	Certificate of Pharmaceutical Product (CPP)	06/27/2014

Once you have selected an application to modify, the system will navigate you to the Final Review Page. There the system will display the application with an Edit button next to each section as shown in **Figure 5-7** below.

Figure 5: Final Review Page Section 1 and 2



Date: April 4, 2016

Created Date: April 4, 2016 Certificate Type: Certificate of Pharmaceutical Product (CPP)

SECTION 1A APPLICANT INFORMATION EDIT

Title: Mr.	
First Name: John	Address: 1 [redacted] Rockville, MD 20850-3164 United States of America
Middle Initial:	
Last Name: Doe	
Firm Name: Bob's Facility	
Telephone Number: 8884636332	Email Address: [redacted]

SECTION 1B BILLING INFORMATION

Is the Billing Name and Address the same as the Applicant Name and Address?

(•) Yes ( ) No

Firm Tax ID Code: 22 [redacted] 4

SECTION 1C DELIVERY INFORMATION

Method of Delivery: FedEx	Return Label Attachment: 1459786071551_Test Upload file.pdf

SECTION 2A GENERAL PRODUCT INFORMATION EDIT

Is this product licensed or approved to be placed on the market for use in the United States?

(•) Yes ( ) No

Select Product Type: Approved Drug Product

Select Approved Drug Type: AADA (Abbreviated Antibiotic Drug Application)

Product on the market in USA?

( ) Yes (•) No

Is the product a PEPFAR? (Presidential Emergency Plan For AIDS Relief)

( ) Yes (•) No

SECTION 2B PRODUCT SPECIFIC INFORMATION

FDA Approval Number: 0[redacted]1

Approval Letter Attachment: 1459787887403_Test Upload file.pdf

FDA Date of Approval: April 12, 2014

FDA Product Listing Number (e.g., NDC): 54868-1857-12

SECTION 2C PRODUCT LICENSE HOLDER INFORMATION

Is the Product License Holder Name and Address the same as the Applicant Name and Address?

(•) Yes ( ) No

Status of Product License Holder: Manufacturer

SECTION 2D PRODUCT CHARACTERISTICS

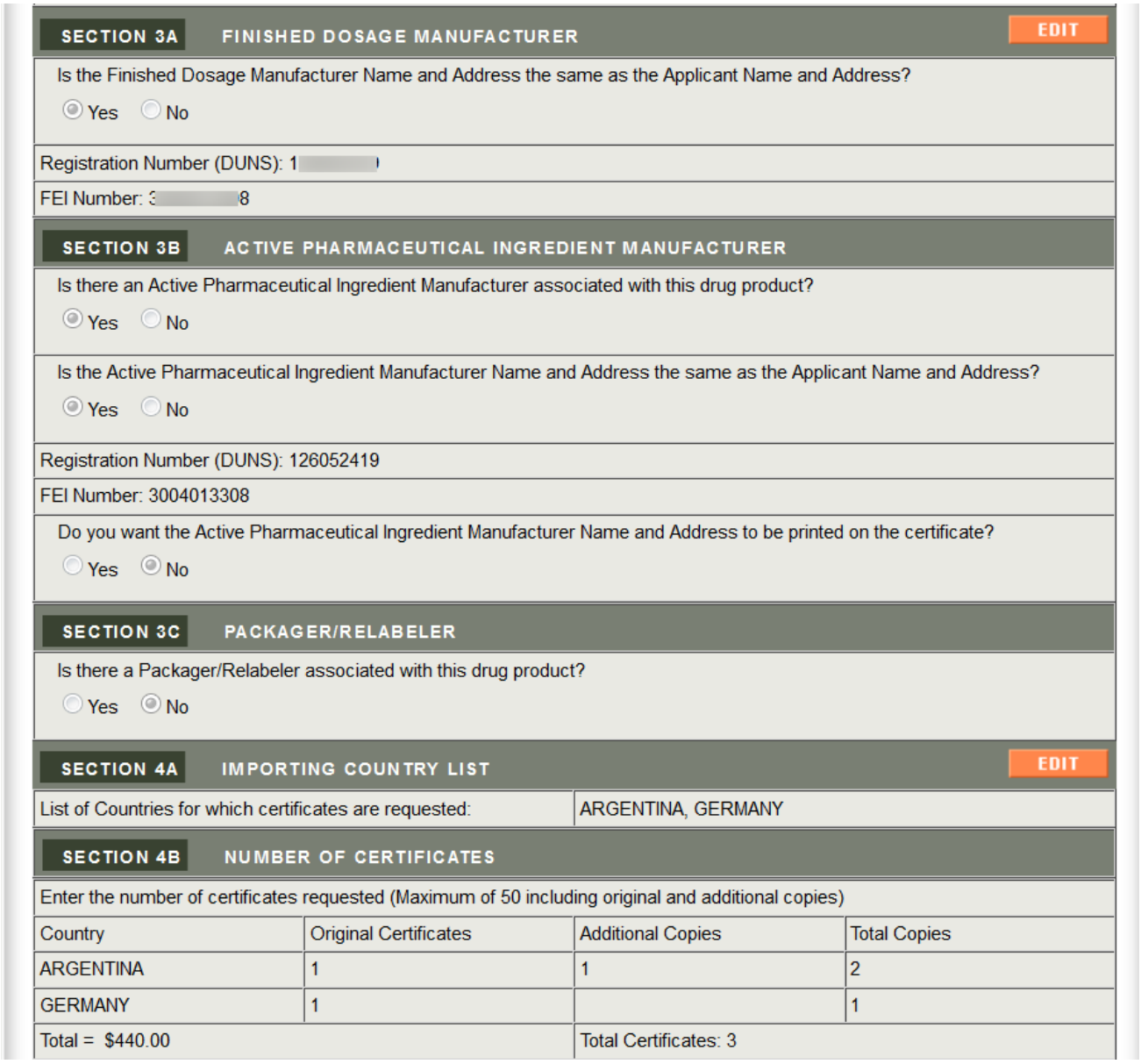
Proprietary Name (Drug, Trade or Brand Name): Cinthol

