U.S. Food and Drug Administration

CDER eCATS External User Guide – Step-by-Step Instructions

March 17, 2022

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1 Overview of CDER eCATS

The FDA Center for Drug Evaluation and Research (CDER) Export Certification Application and Tracking System (CDER eCATS) module facilitates the submission of Certificate of Pharmaceutical Product (CPP) application types.

FDA Industry Systems (FIS)

The FIS is an electronic portal that facilitates and provides general entry to a series of systems which enable electronic submissions to the Food and Drug Administration (FDA). Examples of submissions that can be entered via FIS are registration, listing, and export certification applications. The FIS is available 24 hours a day, seven days a week.

FDA's Unified Registration and Listing System (FURLS)

FURLS is a sub-component of FIS. Persons with an account ID and password for the FIS electronic portal can use FURLS to submit information to FDA. The FURLS system described in this document is intended for submissions of export certification applications to CDER.

Supported Browsers

FURLS can be accessed using Firefox, Chrome, or Edge browsers. Please visit the "Systems Requirements" section of the https://www.access.fda.gov/ page for a list of approved browsers and browser versions found in the lower right-hand corner of the page.

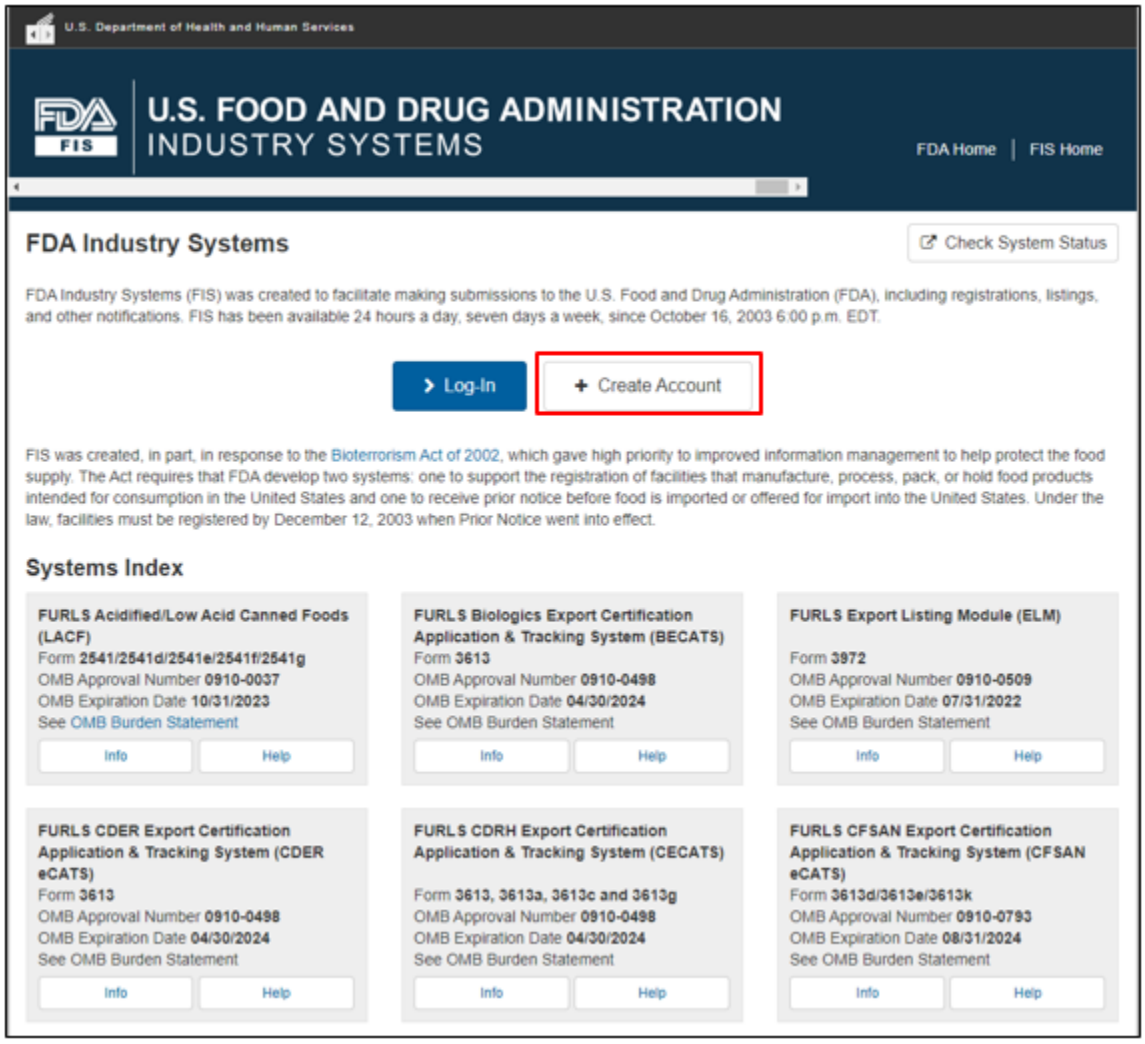
2 Creating a New Account and Accessing CDER eCATS via FIS

All users must create an account through the FIS Electronic Portal. From this portal you will receive a personal account ID and password to use when logging into the CDER eCATS application. This will allow you to create and submit applications.

Access the FIS Electronic Portal:

To access the FIS electronic portal, go to https://www.access.fda.gov/. Click the "Create New Account" button, as shown in Figure 1 (below).

Figure 1 - Create New Account in FDA FIS Electronic Portal

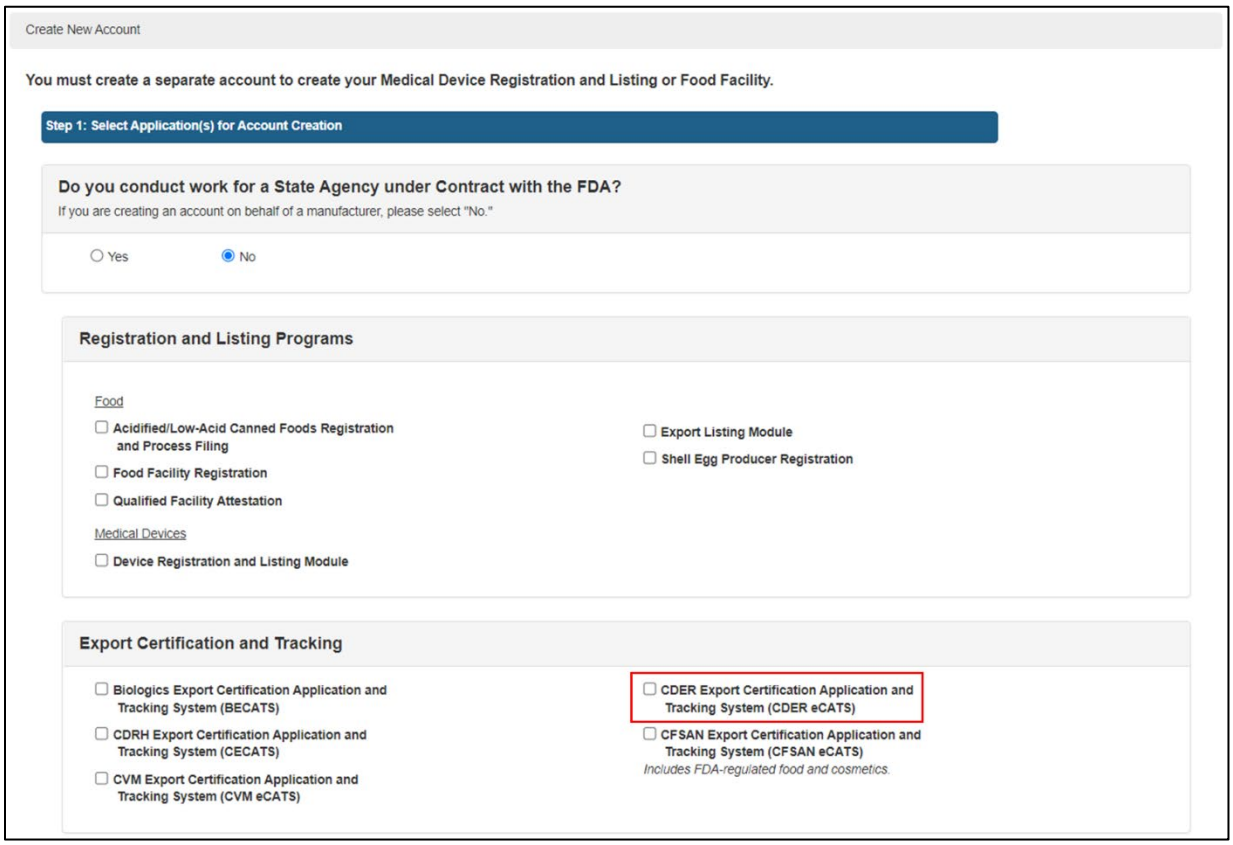


Select CDER Export Certification Application and Tracking System:

Select a response to the question “Do you conduct work for a State Agency under Contract with the FDA?”

Under the Export Certification and Tracking section, select the checkbox for “CDER Export Certification Application and Tracking System (CDER eCATS)”, as shown in Figure 2 (below). Click the “Continue” button at the bottom of the screen.

Figure 2 - Click CDER eCATS Checkbox in FIS Electronic Portal

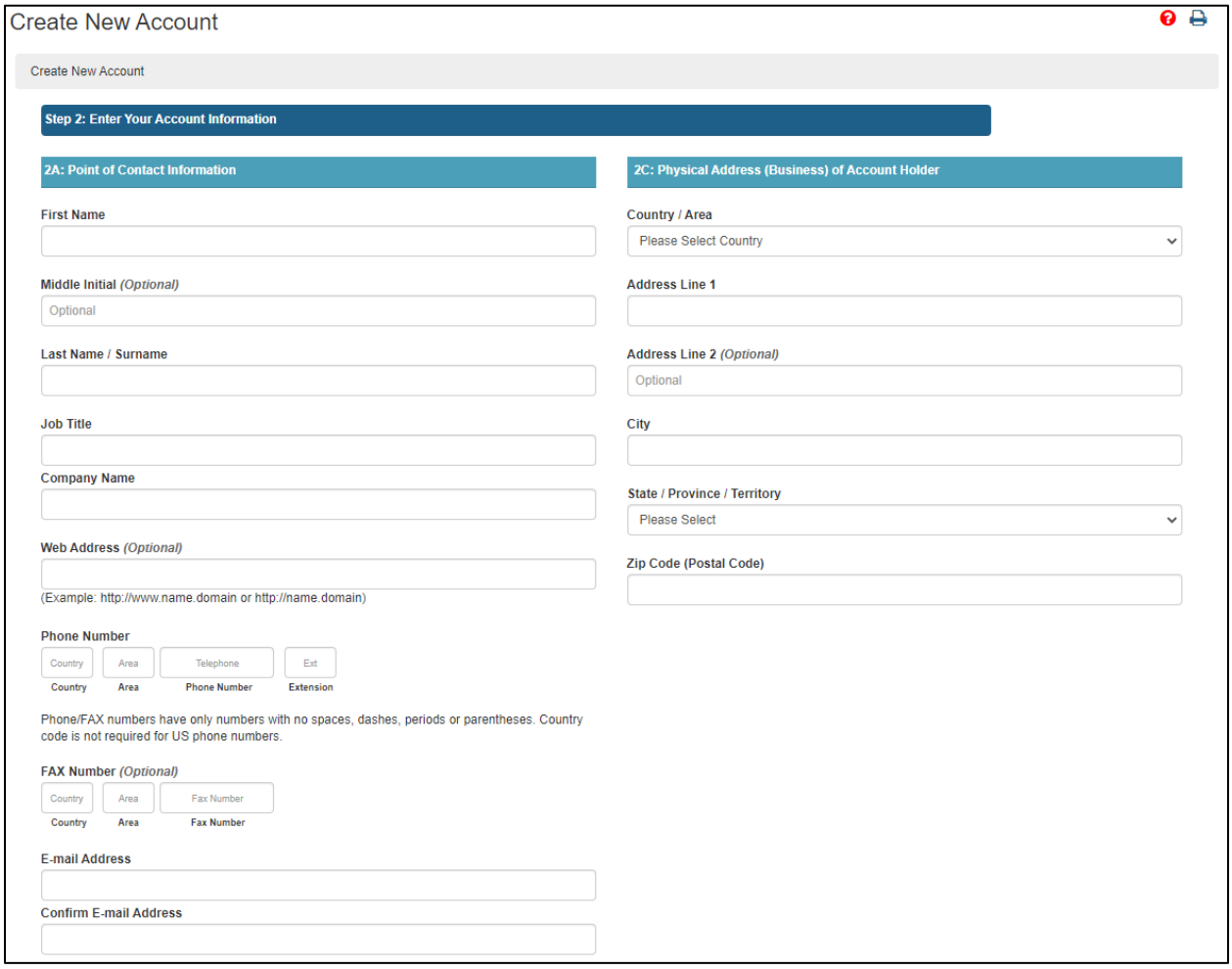


Complete the Contact Information:

Fill out the contact information, including the point of contact's name, address, phone number, and email address, as shown in Figure 3 (below).

NOTE: *FURLS uses the email address for all communication purposes including notifications about your export certification application*.

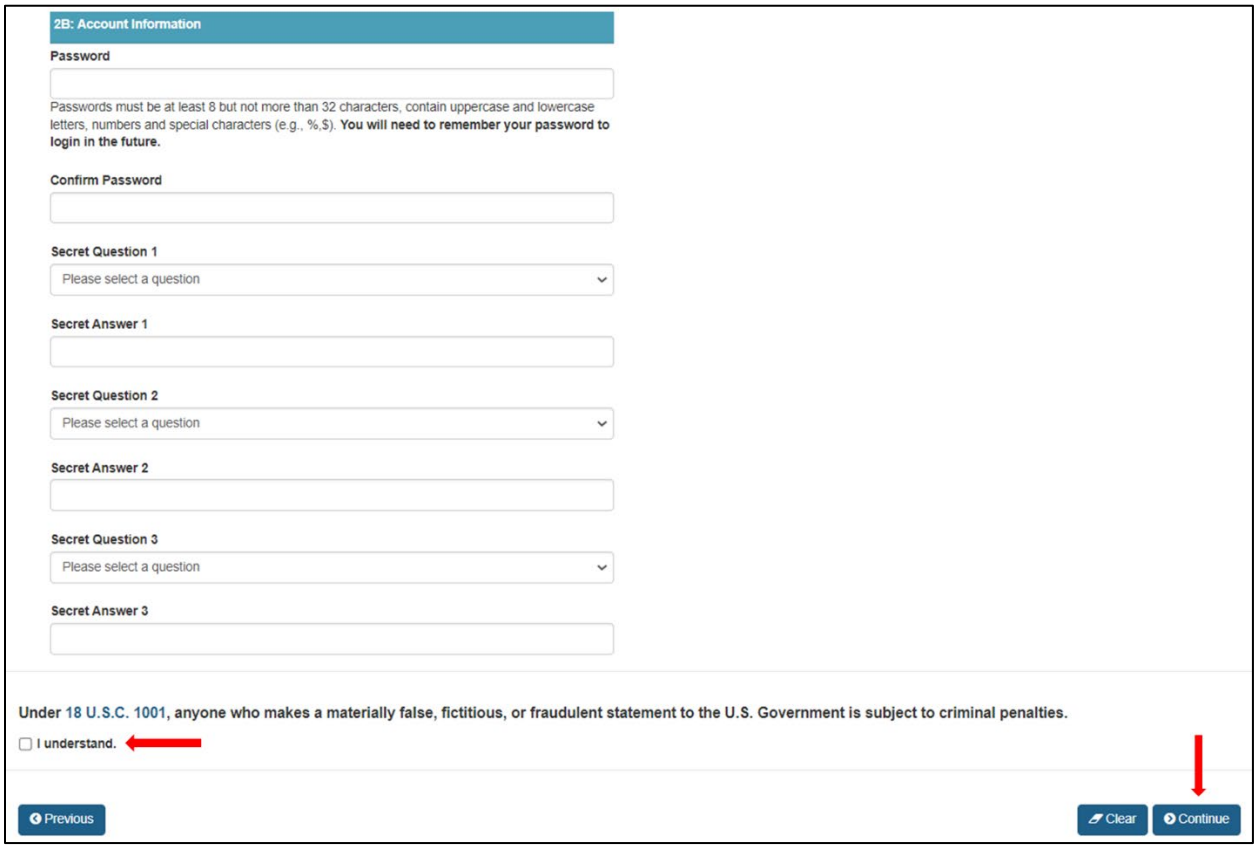
Figure 3 - Fill out Contact Information in FIS Electronic Portal



Enter the Security Information and Submit:

Follow the prompt to enter a password and answer the secret questions. After reading the statement, select the “I understand” checkbox and click the “Continue” button at the bottom of the screen, as shown in Figure 4 (below).

Figure 4 - Complete Contact Information in FIS Electronic Portal



After you clicked the “Continue” button, the system will ask you to review your contact information.

Complete the submission by clicking on the “Submit” button. If you need to modify your information, you may click the “Modify” button first. Upon submission, the system provides you with an account ID and password. You can then use this account to log onto the “Online Account Administration” (OAA) Home page.