Active Ingredient: soap, lime

Dosage Form: gel

Amount per Unit Dose: 1 Liter

Figure 6: Final Review Page Section 3 and 4



SECTION 3A FINISHED DOSAGE MANUFACTURER EDIT

Is the Finished Dosage Manufacturer Name and Address the same as the Applicant Name and Address?

(•) Yes ( ) No

Registration Number (DUNS): 1

FEI Number: 3 8

SECTION 3B ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURER

Is there an Active Pharmaceutical Ingredient Manufacturer associated with this drug product?

(•) Yes ( ) No

Is the Active Pharmaceutical Ingredient Manufacturer Name and Address the same as the Applicant Name and Address?

(•) Yes ( ) No

Registration Number (DUNS): 126052419

FEI Number: 3004013308

Do you want the Active Pharmaceutical Ingredient Manufacturer Name and Address to be printed on the certificate?

( ) Yes (•) No

SECTION 3C PACKAGER/RELABELER

Is there a Packager/Relabeler associated with this drug product?

( ) Yes (•) No

SECTION 4A IMPORTING COUNTRY LIST EDIT

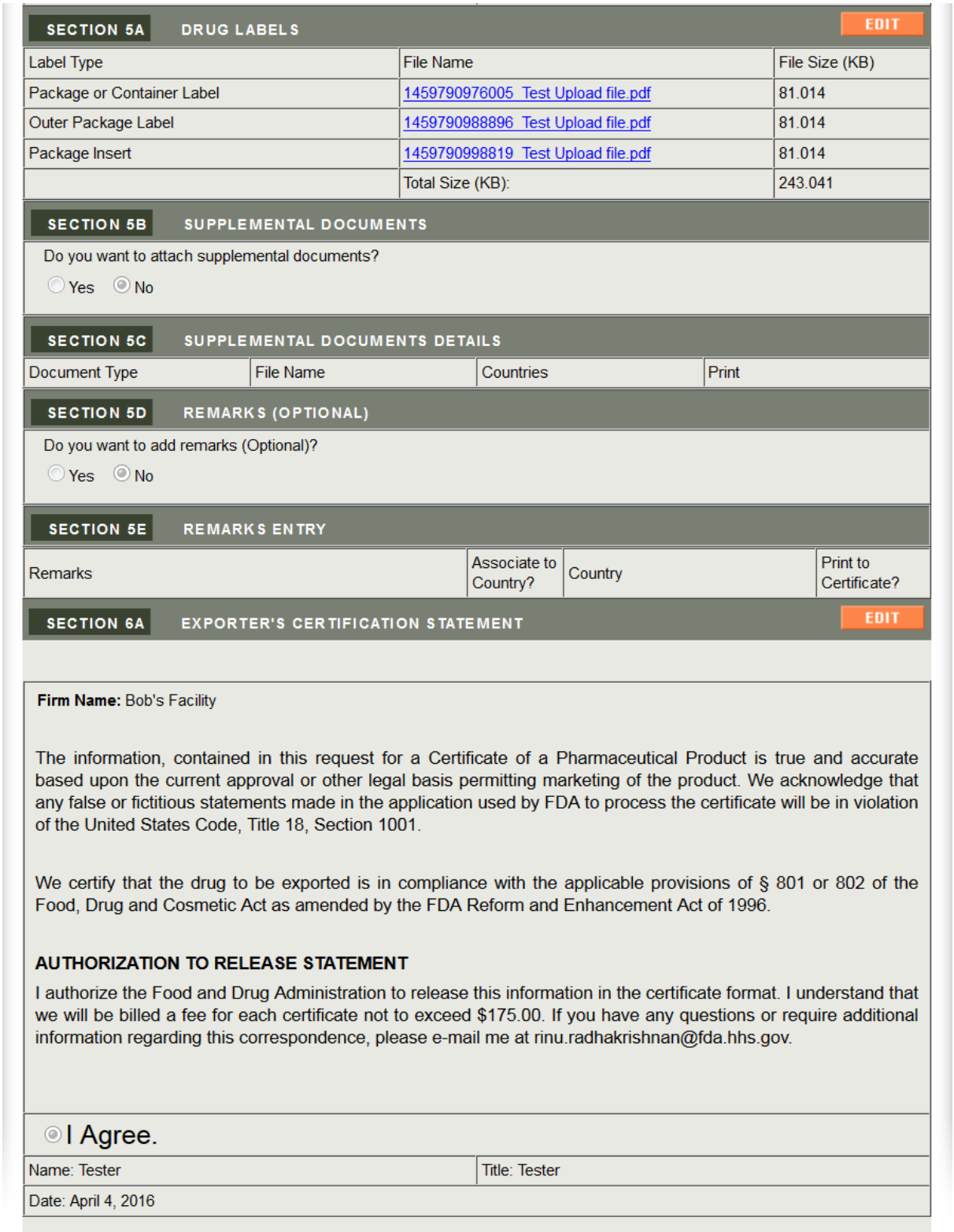
List of Countries for which certificates are requested:	ARGENTINA, GERMANY

SECTION 4B NUMBER OF CERTIFICATES

Enter the number of certificates requested (Maximum of 50 including original and additional copies)

Country	Original Certificates	Additional Copies	Total Copies
ARGENTINA	1	1	2
GERMANY	1		1
Total = $440.00		Total Certificates: 3	

Figure 7: Final Review Page Section 5 and 6



SECTION 5A DRUG LABELS EDIT

Label Type	File Name	File Size (KB)
Package or Container Label	1459790976005_Test Upload file.pdf	81.014
Outer Package Label	1459790988896_Test Upload file.pdf	81.014
Package Insert	1459790998819_Test Upload file.pdf	81.014
	Total Size (KB):	243.041

SECTION 5B SUPPLEMENTAL DOCUMENTS

Do you want to attach supplemental documents?

○ Yes ◉ No

SECTION 5C SUPPLEMENTAL DOCUMENTS DETAILS

Document Type	File Name	Countries	Print

SECTION 5D REMARKS (OPTIONAL)

Do you want to add remarks (Optional)?

○ Yes ◉ No

SECTION 5E REMARKS ENTRY

Remarks	Associate to Country?	Country	Print to Certificate?

SECTION 6A EXPORTER'S CERTIFICATION STATEMENT EDIT

Firm Name: Bob's Facility

The information, contained in this request for a Certificate of a Pharmaceutical Product is true and accurate based upon the current approval or other legal basis permitting marketing of the product. We acknowledge that any false or fictitious statements made in the application used by FDA to process the certificate will be in violation of the United States Code, Title 18, Section 1001.

We certify that the drug to be exported is in compliance with the applicable provisions of § 801 or 802 of the Food, Drug and Cosmetic Act as amended by the FDA Reform and Enhancement Act of 1996.

AUTHORIZATION TO RELEASE STATEMENT

I authorize the Food and Drug Administration to release this information in the certificate format. I understand that we will be billed a fee for each certificate not to exceed $175.00. If you have any questions or require additional information regarding this correspondence, please e-mail me at rinu.radhakrishnan@fda.hhs.gov.

◉ I Agree.

Name: Tester	Title: Tester
Date: April 4, 2016	

Click on the Edit button next to the section you would like to modify.

Once you have made the necessary updates to the application and have returned to the final review page, the system will display all sections for your final review.