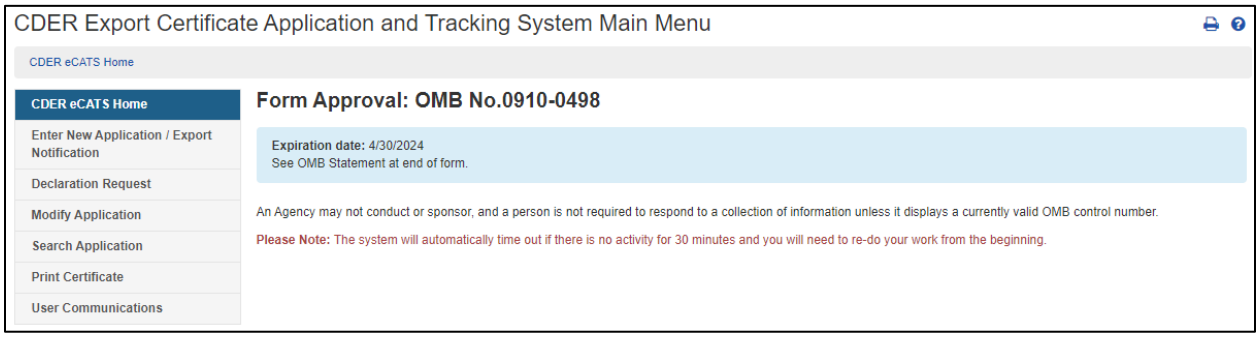
3 Accessing CDER eCATS

After you have logged into FIS, select **CDER Export Certification Application & Tracking System** from the list of systems available on the FURLS Home page, as shown in Figure 5 (below).

Figure 5 - FDA Industry Systems Page

Once you have selected **CDER Export Certification Application & Tracking System**, the system will direct you to the CDER eCATS Main Menu page, as shown in Figure 6 (below).

Figure 6 - CDER eCATS Main Menu



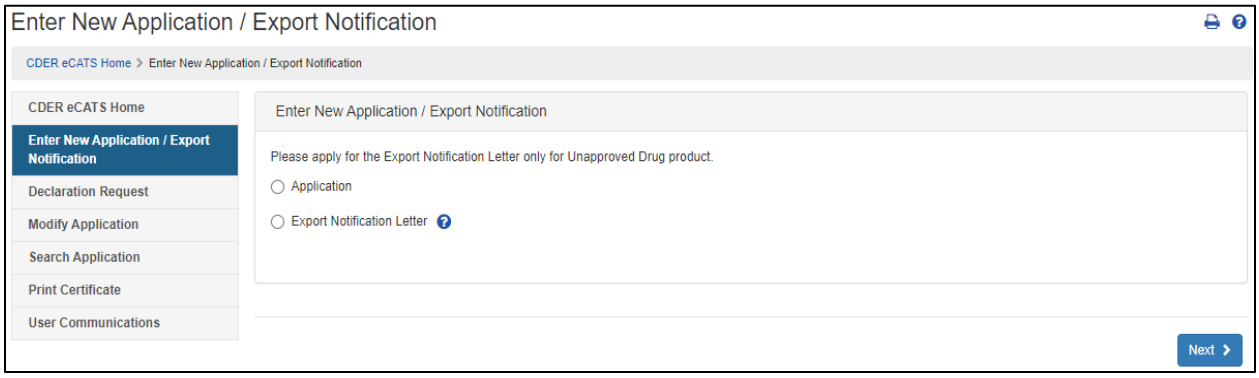
To begin the application process, select “Enter New Application” from the list of options.

From the Main Menu page, you may select “Modify Application” (when applicable). You may also use the “Search Application” feature when you need to search for an application. To respond to the inquiries regarding your application you may select “User Communications “ from the main menu.

After you select the “Enter New Application” option, the system will display a screen for you to indicate whether you want to create new application or an export letter, as shown in Figure 7 (below).

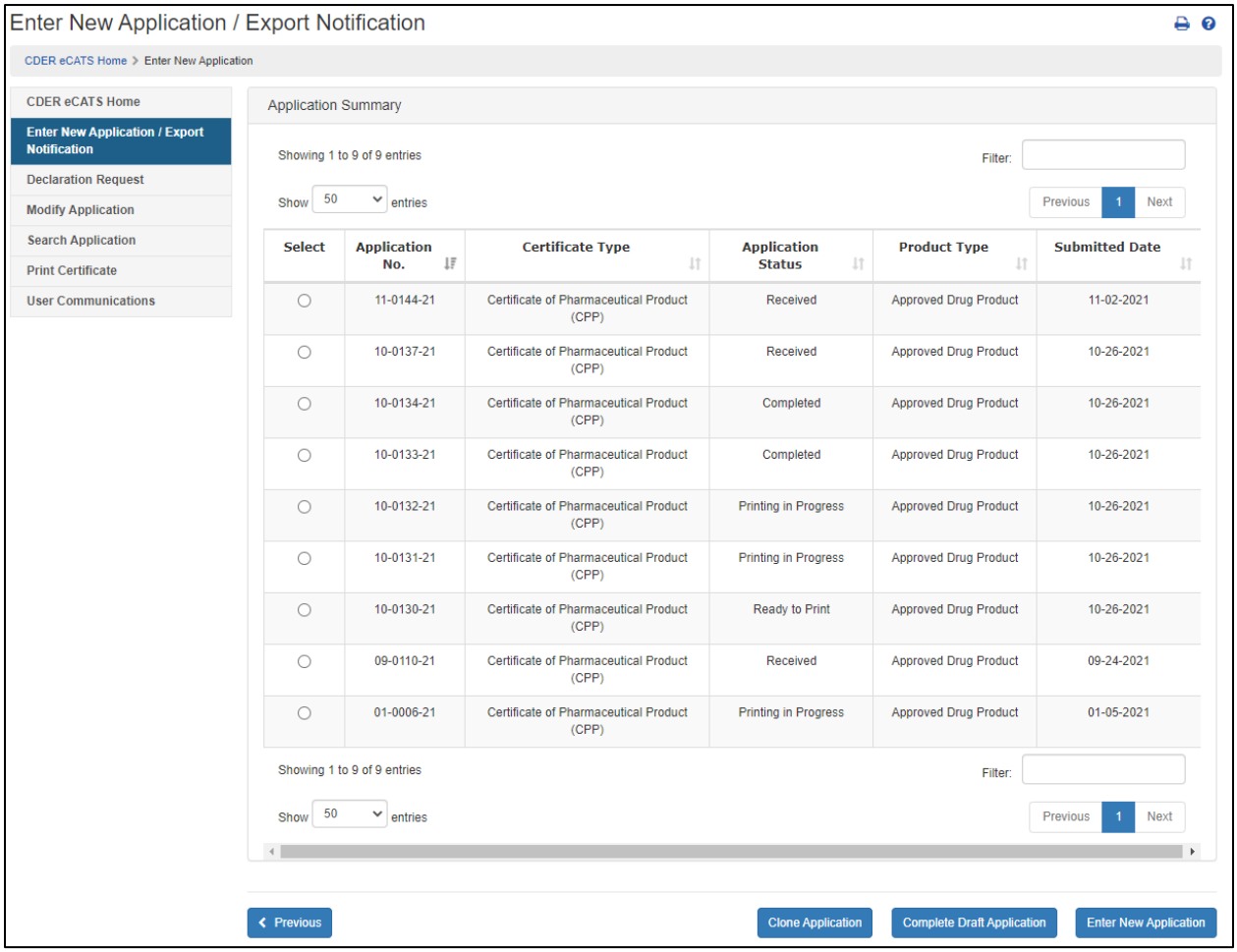
NOTE: If this is your first application, you will be directed the General/Contact Information page, as shown in Figure 9 (below).

Figure 7 - Select New Application or Export Notification Letter



Select the “Application” type. Once you select an application type, all of the applications you have saved or submitted will be displayed, as shown in Figure 8 (below).

Figure 8 - 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’s radio button and click “Complete Draft Application”.
- If you wish to copy an existing application, select the desired application’s radio button and click “Clone Application”.
    - Please refer to “Create an application based on the existing application” section under the Modify Application section of this document for more details.
- If you wish to create a new application, click “Enter 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 9 and Figure 10 (below). If you have any questions, please refer to the links provided.

Click “Next” to begin the application process.

Figure 9 - General/Contact Information

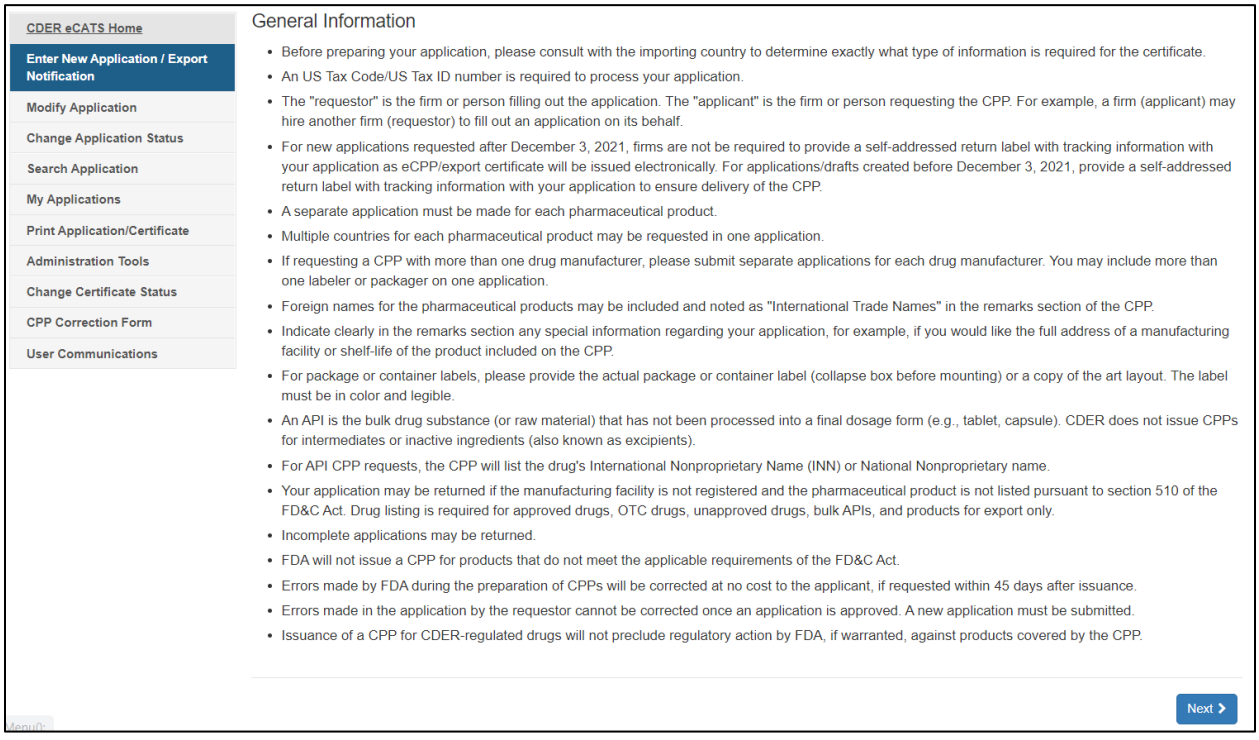
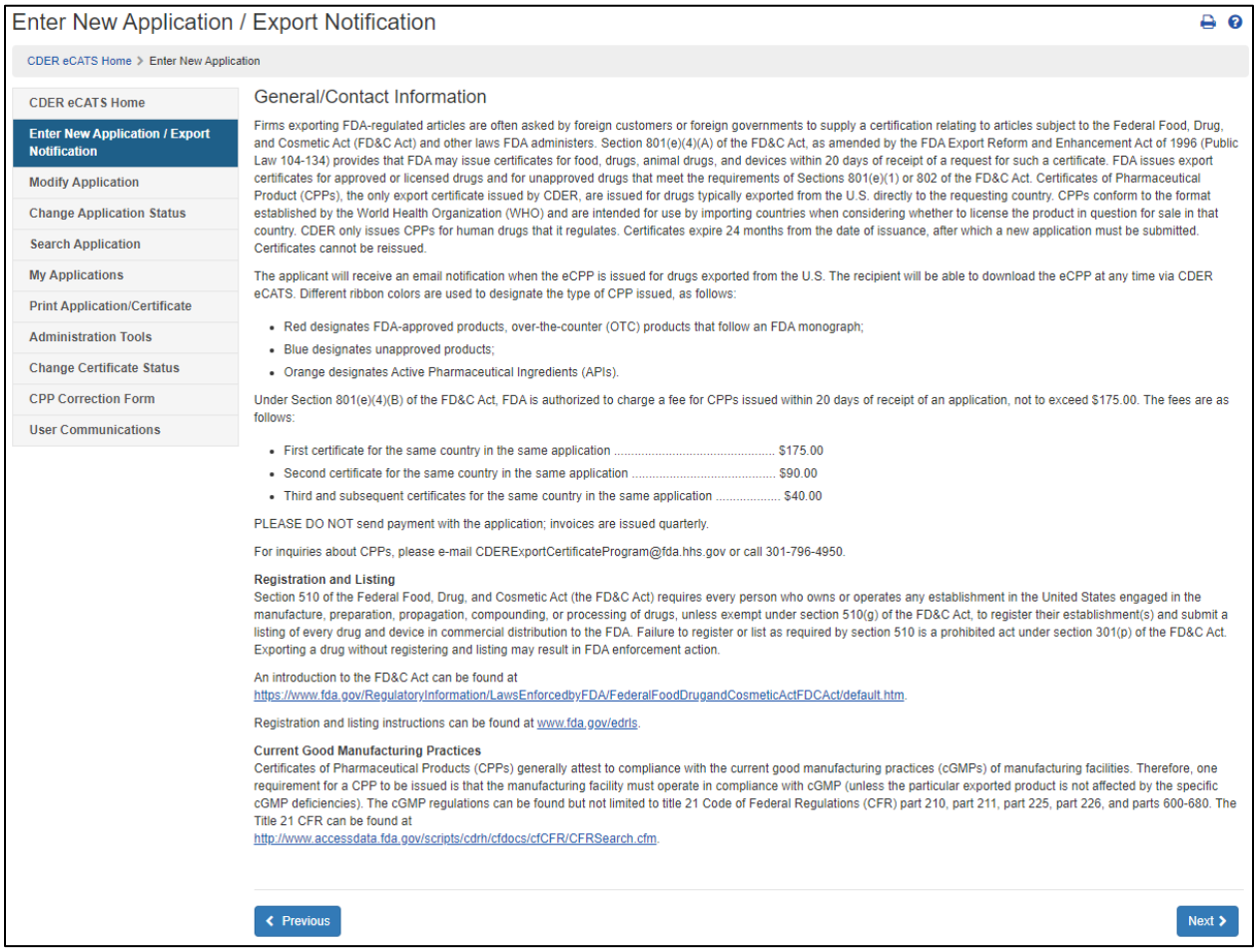
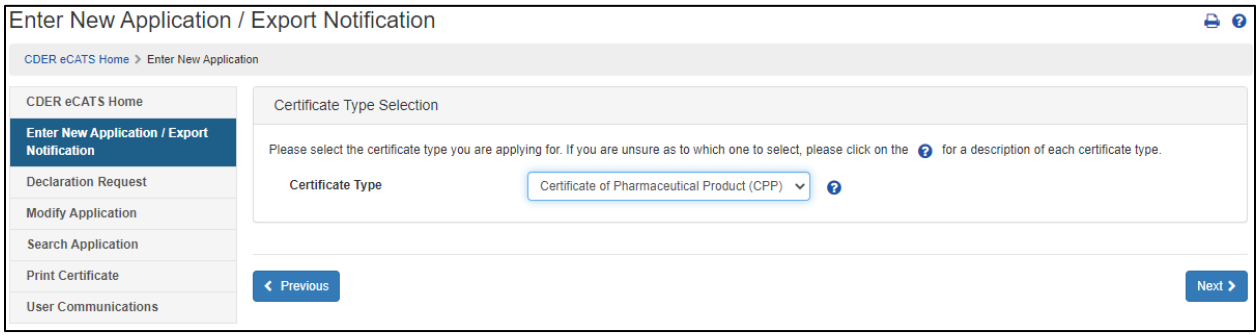


Figure 10 - General/Contact Information (cont.)



CDER is responsible for the issuance of Certificate of Pharmaceutical Products (CPPs). Please select “Certificate of Pharmaceutical Product (CPP)” from the Certificate Type dropdown list, as shown in Figure 11 (below).

Figure 11 - Certificate Types



Certificate of Pharmaceutical Product (CPP):

The following section provides an overview of the CPPs and Simple Notifications that are generated within the application.

- CPP Certificate of Pharmaceutical Product and World Health Organization (Labeling required)

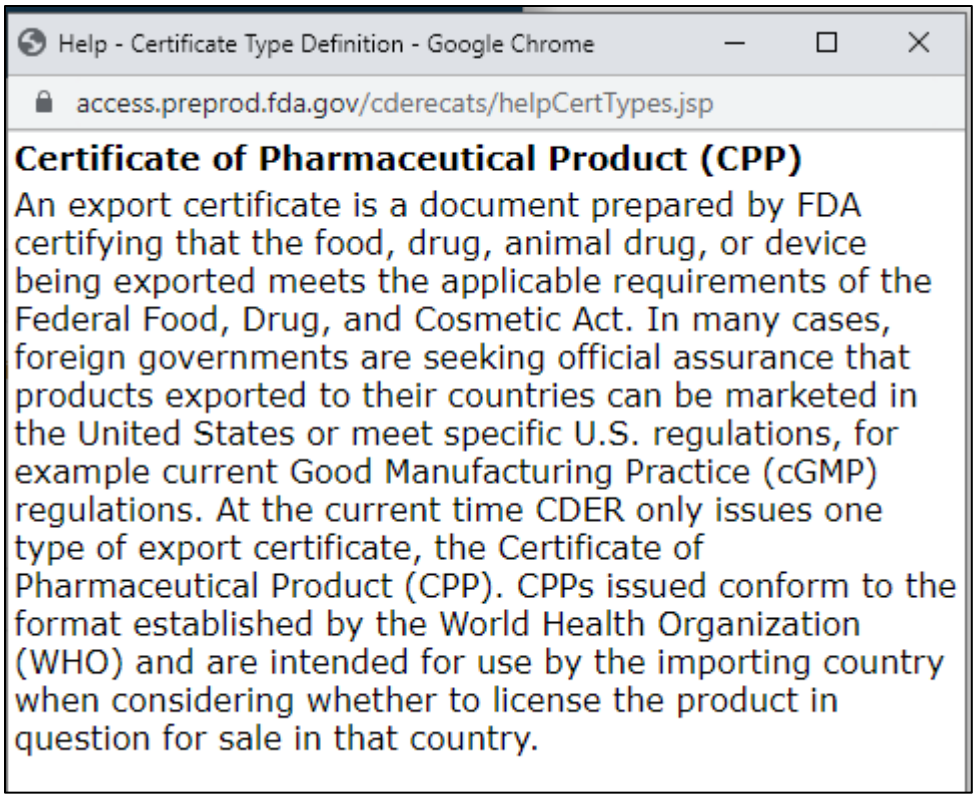
- Simple Notification

    - 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 blue question mark icon located next to the certificate type list. The system will display in a new window with a description of the CPP certificate type, as shown in Figure 12 (below).

Figure 12 - Certificate of Pharmaceutical Product (CPP)



NOTE: At this time the Certificate of 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 of the Enter New Application section, a status bar will track your progress through each step of the online application process, as shown in Figure 13 (below).

Figure 13 - Navigation Bar

A “Get Help” icon (located at the top right of each step) will provide page specific help. For an overview of all the 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. To log out of the system, select “FURLS Home” and click “Logout”.

At the top and bottom of each screen are navigation buttons, as shown in Figure 14 (below).

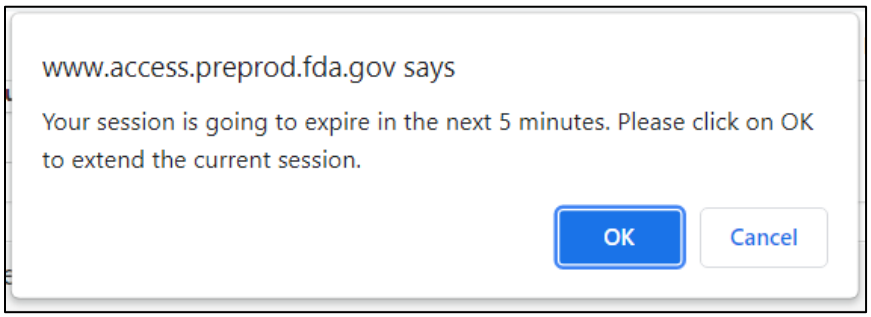
- **Previous** – Return to the previous screen and continue entering application information. Information entered on the current screen will NOT be saved.
- **Save & Exit** – Information entered up to this point will be saved. The system will provide you with an application number and your application 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.
- **Next** – Navigate to the next screen and continue entering the application form.
- **Cancel & Start Again** – The system will return you to the screen where you selected the Certificate Type. Any information you have entered will NOT be saved.

Figure 14 - General Navigation Buttons

Session Timeout:

An active session is limited to 30 minutes. After 25 minutes, a warning will display as shown in Figure 15 below.

Figure 15 – Session Timeout Warning



Click “OK” to continue the session and reset the timer back to 30 mins. Click “Cancel” to log out of the application. If no response is provided, the system will automatically log you out.

4 Enter New CPP Application

4.1 Section 1A – Applicant Information

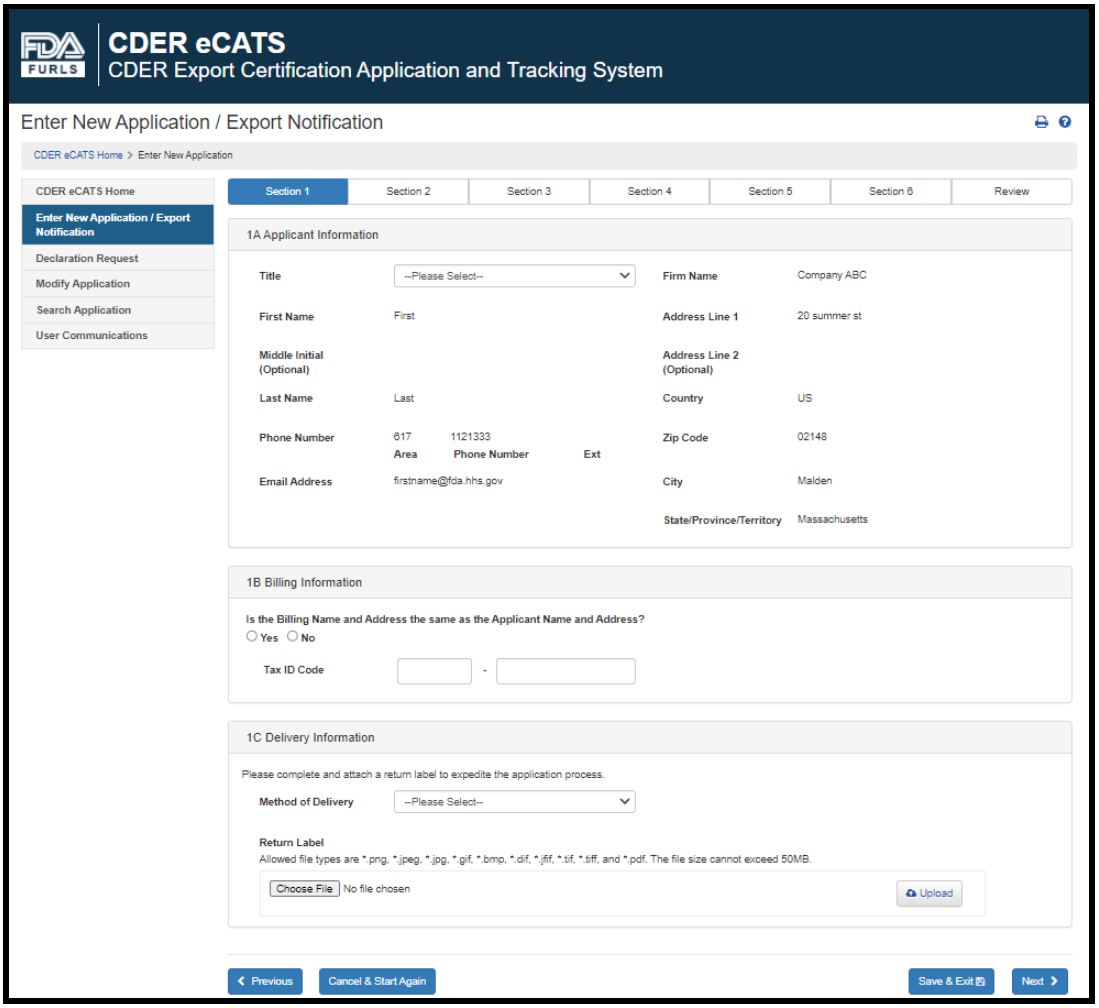
The applicant is the owner of the account through which the CPP application is filed and is the person requesting the export certificate. The applicant is responsible for completing and signing the application form. Most of the fields in Section 1 are automatically populated based on the information 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-hand corner), 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 application and verify your changes.

Fields marked with “(Optional)” are not mandatory.

Once you have completed this section, click “Next”. See Figure 16 below.

Figure 16 - Applicant Information

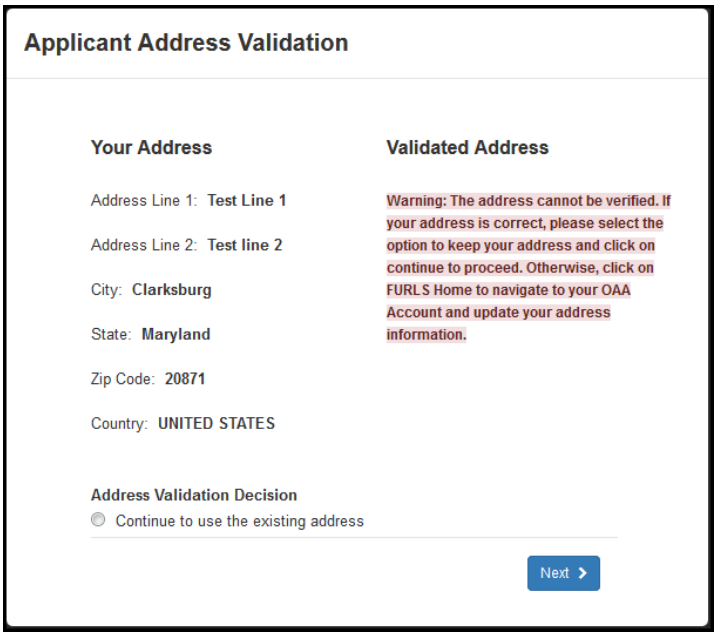


Address Validation

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 OAA account. If you wish to use the address without any changes, select “Continue to use the existing address” using the associated radio button.

Click the “Next” button. Otherwise, select the “Accept validated address and continue” radio button and click “Next” to proceed. See Figure 17 (below).

Figure 17 - Address Validation



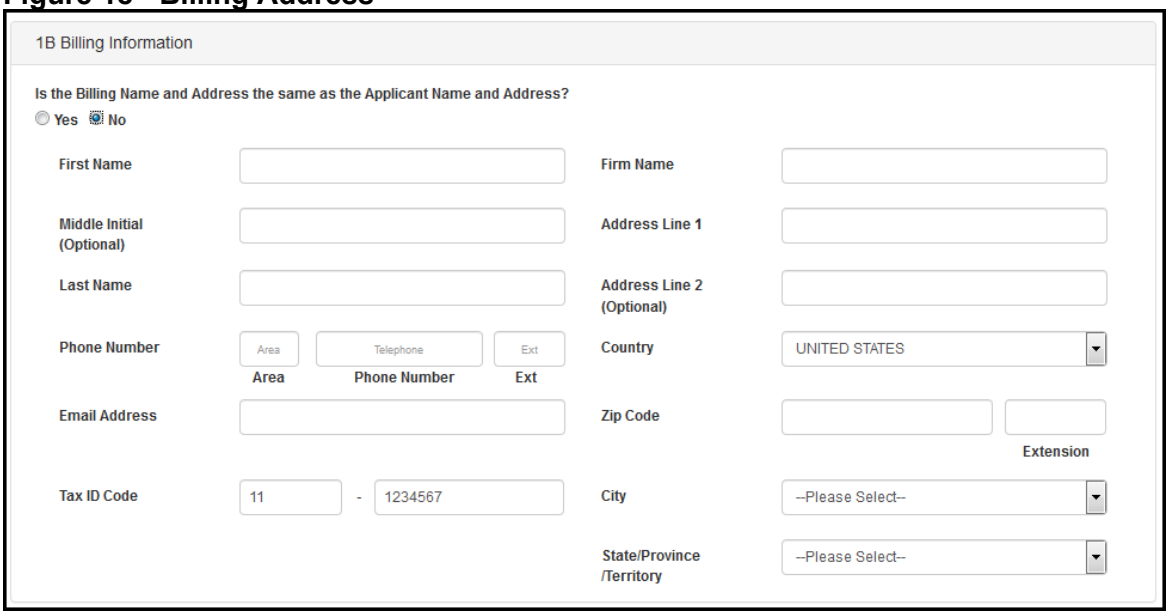
4.2 Section 1B – Billing Information

Billing Address

You will need to verify the billing name and address information 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 correct billing name and address information.

Note: You must also provide the Tax ID Code or you will not be able to continue with the application process, as shown in Figure 18 (below).

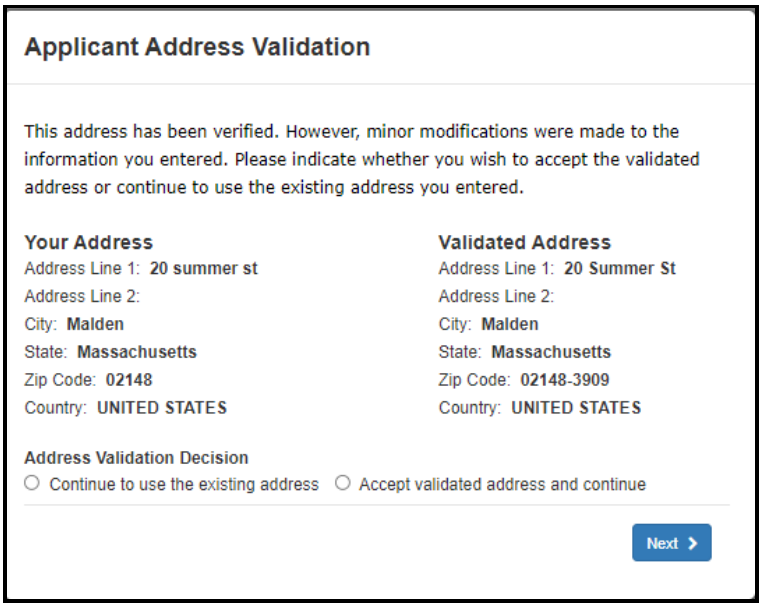
Figure 18 - Billing Address



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, as shown in Figure 19 below.

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 “Next”.

Figure 19 - Applicant Address Validation



4.3 Section 1C – Delivery Information

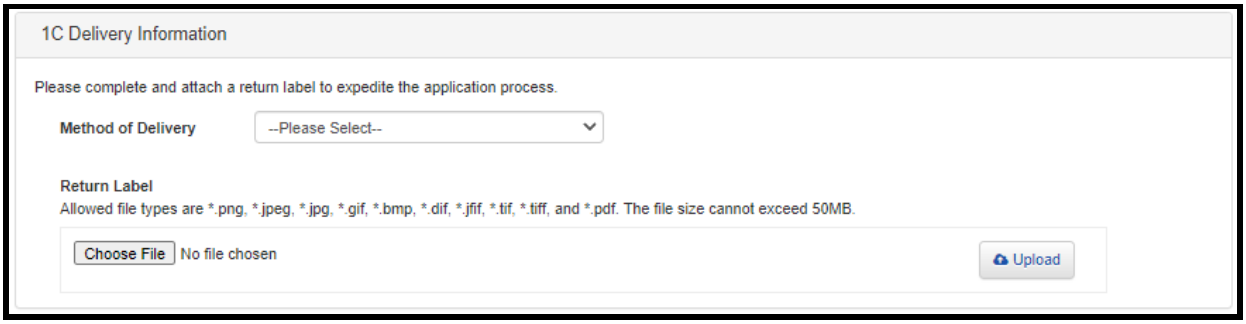
Method of Delivery:

You can select the method of delivery from a dropdown list, as shown in Figure 20 (below). You must select either “FedEx” or “UPS”. Once you have made your carrier selection, you must also fill out both the “Sender” and “Receiver” sections of the return label. You must attach the return label file as part of the application.

NOTE: Enter the appropriate FDA information in the “Sender” section and your contact name and address in the “Receiver” section of the return label.

For applications created and submitted after December 3, 2021, this section will not be available. Electronic certificates will be issued for new applications and the method of delivery is not applicable.

Figure 20 - Method of Delivery



4.4 Section 2A – General Product Information

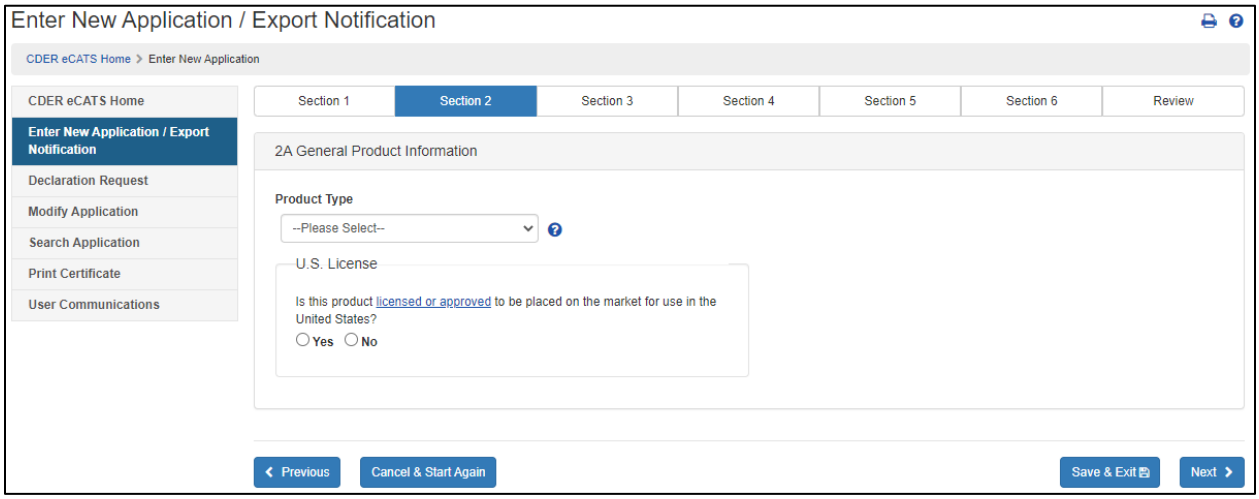
Please select “Yes” or “No” depending on whether the drug product is licensed to be placed on the market in the United States, as shown in Figure 21 (below).