Submit the Application

Once you have submitted the application, the system will perform the following:

- Displays the application number and a message that the application has been successfully updated
- Sends a confirmation email

Update number of certificates requested

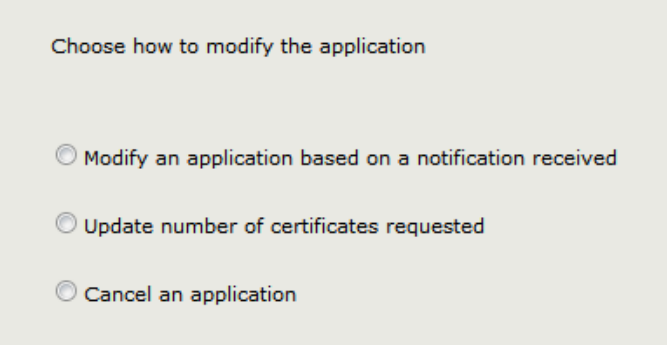
This option allows you to request for additional certificates after you have initially submitted the application. The application must be in one of the following states in order to update the number of certificates requested:

- Received
- Ready to Review
- Under Review
- Return for Action

NOTE: Once the application is in a 'Ready to Print', 'Printing in Progress', or 'Completed' status, you will not be able to update the number of certificates requested and you will need to submit a new application.

Select the Modify Application option from the main menu. Then select the 'Update number of certificates requested' option as shown in **Figure 8** below.

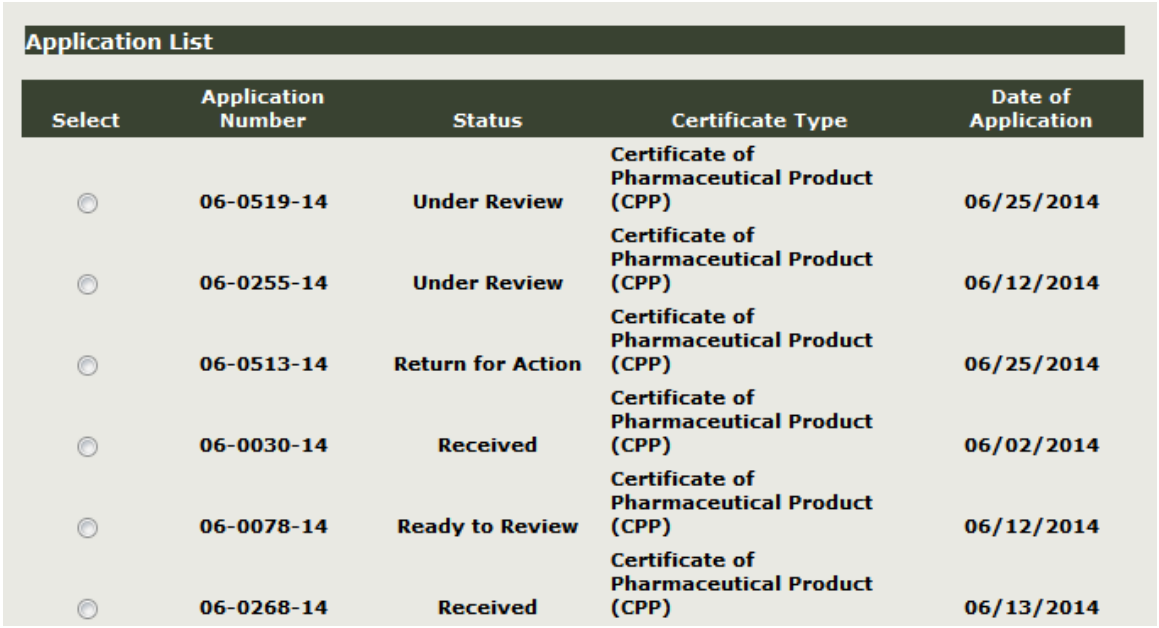
Figure 8: Update number of certificates requested



The system will only display those applications in the following status as shown in **Figure 9** below:

- Received
- Ready to Review
- Under Review
- Return for Action

Figure 9: Request additional certificates application list

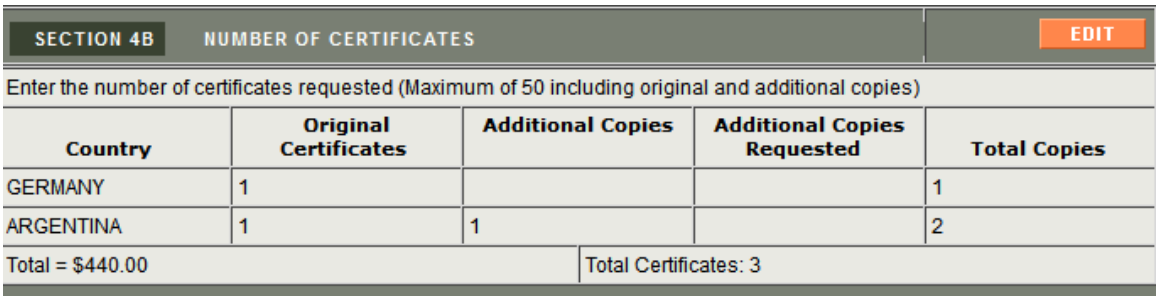


Application List

Select	Application Number	Status	Certificate Type	Date of Application
○	06-0519-14	Under Review	Certificate of Pharmaceutical Product (CPP)	06/25/2014
○	06-0255-14	Under Review	Certificate of Pharmaceutical Product (CPP)	06/12/2014
○	06-0513-14	Return for Action	Certificate of Pharmaceutical Product (CPP)	06/25/2014
○	06-0030-14	Received	Certificate of Pharmaceutical Product (CPP)	06/02/2014
○	06-0078-14	Ready to Review	Certificate of Pharmaceutical Product (CPP)	06/12/2014
○	06-0268-14	Received	Certificate of Pharmaceutical Product (CPP)	06/13/2014

Select the application to request for additional certificates and click on 'Continue'. The system will navigate you to the final review page as shown in **Figure 10** below. The system will display the application with an Edit button next to only **Section 4B** - Number of Certificates.

Figure 10: Final Review Page with Edit button only for Section 4B Number of Certificates



SECTION 4B NUMBER OF CERTIFICATES EDIT

Enter the number of certificates requested (Maximum of 50 including original and additional copies)

Country	Original Certificates	Additional Copies	Additional Copies Requested	Total Copies
GERMANY	1			1
ARGENTINA	1	1		2

Total = $440.00 | Total Certificates: 3

Click on the Edit button to navigate to Section 4B - Number of Certificates. The system will display the original and additional copies you requested. You will need to enter the additional copies in the 'Additional Copies Requested' field or fields based on the number of countries you entered in the application as shown in **Figure 11** below.

Figure 11: Additional Copies Requested

Enter the number of additional copies in the 'Request Additional Copies field'. Once you have entered the number click on 'Continue' to navigate back to the final review page, and submit the application.

The system will perform the following:

- Displays the application number and a message that the application has been successfully updated
- Sends a confirmation email

Modify application - Cancel the Application

This option allows you to cancel an application. However, in order to cancel an application, the status of the application must be in one of the following statuses:

- Received
- Ready to Review
- Return for Action

Select the Modify Application option from the main menu. You will then need to select 'Cancel the Application' option as shown in **Figure 12** below.

Figure 12: Cancel the Application

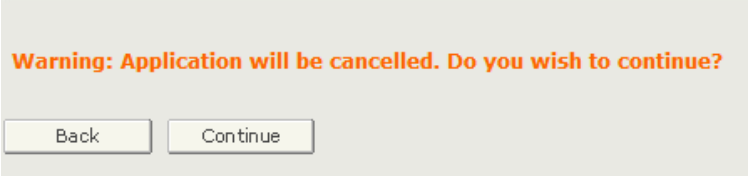
NOTE: If the application is in any other status than Received, Ready to Review, or Return for Action, you will not be able to cancel the application. Furthermore, you will be responsible for any cost associated to the issuance of the certificate requested. Please contact the FDA at CDERExportCertificateProgram@fda.hhs.gov if you have any further question.

The system will display all applications that can be cancelled as shown in **Figure 13** below.

Figure 13: Selecting an application for cancellation

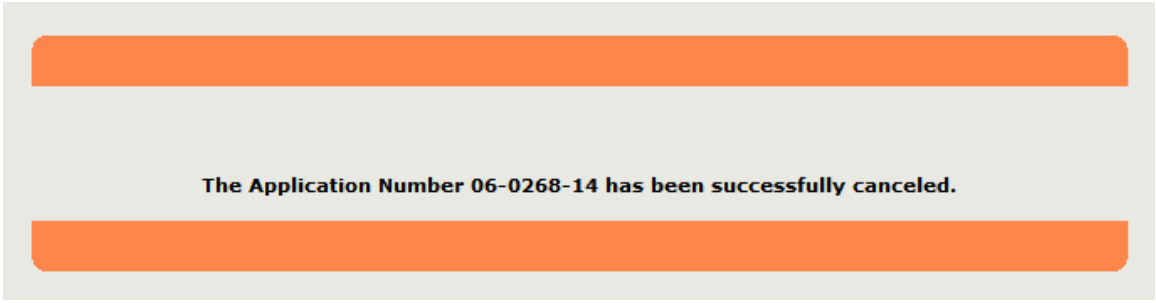
Once you have selected the application, the system will provide a warning message prior to cancelling an application as shown in **Figure 14** below.

Figure 14: Cancel the Application Warning



Once confirmed, the system will cancel the application and you will receive an email notification confirming the cancelled application as shown in **Figure 15** below.