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

Select the product type from the following dropdown list:

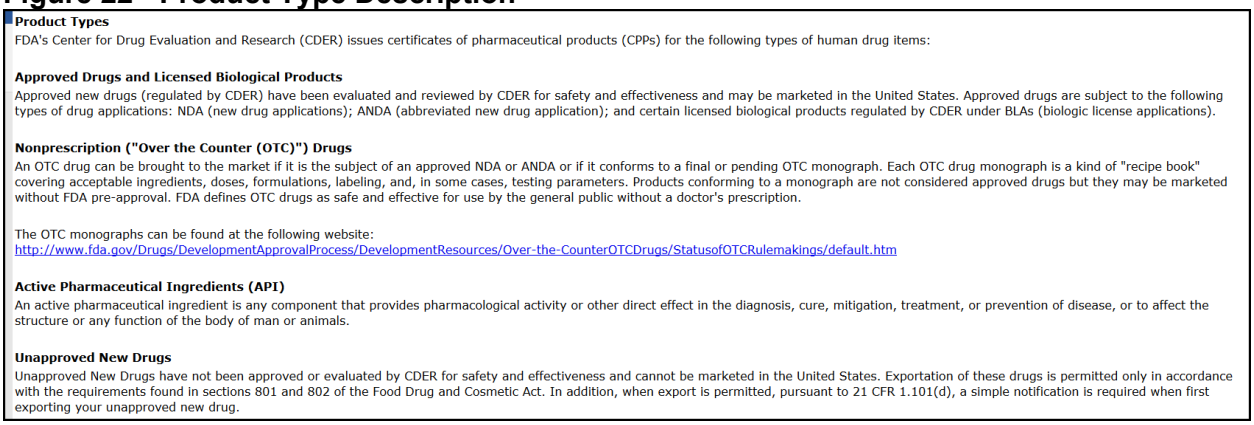
- Approved Drug Product
- Over-the-Counter (OTC)
- Active Pharmaceutical Ingredient (API)
- Unapproved Drug Product

Figure 21 - General Product Information



Click on the "**?**" icon to view the definition for each product type, as shown in Figure 22.

Figure 22 - 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.

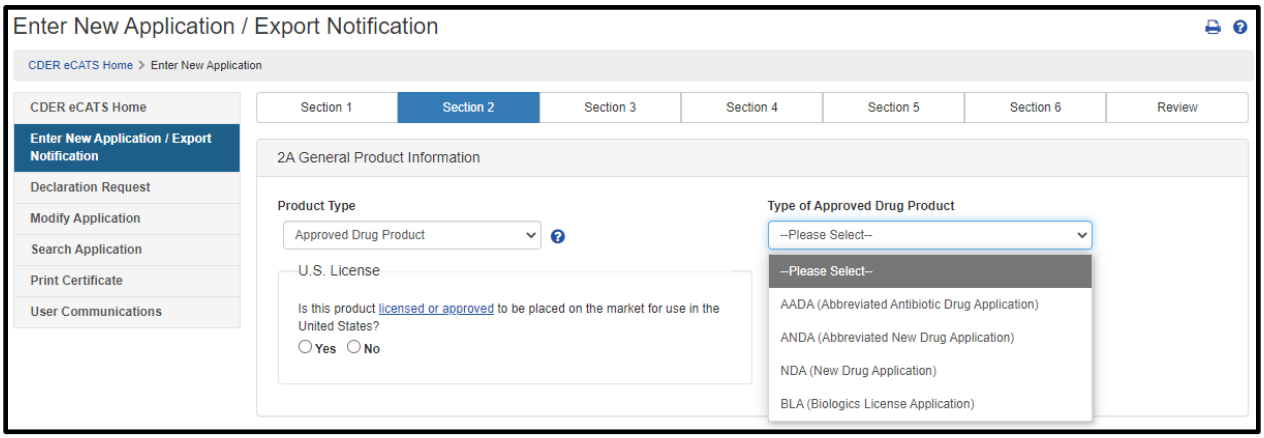
Approved Drug Product Flow:

If you select "Approved Drug Product", the system will display the "Type of Approved Drug Product" dropdown list.

Please select from the following, as shown in Figure 23, (below):

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

Figure 23 - Type of Approved Drug Product List



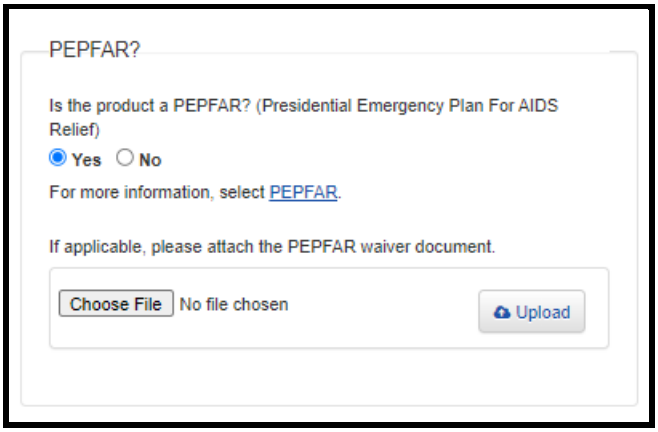
Select “Yes” or “No” depending on whether the approved drug product is actually on the market in the United States, as shown in Figure 24 (below).

Figure 24 - Actually marketed in the U.S.

Select “Yes” or “No” depending on whether the approved drug product is a PEPFAR. If the approved drug product is a PEPFAR, you have the option to attach the PEPFAR waiver document, as shown in Figure 25 (below).

NOTE: PEPFAR does not apply to BLAs. Click on the “**PEPFAR**” hyperlink to view the definition of PEPFAR.

Figure 25 - PEPFAR Waiver Document



4.5 Section 2B – Product Specific Information - Approved Drug

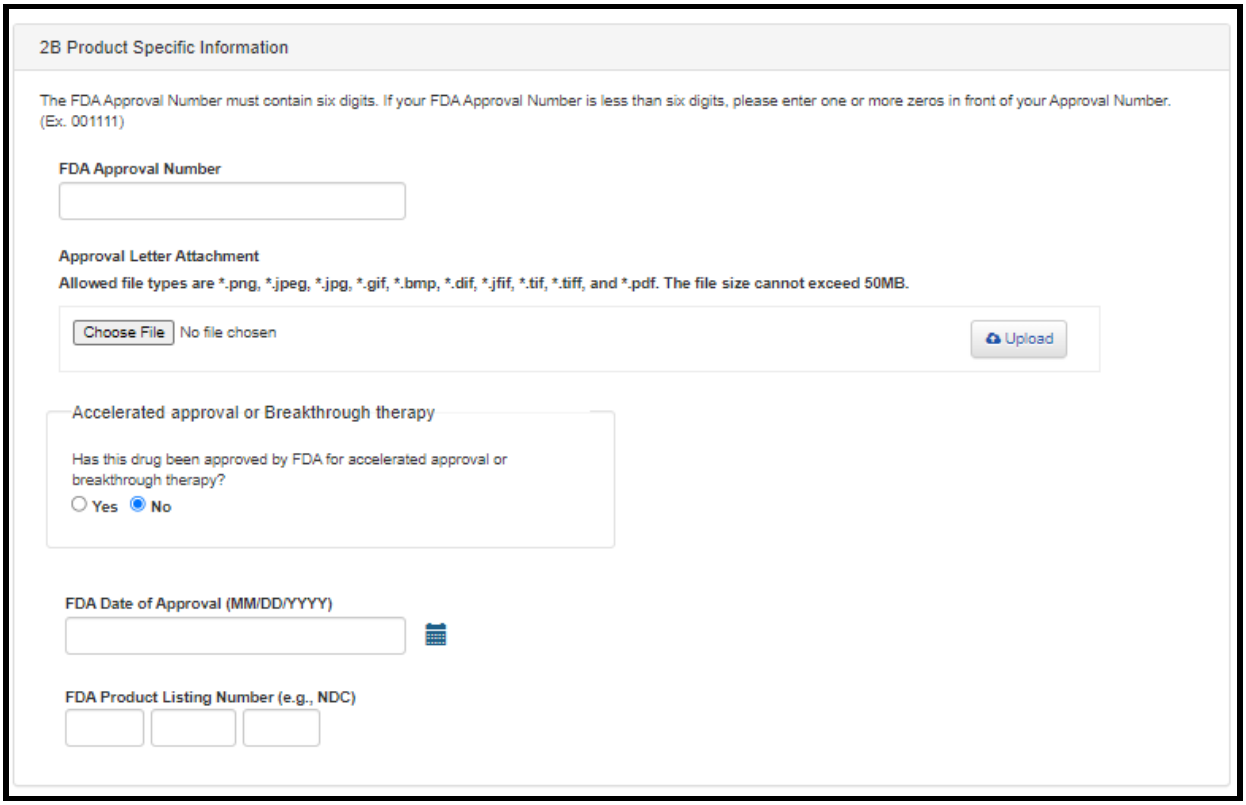
Applies to AADA, ANDA, or NDA if:

1. The approved drug product is **NOT** a PEPFAR

   OR

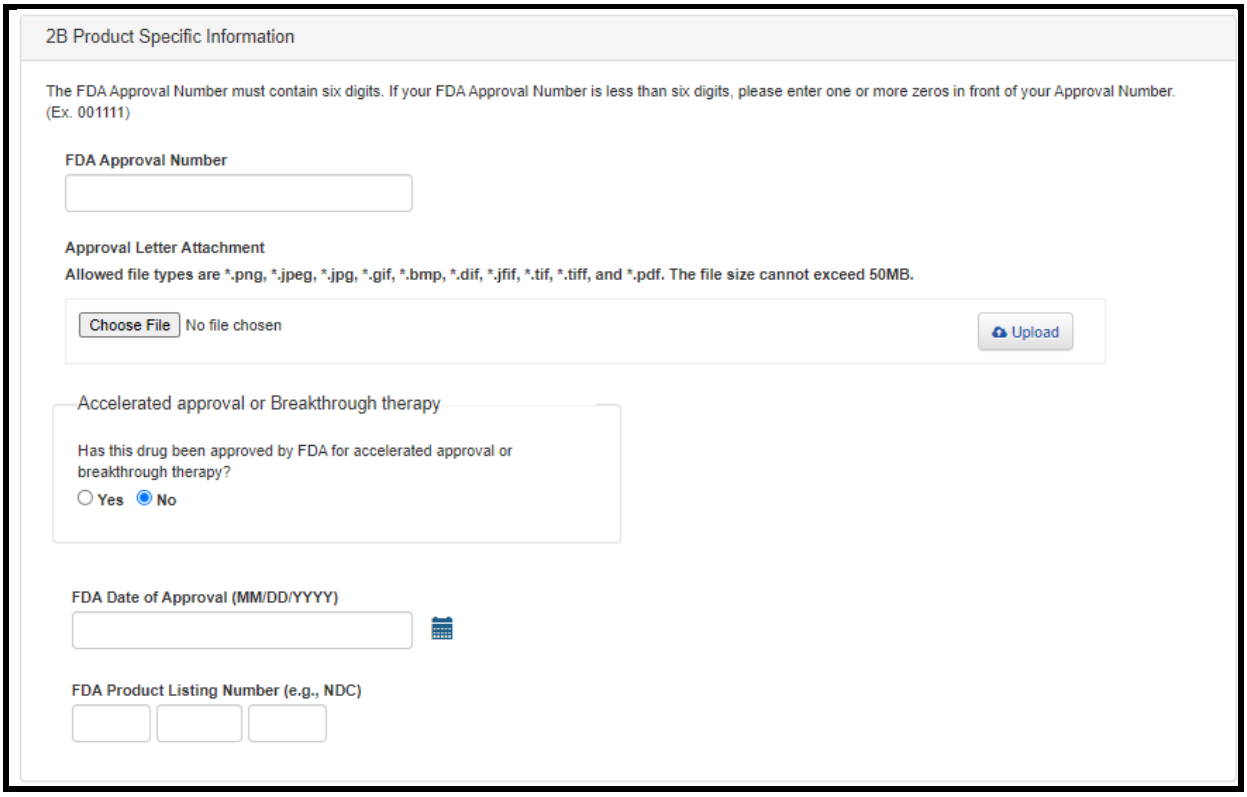
2. The approved drug product is a PEPFAR, and you did NOT upload a waiver document, enter/upload the following information, as shown in Figure 26 (below):
   - FDA Approval Number
   - Approval Letter Attachment
   - FDA Date of Approval (MM/DD/YYYY)
   - FDA Product Listing Number

Figure 26 - 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 27 (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 27 - Approved Drug is a PEPFAR with Waiver Document

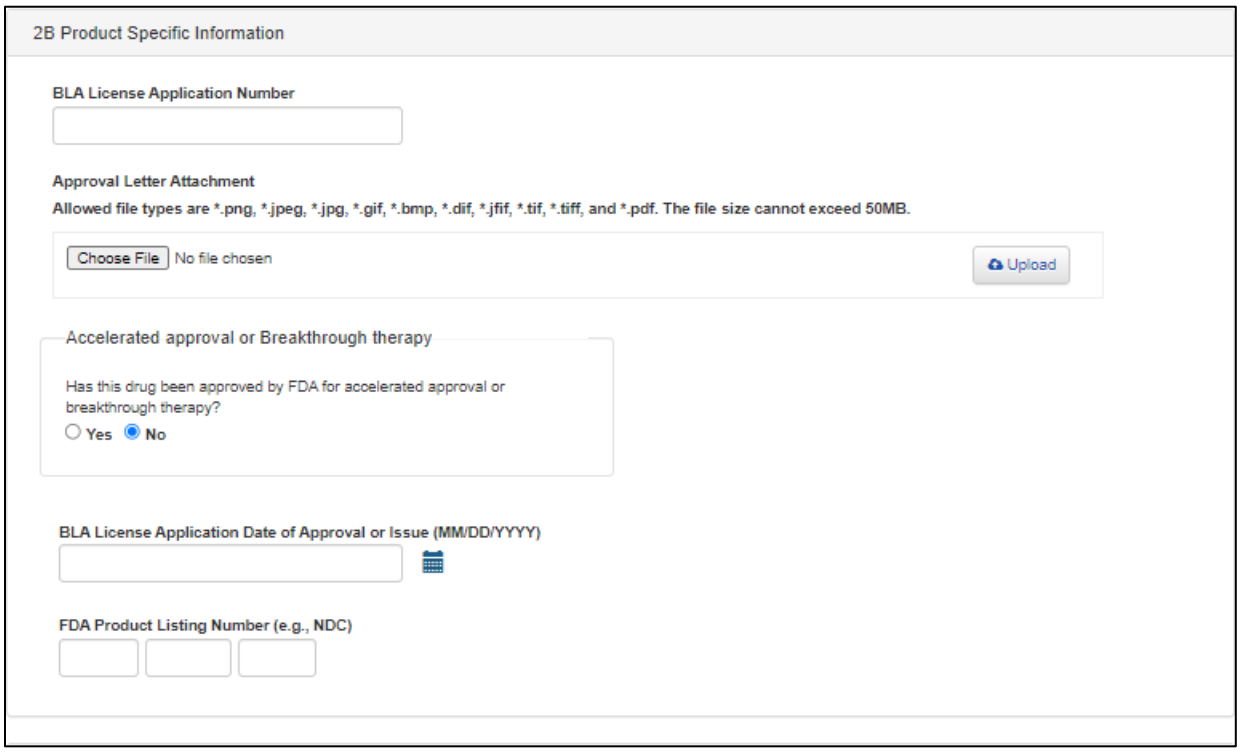


Applies to BLA:

If the approved drug product is a BLA, enter/upload the following information, as shown in Figure 28 (below):

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

Figure 28 - BLA with Approval Letter



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.

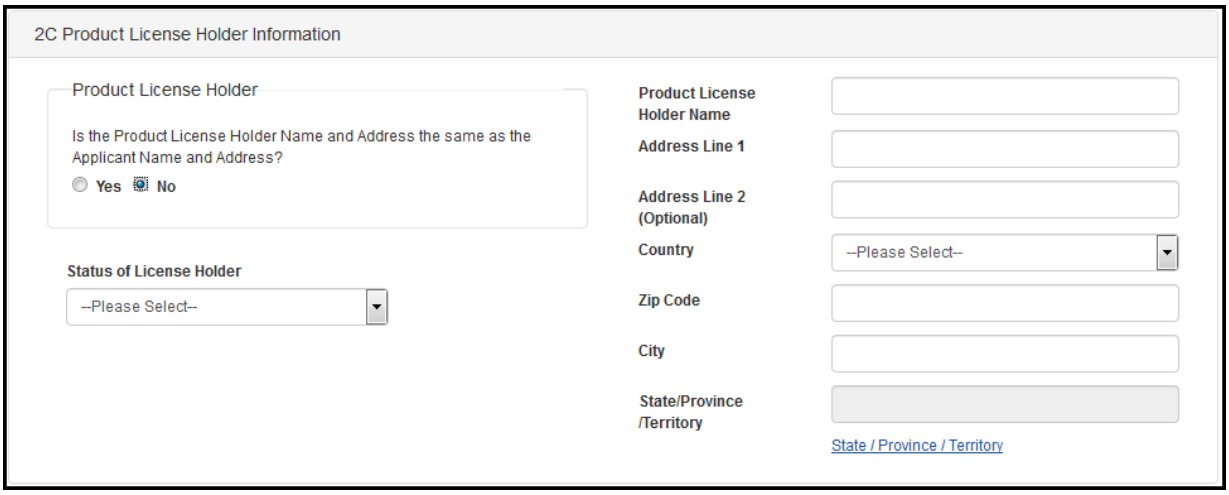
4.6 Section 2C – Product License Holder Information – Approved Drug

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.

Additionally, you must select a “Status of License Holder” option from the dropdown list, as shown in Figure 29 (below).

Figure 29 - Product License Holder Name and Address



4.7 Section 2D – Product Characteristics

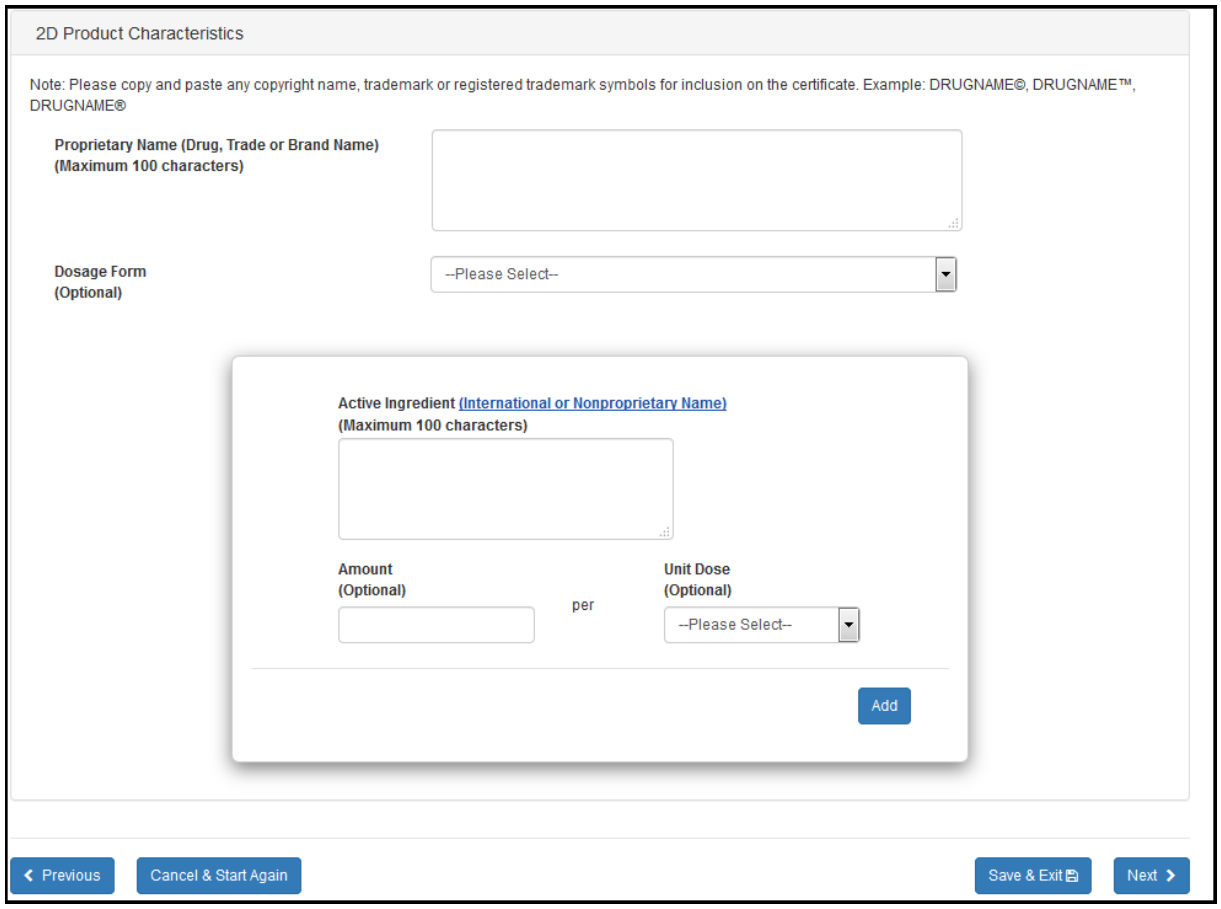
4.7.1 Approved Drug

Applies to all Product Types including AADA, ANDA, NDA, and BLA:

Enter the following product characteristics information, as shown in Figure 30 (below):

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

Figure 30 - Product Characteristics

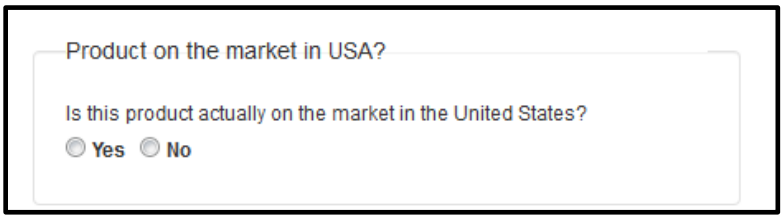


Click “Next” to navigate to Section 3A.

Over-the-Counter (OTC) Flow:

If you select “Over-the-Counter (OTC)”, click “Yes” or “No” based on whether the approved drug product is actually on the market in the United States, as shown in Figure 31 (below).

Figure 31 - Actually marketed in the U.S.

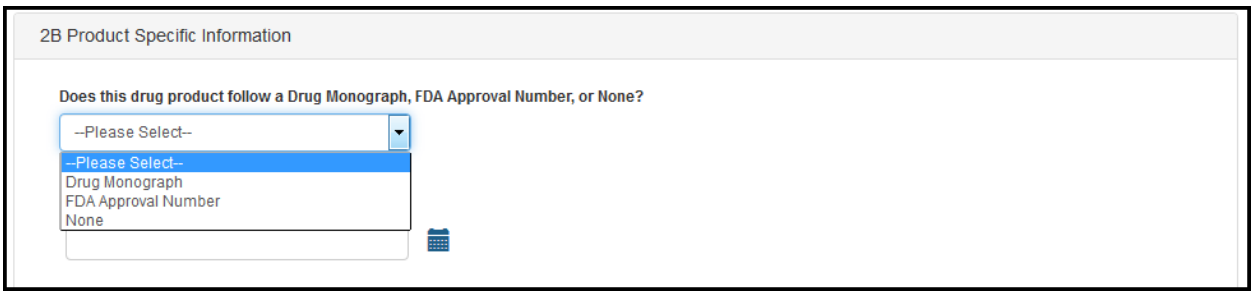


4.7.2Section 2B – Product Specific Information - OTC

For OTC, select from the following dropdown list which method the drug follows, as shown in Figure 32 (below):

- Drug Monograph
- FDA Approval Number
- None

Figure 32 - OTC Type



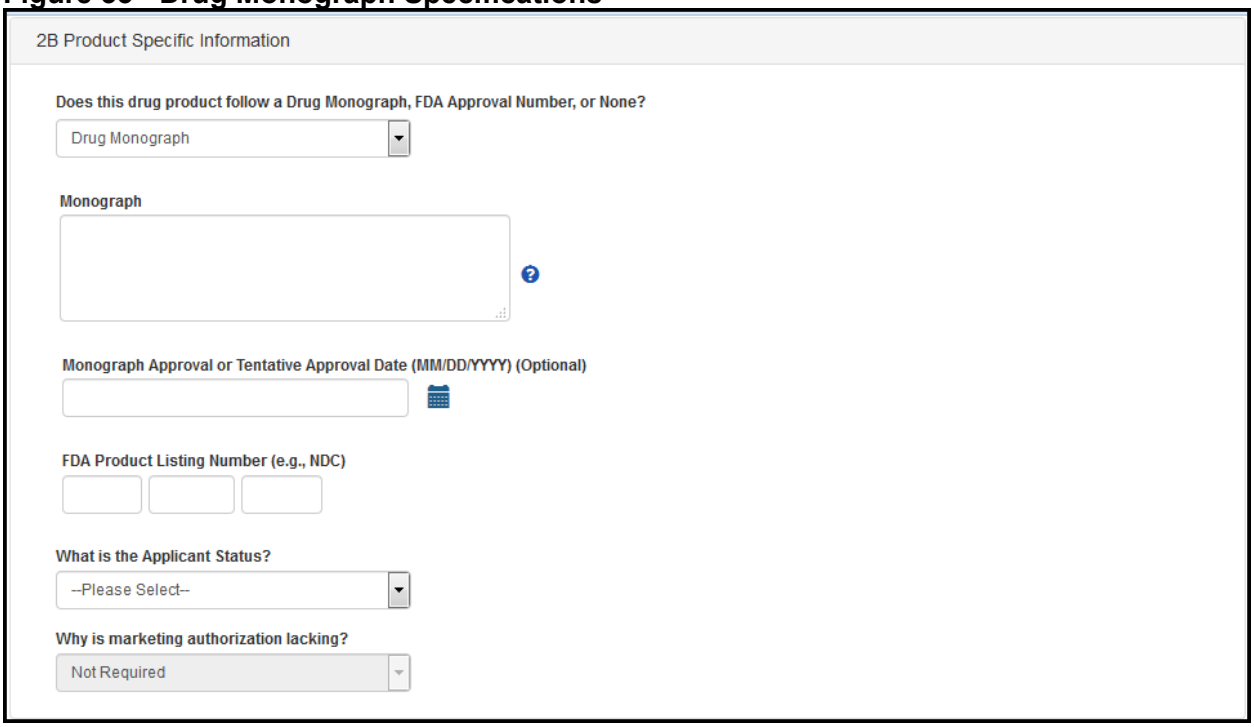
If the drug follows a Drug Monograph, enter the following information, as shown in Figure 33 (below):

- Monograph
- Monograph Approval or Tentative Approval Date
- FDA Product Listing Number
- What is the Applicant Status?
- Why is marketing authorization lacking?

NOTE: Click on the "**?**" icon for more information regarding 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.

Return to the Section 2B and select the "Unapproved Drug Product Type".

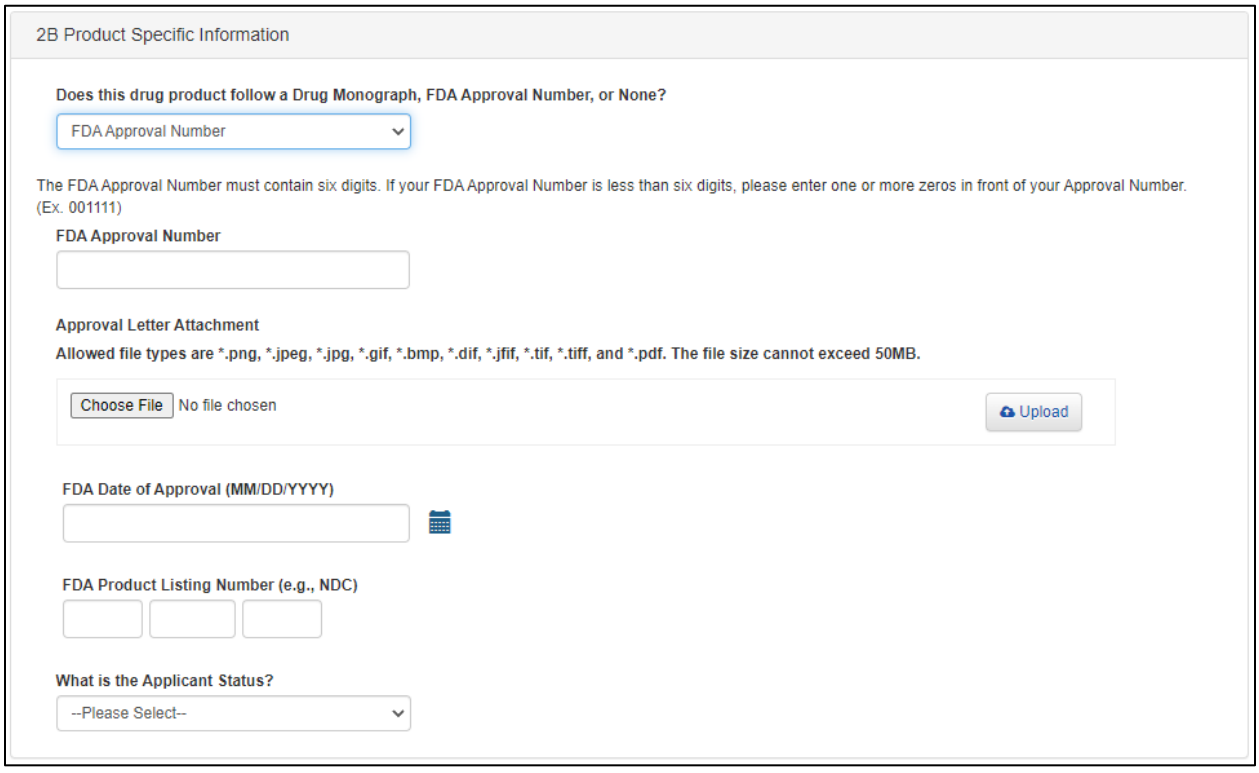
Figure 33 - Drug Monograph Specifications



If the drug follows an FDA Approval Number, enter/upload the following information, as shown in Figure 34 (below):

- FDA Approval Number
- Approval Letter Attachment
- FDA Date of Approval
- FDA Product Listing Number
- What is the Applicant Status?

Figure 34 - Follow FDA Approval Number

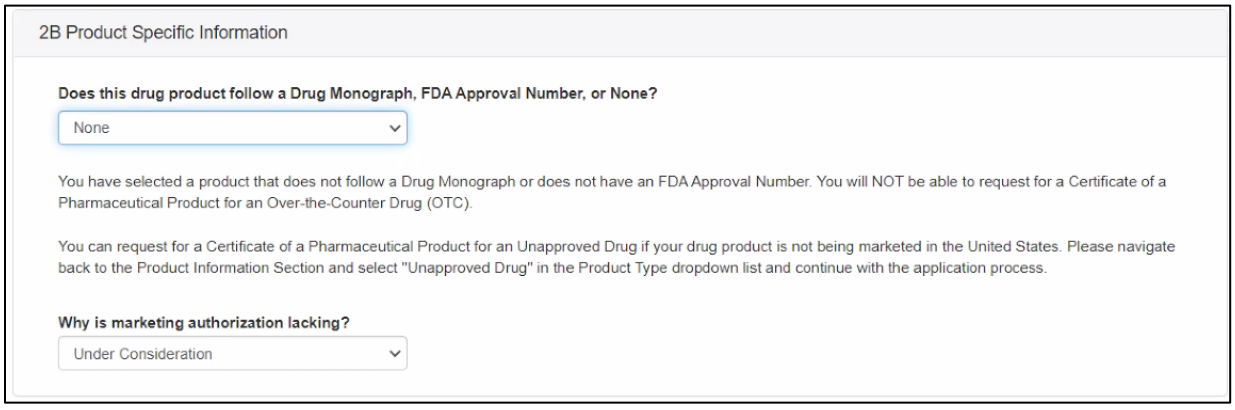


WARNING: The FDA Approval Number entered in Section 2B for an OTC must be a valid FDA Approval Number or you will not be able to continue with the application process.

If the drug follows None, enter the following information, as shown in Figure 35 (below):

- Why is marketing authorization lacking?

Figure 35 - Follow None

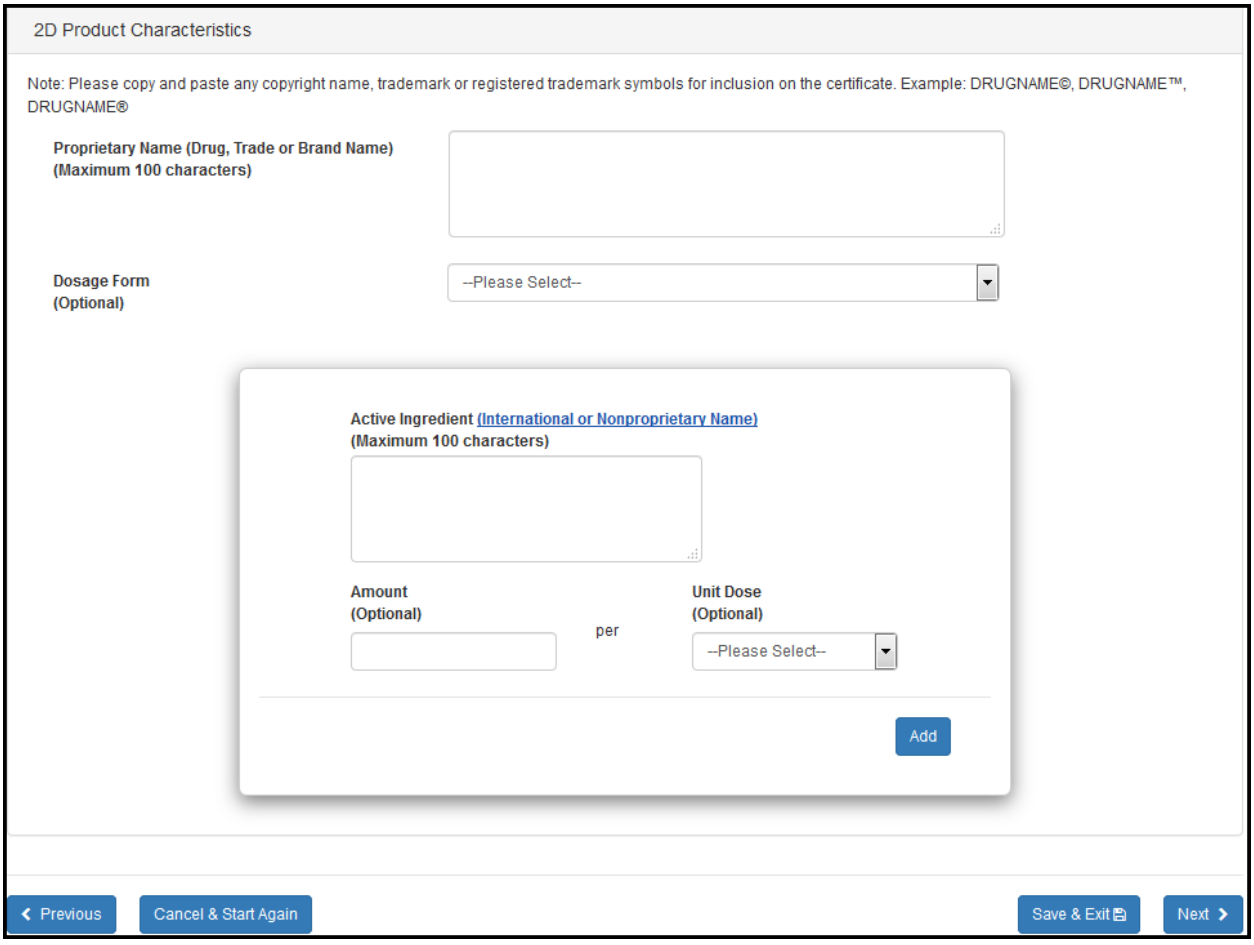


4.7.3Section 2D – Product Characteristics - OTC

Enter the following product characteristics information, as shown in Figure 36 (below):

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

Figure 36 - Product Characteristics



Click the “Next” button. to navigate to Section 3A.

Active Pharmaceutical Ingredient (API) Flow:

If you select “Active Pharmaceutical Ingredient (API)”, you must select a response of “Yes” or “No” for both of the following questions, as shown in Figure 37 (below):

- Is the product licensed or approved to be placed on the market in the United States? The system will default the response to “No”.
- Is the product actually on the market in the United States?