Figure 15: Application Successfully Cancelled Message Displayed



Search Application Process Step-by-Step Instructions

April, 2016

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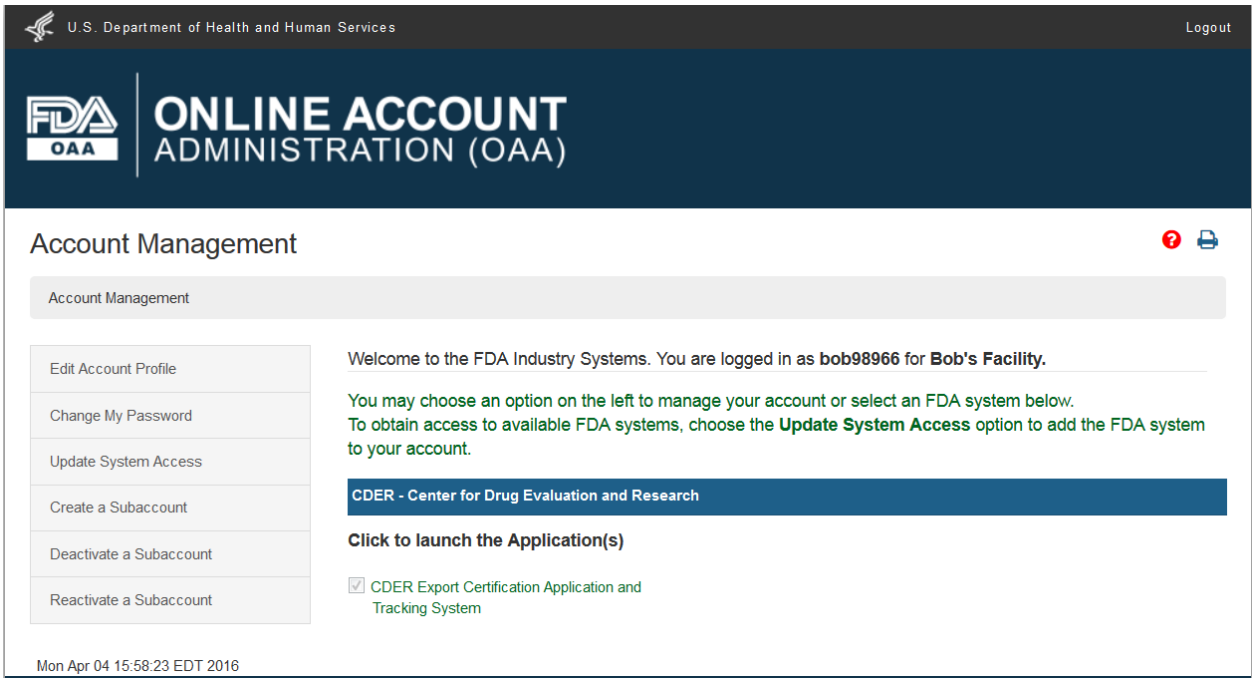
Search Application

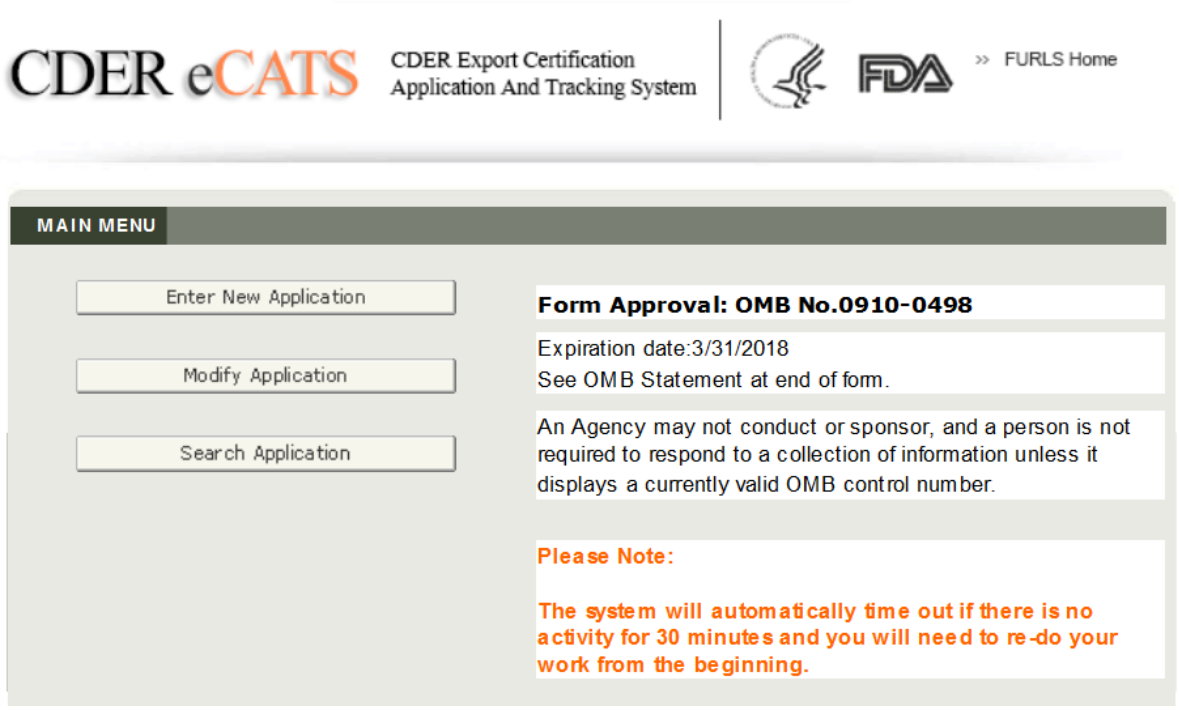
After you have logged in to FDA Industry Systems, choose ‘CDER eCATS from the list of systems available on the FURLS Home Page as shown in **Figure 1** below.