Figure 37 - Active Pharmaceutical Ingredient

4.7.4Section 2B – Product Specific Information - API

For the API, provide the following information – as shown in Figure 38 (below):

FDA Product Listing Number:

- What is the Applicant Status?
- Why is marketing authorization lacking?

Figure 38 - Product Specific Information – API

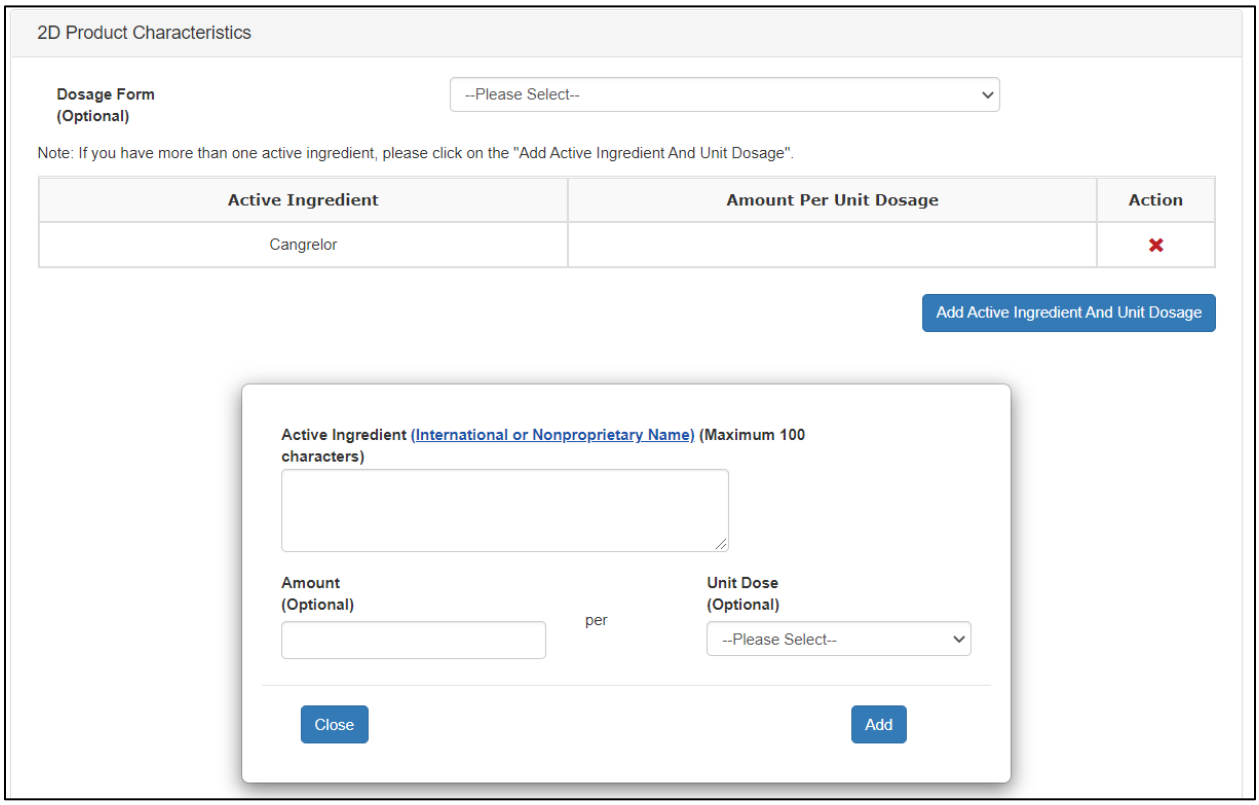
NOTE: Section 2C does not apply to an API product type.

4.7.5Section 2B – Product Characteristics - API

Enter the following product characteristics information, as shown in Figure 39 (below):

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

Figure 39 - Product Characteristics – API



Click the “Next” button to navigate to Section 3B. Note: 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.

4.7.6 Section 2B – Product Specific Information - Unapproved Drug

For Unapproved Drug Product, enter the following information, as shown in Figure 40 (below):

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

Figure 40 - Product Specific Information – Unapproved Drug

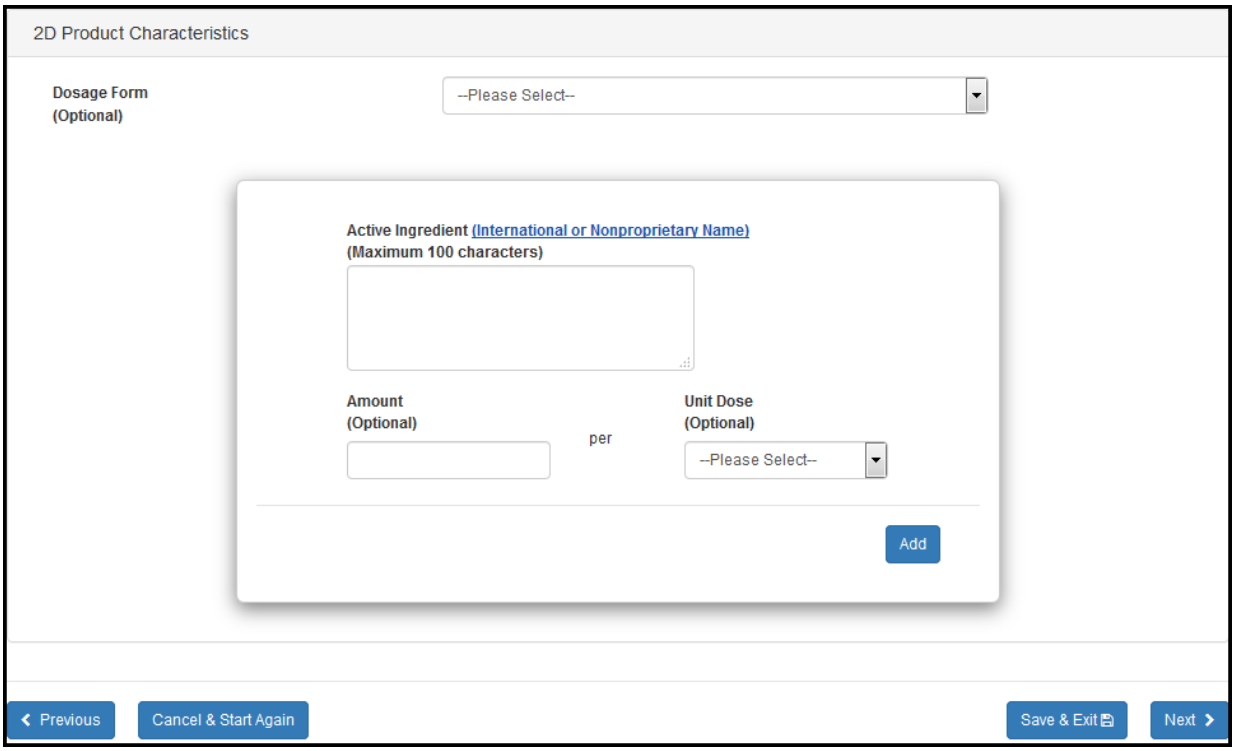
NOTE: Section 2C does not apply to an Unapproved Drug product type.

4.7.7 Section 2D – Product Characteristics - Unapproved Drug

Enter the following product characteristics information, as shown in Figure 41 (below):

- Dosage Form
- Active Ingredient
- Amount
- Unit Dose

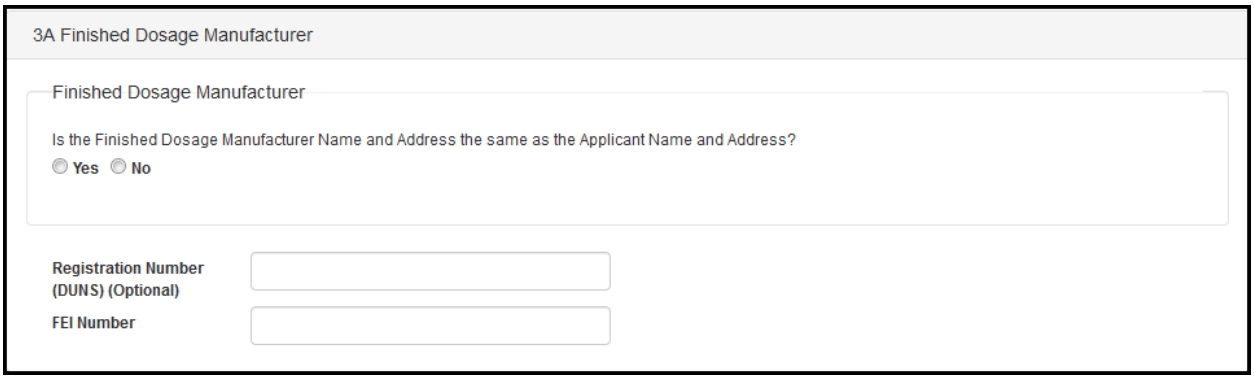
Figure 41 - Product Characteristics – Unapproved Drug



4.8 Section 3A – Finished Dosage Manufacturer

Select “Yes” or “No” based on whether the Finished Dosage Manufacturer’s Name and Address is the same as the Applicant Name and Address, as shown in Figure 42 (below).

Figure 42 - Finished Dosage Manufacturer same as Applicant



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

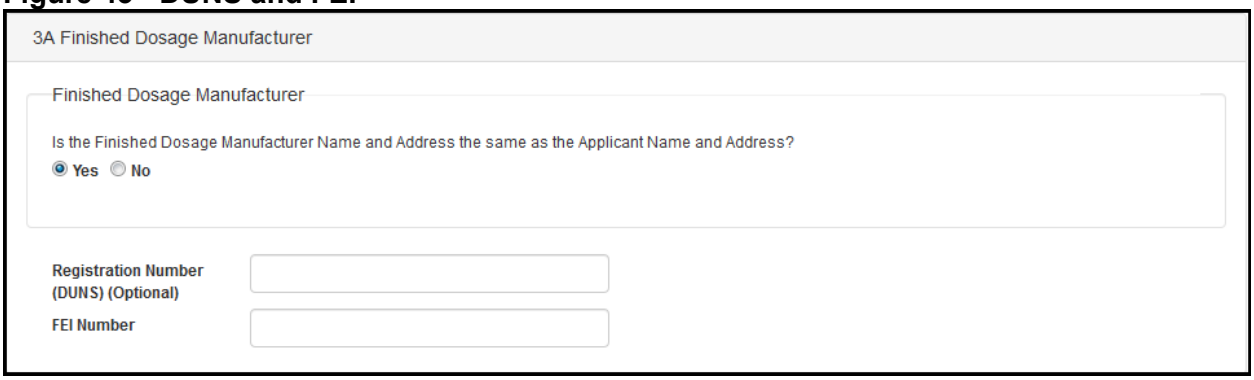
If you select “No”, enter the following Finished Dosage Manufacturer information:

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

If you select “Yes”, enter the following Finished Dosage Manufacturer information, as shown in Figure 43 (below):

- Registration Number (DUNS)
- FEI Number

Figure 43 - DUNS and FEI



4.9 Section 3A – Active Pharmaceutical Ingredient Manufacturer

Select “Yes” or “No” based on whether there is an API Manufacturer associated with the drug product. **This applies to all product types except API.**

If “No” is selected, enter the following:

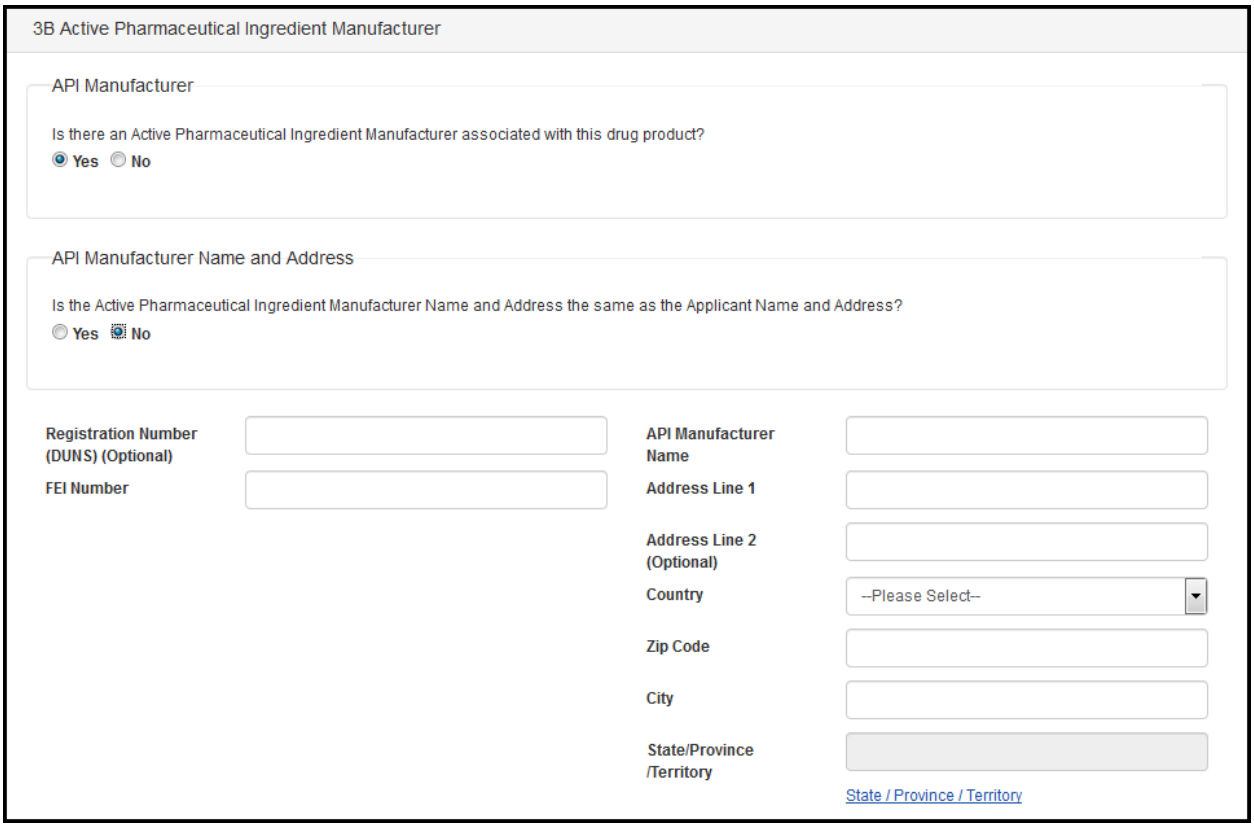
- Registration Number
- FEI

If “Yes” is selected enter the following, as shown in Figure 44 (below):

- Registration Number
- FEI Number

- API Manufacturer Name
- Address Line 1
- Country
- Zip Code
- City
- State/Province/Territory

Figure 44 - API Manufacturer Contact Information

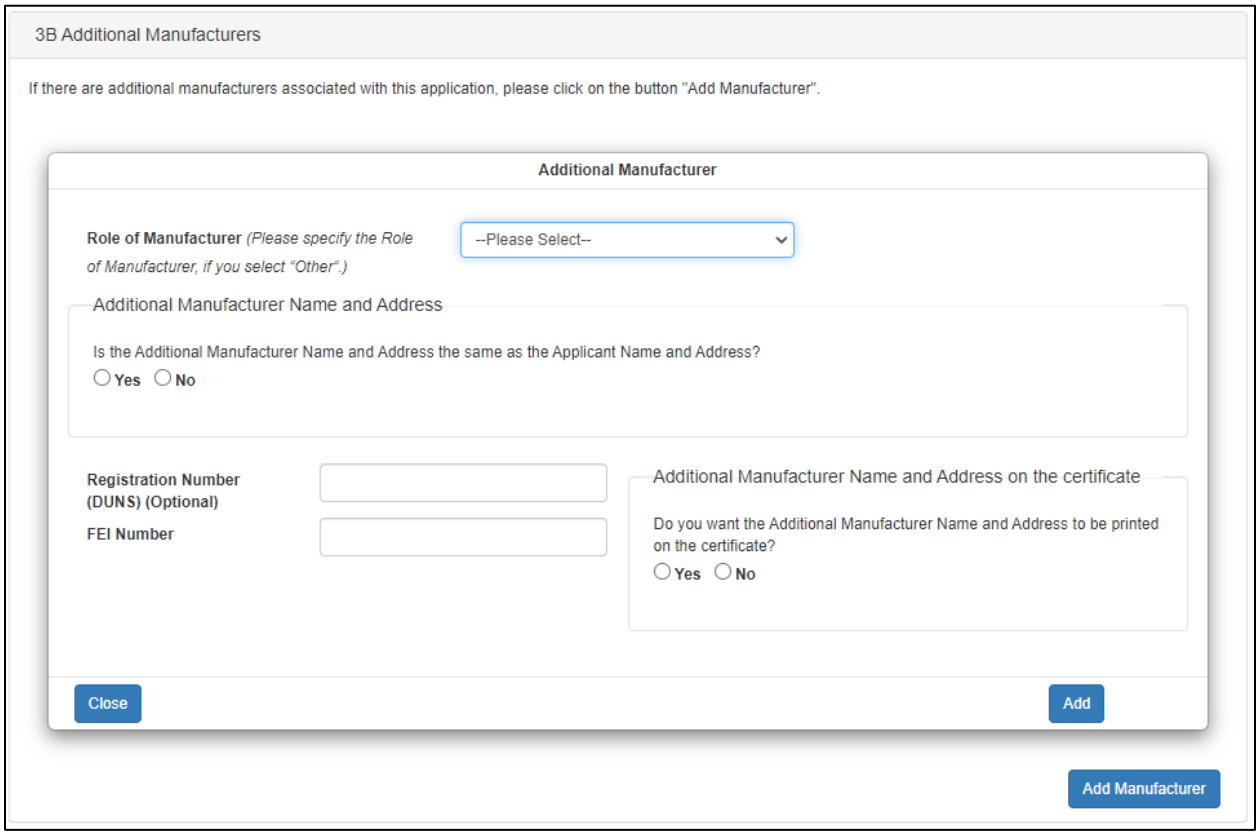


NOTE: If your product type is an API, you will NOT be prompted to answer whether there is an API associated with the drug product (as shown in Figure 44). You must complete Section 3B.

4.10 Section 3B – Additional Manufacturers

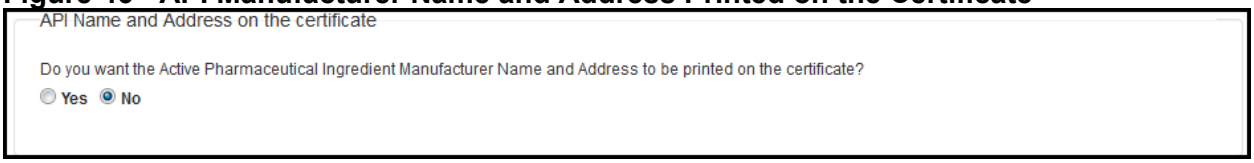
If there are additional manufacturers associate with a given application, these can be added by clicking on the “Add Manufacturer” button. Enter the information, as shown in Figure 45 (below).

Figure 45 - Additional Manufacturers Contact Information



For all product types (except API), select “Yes” or “No” based on whether you would like to print the API Manufacturer name and address on the certificate, as shown in Figure 46 (below).

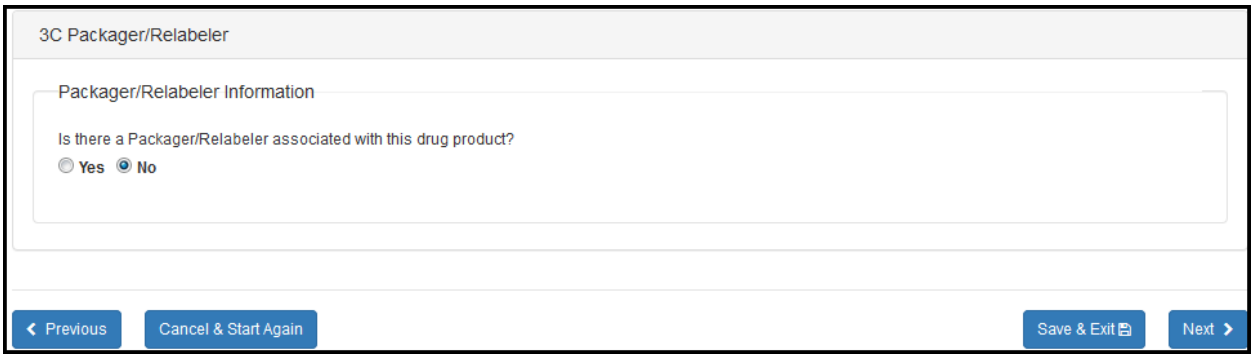
Figure 46 - API Manufacturer Name and Address Printed on the Certificate



4.11 Section 3C – Packager / Relabeler

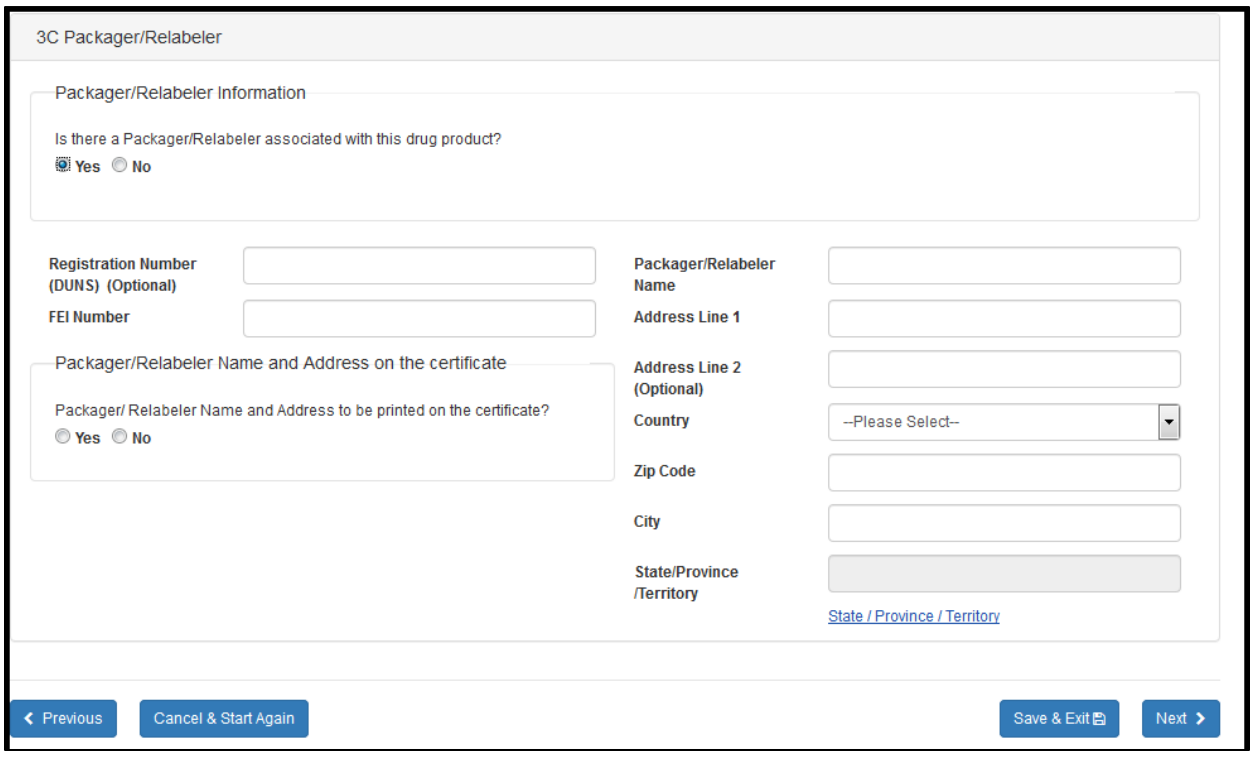
Select “Yes” or “No” depending on whether there is a Repackager associated with the drug product, as shown in Figure 47 (below).

Figure 47 - Packager/Relabeler Association



If you answer “Yes” to the prompt, the system will display the following to be filled out in Section 3C, as shown in Figure 48 (below):

Figure 48 - Packager/Relabeler Information



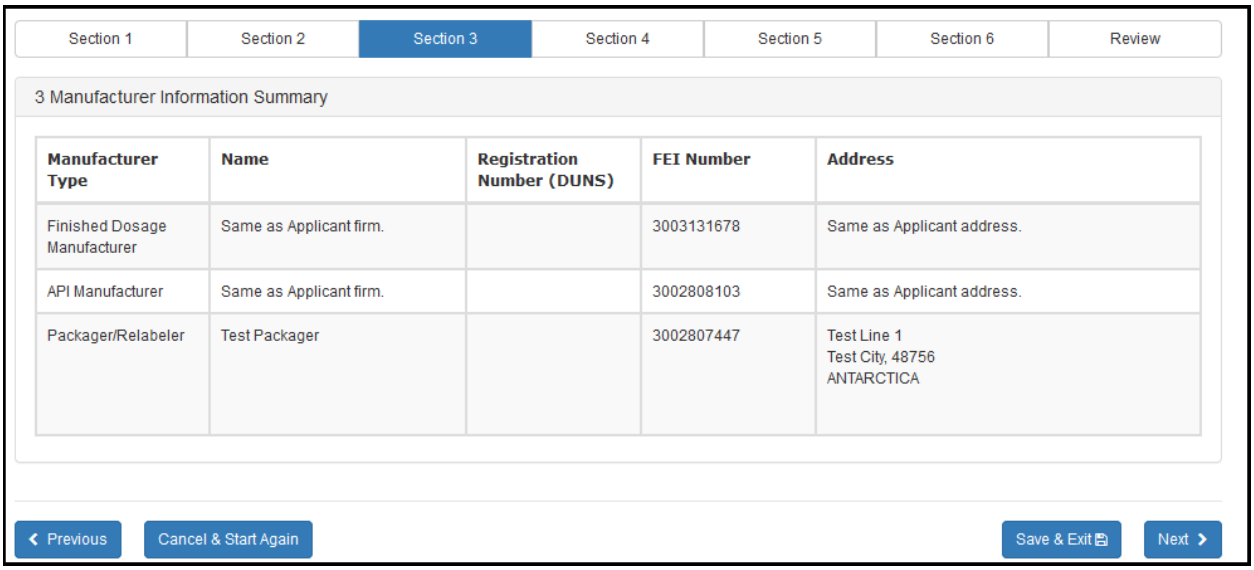
Click “Next”.

4.12 Section 3 – Summary Page of Manufacturers

Prior to navigating to Step 4 of the application, the system will display a summary of all manufacturers entered in the application. Please review each manufacturer entered and

(if necessary) click on the “Edit” icon next to the facility you wish to modify/update, as shown in Figure 49 (below).

Figure 49 - Summary Page – Manufacturers



Click “Next”.

4.13 Section 4A – Importing Country List

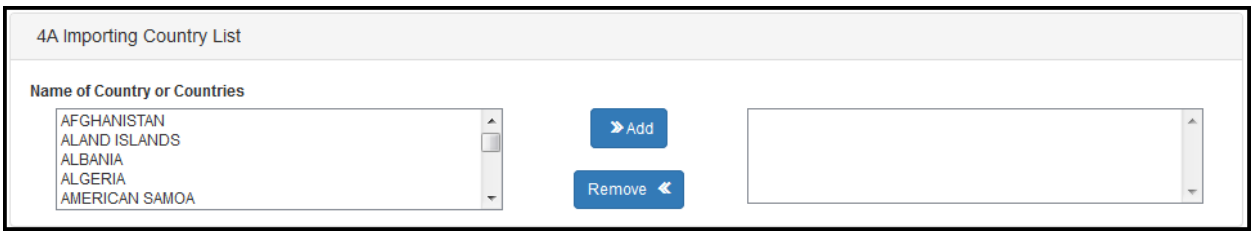
Name of Country or Countries:

Select one or more countries to indicate the product destination, as shown in Figure 50 (below).

NOTE: Another method to select a country (other than scrolling through the list) is to click on a country from the country list and then enter in the first few letters of the desired country name. The system will navigate to the country which begins with the letters entered.

You also have the option to hold the Ctrl button and select multiple countries.

Figure 50 - List of Countries



4.14 Section 4B – Number of Certificates

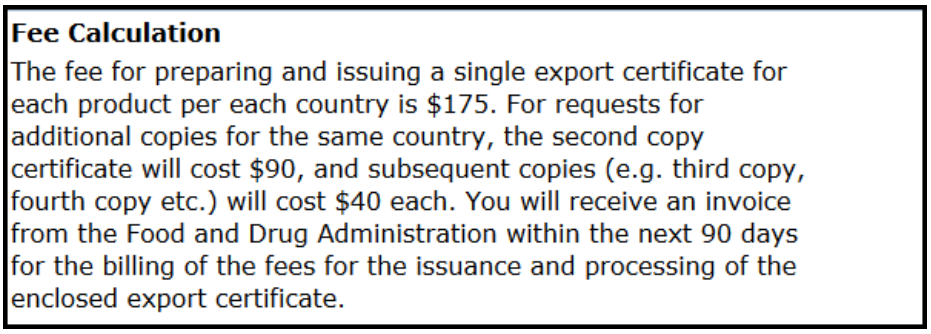
The system will display the selected country or countries (from Section 4A). You will be able to request additional certificate copies by country, as shown in Figure 51 (below).

NOTE: The system will also calculate the user fee based on the number of additional certificates requested. The total number of certificates cannot exceed 50 per application.

Figure 51 - Number of Certificates Requested by Country

Selecting the "**?**" icon displays help text explaining the fee calculation, as shown in Figure 52 below.

Figure 52 - Fee Calculation



Click the "Next" button.

4.15 Section 5A – Drug Labels

In this section, you must provide labels for your drug product(s). 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 API

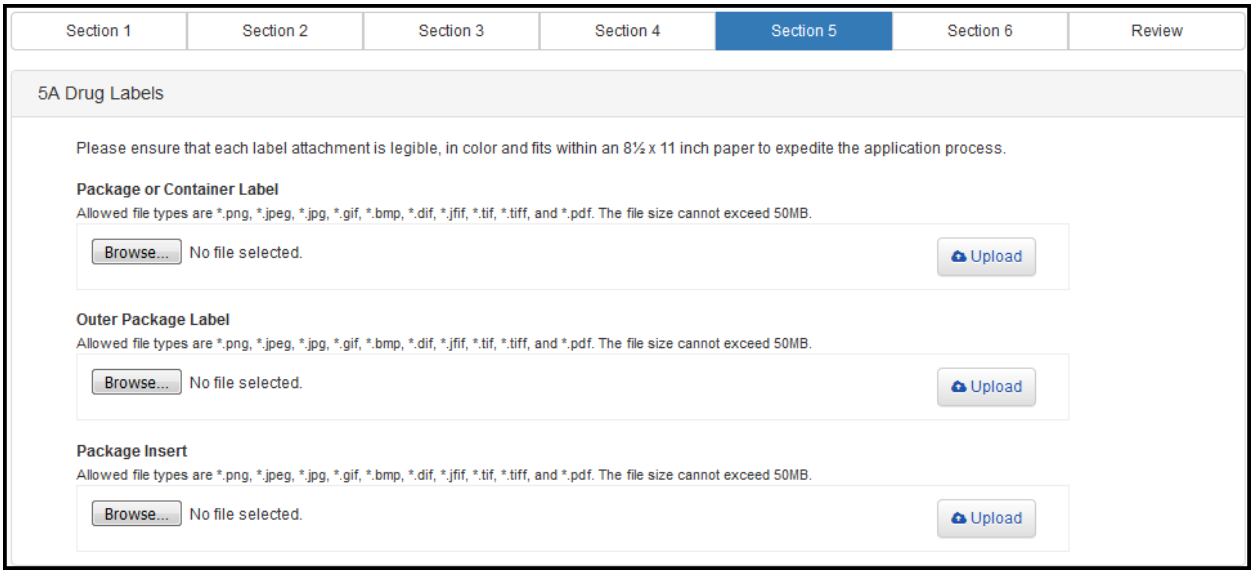
- Package or Container Label

For an Unapproved Drug

- Outer Package Label
- Formulation page

Note: Users can include formulation information in the “Supplemental Doc” section of the application for Approved, OTC, and APIs. Figure 53 below shows the labels required for an Approved Drug Type.

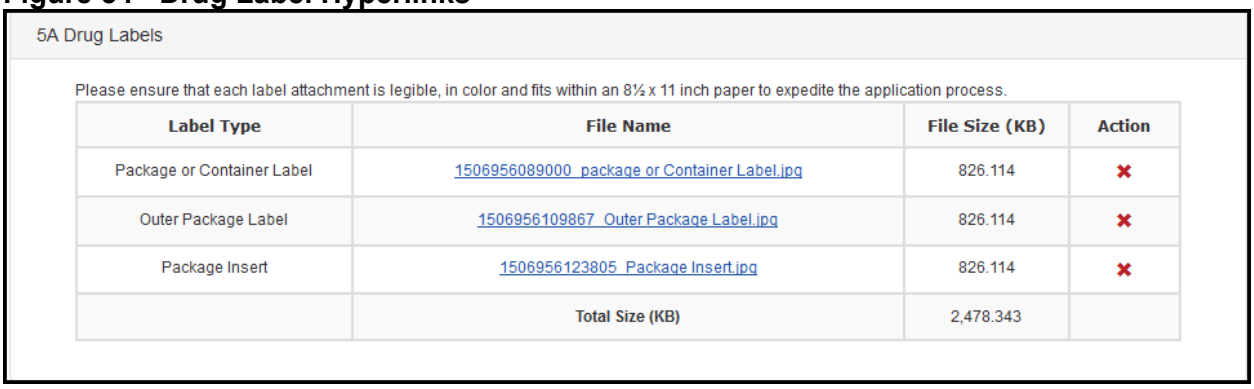
Figure 53 - Drug Labels (for an Approved Drug Type)



Once you have attached each drug label, the system will display 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 54 (below).

Figure 54 - Drug Label Hyperlinks



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

4.16 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 55 (below). Otherwise, click “No” and proceed to Section 5D.

Figure 55 - Add Supplemental Documents Prompt

If you click “Yes”, select an option from the “Attachment Type” dropdown list.

If you click “Other”, you must provide a description of the attachment in the freeform text field shown in Figure 56 (below).

Figure 56 - Attachment Type and Associate Document with Country and Print on Certificate Prompt

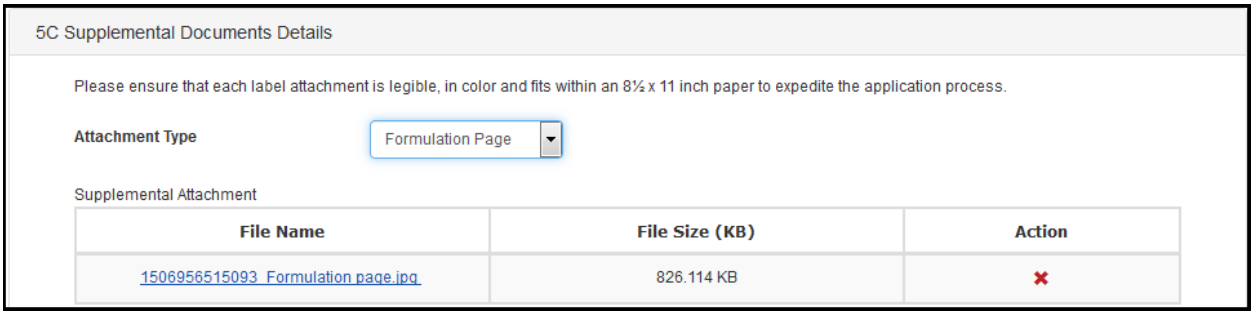
If you click “Yes” to associate one or more countries to this attachment, the system will display all of the countries selected in Section 4A. Please select one or more countries.