Figure 1: FDA Industry Systems Page



To search for applications, select 'Search Application' from the CDER eCATS Main Menu Page as shown in **Figure 2** below.

Figure 2: CDER eCATS Main Menu

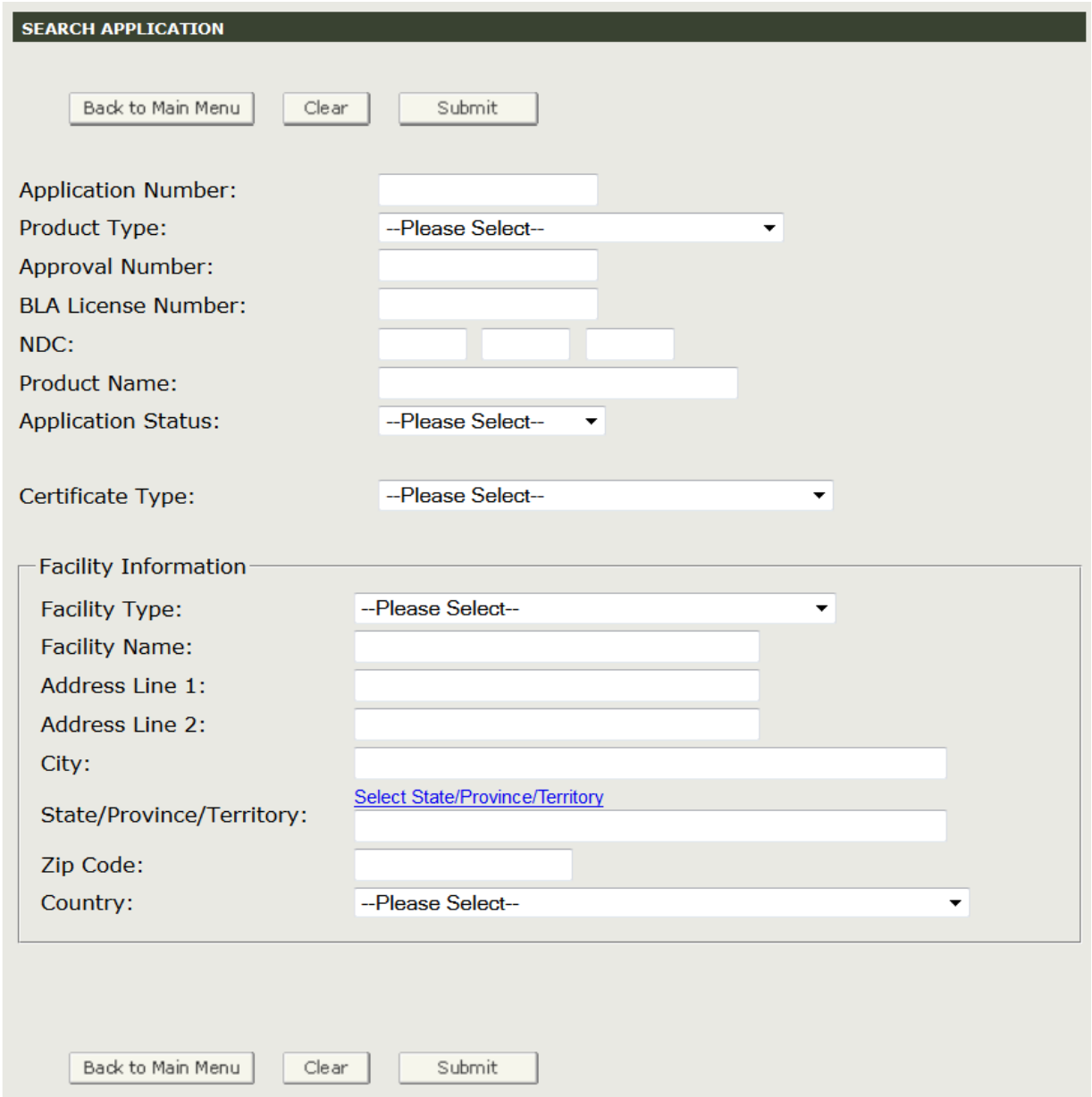


Select the 'Search Application' option to search your applications by various criteria. Once you have found the application, you can modify the application (if applicable), request for additional certificates, or print the application.

You can search using any or all of the following fields as shown in **Figure 3** below:
NOTE: You must enter at least one search criteria.

- Application Number
- Product Type (dropdown list)
- Approval Number
- BLA License Number
- NDC
- Product Name
- Application Status (dropdown list)
- Certificate Type (dropdown list)
- Facility Type (this includes Finished Dosage Manufacturer, API Manufacturer, Packager/Relabeler)
- Facility Name
- Facility Address (this includes Finished Dosage Manufacturer, API Manufacturer, Packager/Relabeler)

Figure 3: **Search Parameters**



Search Results

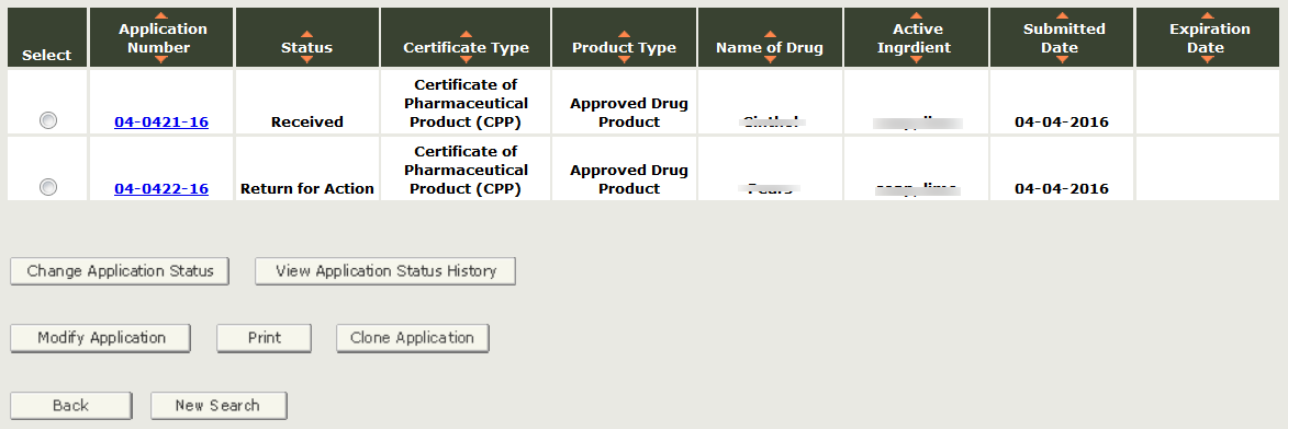
The system will display the results which correspond to your search as shown in **Figure 4** below.

NOTE: If your OAA account is an Enterprise-Level account, you will be able to search on all applications that pertain to your account and any sub-account applications.

If your OAA account is Sub-account, you will only be able to search on applications that pertain to your account.

NOTE: For the Facility Information section of the Search, you must select an option from the Facility Type dropdown list in order to perform a search using the Facility Information parameters.

Figure 4: Search Results



The system displays the Application Number, Status, Certificate Type, Product Type, Name of Drug, Active Ingredient, Submitted Date, and the Expiration Date.

You can use the up and down (orange-colored) arrows in the column headings to sort the application list in ascending or descending order.

View an Application
To view an application, click on the Application Number hyperlink.
Once the application is displayed, you can print a copy of the application.

Modify an Application
To modify an application, select the radio button to the left of the Application Number and choose Modify Application.

NOTE: The application must be in a specific status in order to select the Modify option. See the Modify Application or Update number of additional certificates online help section for more information on how to use these features after a search.

Clone Application
At any time you have the option to copy/clone an existing submitted application. To clone an application, select the radio button to the left of the Application Number and choose Clone Application. The system will automatically create a copy of the application. The system will navigate to the final review page where you can submit the application or make the necessary edits prior to submitting the application.