4.17 Section 5C – Summary of Attached Supplemental Documents

The system will display attachments as hyperlinks. You may click on the hyperlink to view the document.

You also have the ability to remove any attachment or add documents, as shown in Figure 57 (below).

Figure 57 - Summary of Attached Supplement Documents

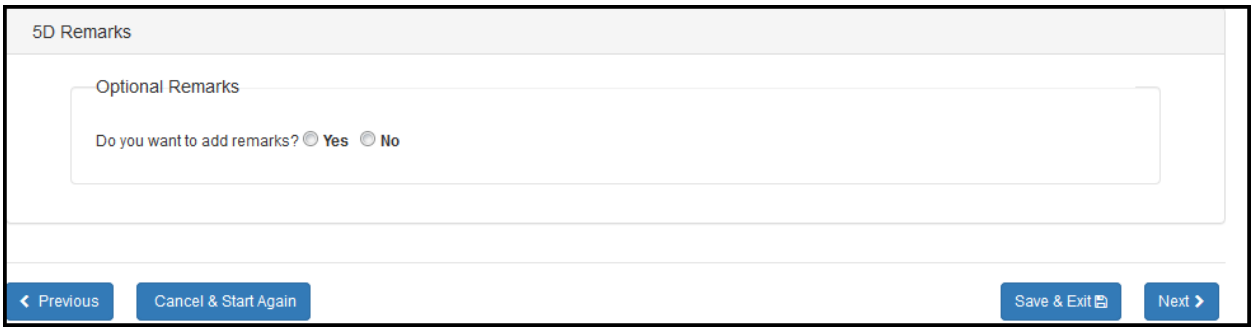


4.18 Section 5D – Remarks

In this section, you have the option to add remarks. To add a remark, click the “Yes” radio button, as shown in Figure 58 (below).

Otherwise, click “No” and proceed to the next section.

Figure 58 - Add a Remark Prompt



4.19 Section 5E – Remarks Entry

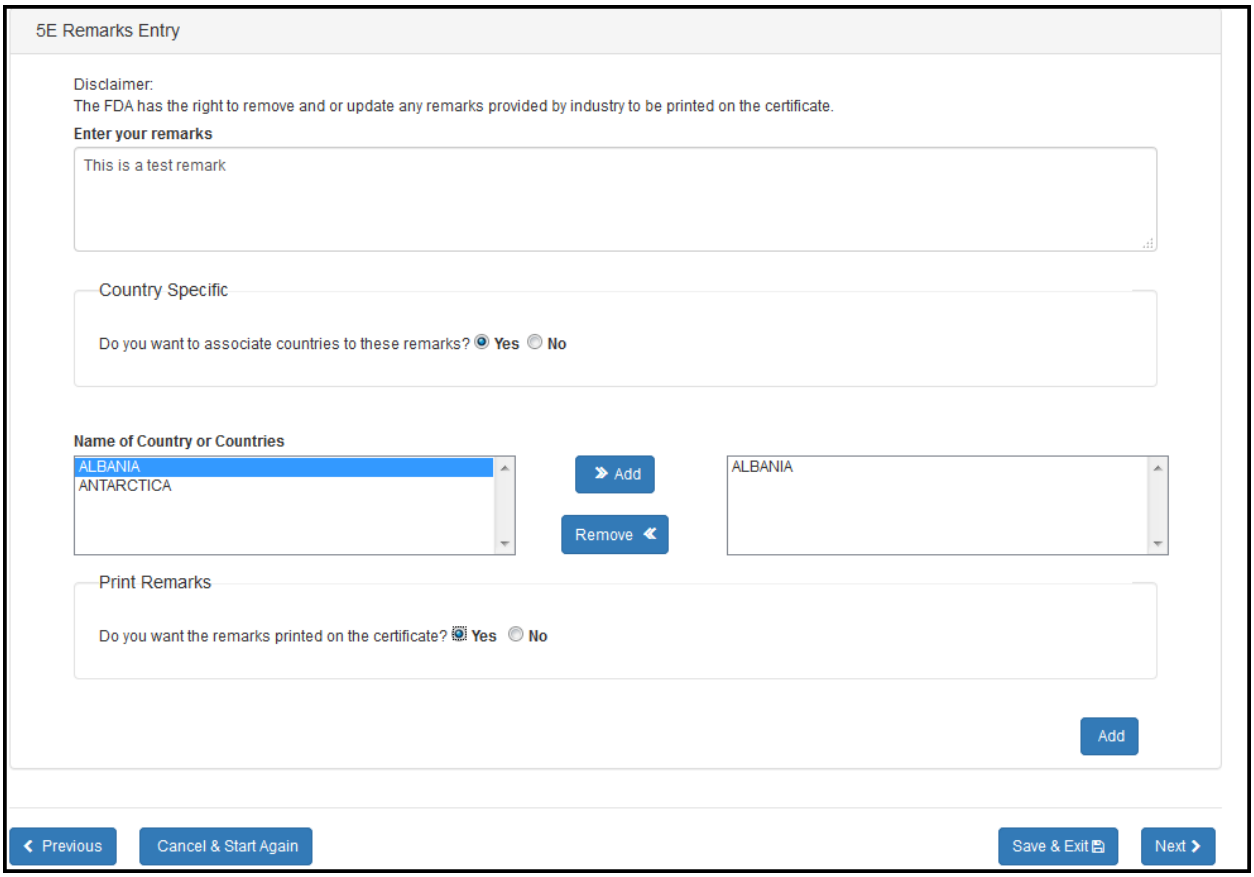
If you select “Yes”, please enter your remark in the freeform text field.

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 will display all of the 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 59 (below):

Figure 59 - Remarks Entry



Click the “Next” button.

The system will display a summary of the remark entered. You have the ability to remove any remarks or add additional remarks to the application, as shown in Figure 60 (below).

Figure 60 - Summary of Remarks

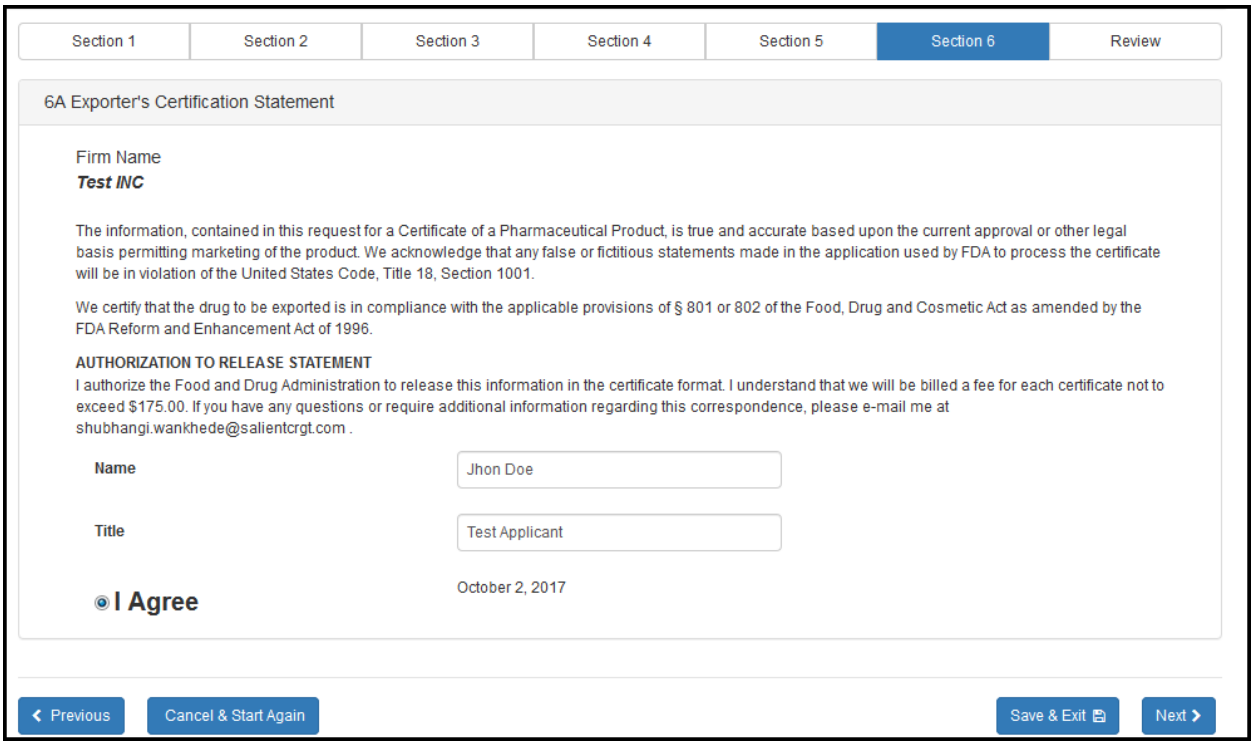
Click the “Next” button.

4.20 Section 6A – Exporter’s Certification Statement (ECS)

The Exporter’s Certification Statement (ECS) acknowledges that you, the responsible official or designee, certify 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 (FD&C) and all applicable or pertinent regulations.

NOTE: You must click on the “I Agree” button located at the bottom of this section and enter your full name and title. You will not be able to continue with the application until these fields have been completed, as shown in Figure 61 (below).

Figure 61 - Exporter's Certification Statement



Once you have completed this step, click on the "Next" button to proceed to the Final Review page.

4.21 Final Review Page

The system will display the entire application (broken out by section), as shown in Figure 62 - Figure 67 (below). You may choose to modify a section by selecting the "Edit" icon 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 62 - Final Review Page Section 1

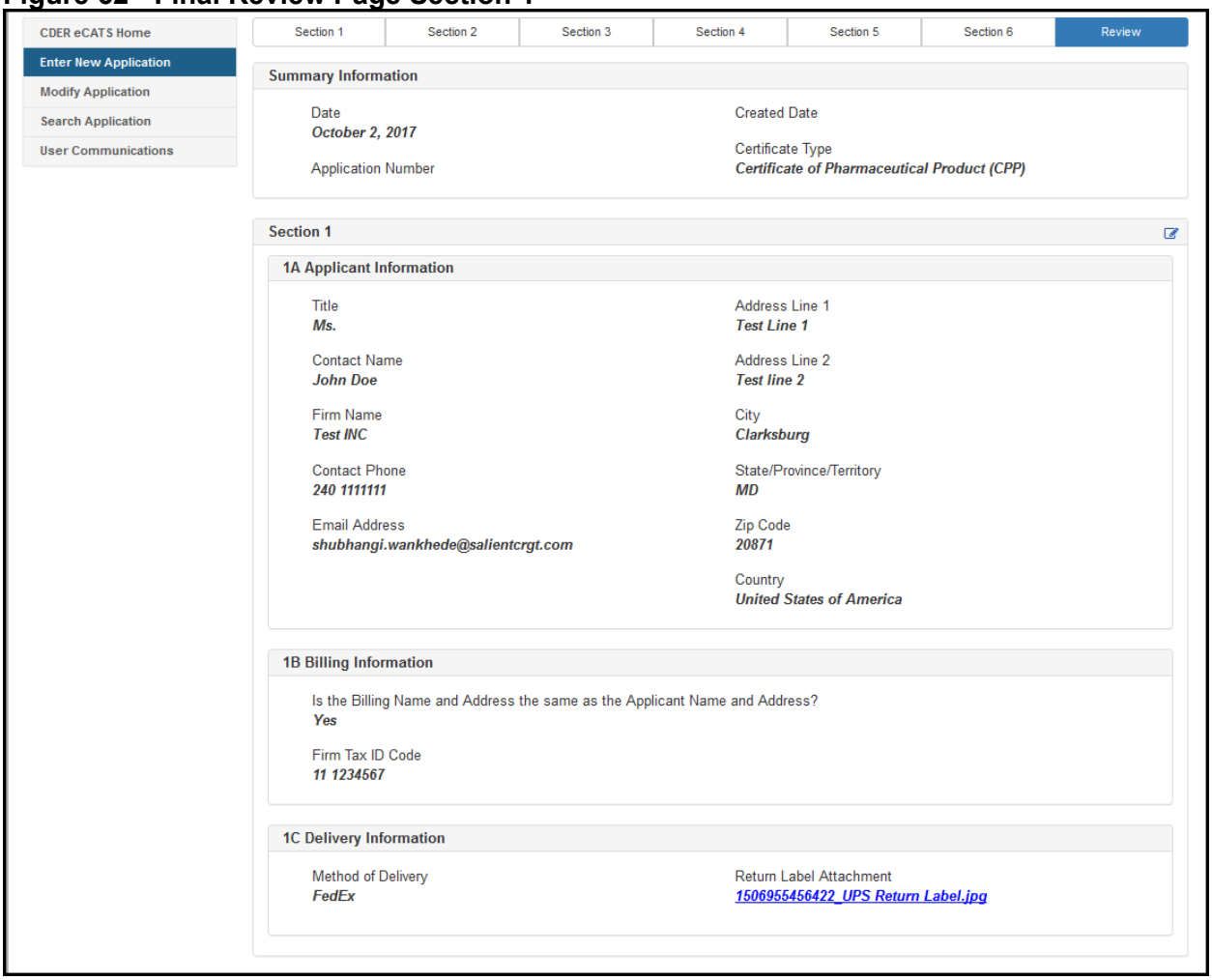
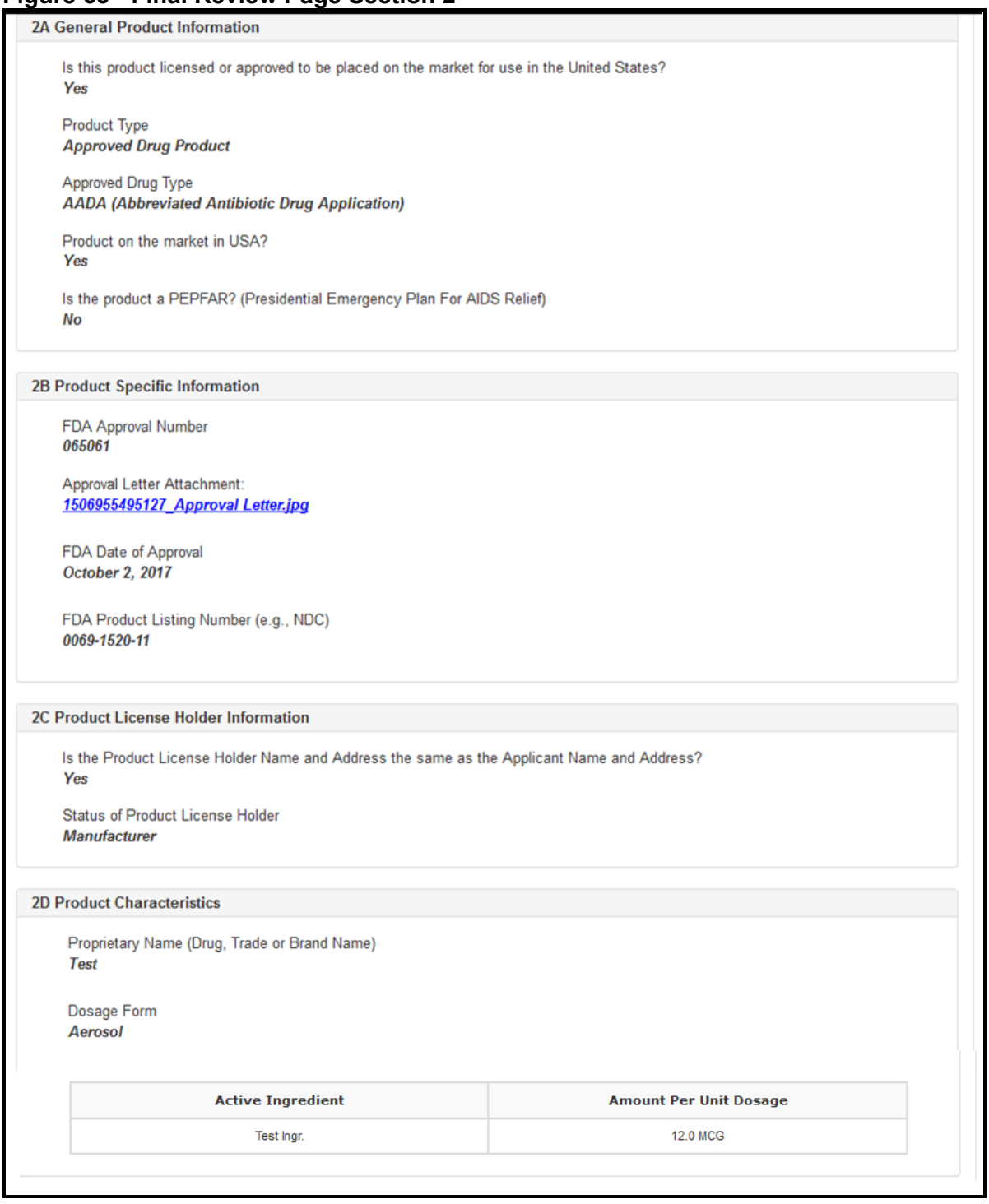


Figure 63 - Final Review Page Section 2



2A General Product Information

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

Product Type
Approved Drug Product

Approved Drug Type
AADA (Abbreviated Antibiotic Drug Application)

Product on the market in USA?
Yes

Is the product a PEPFAR? (Presidential Emergency Plan For AIDS Relief)
No

2B Product Specific Information

FDA Approval Number
065061

Approval Letter Attachment:
1506955495127_Approval Letter.jpg

FDA Date of Approval
October 2, 2017

FDA Product Listing Number (e.g., NDC)
0069-1520-11

2C Product License Holder Information

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

Status of Product License Holder
Manufacturer

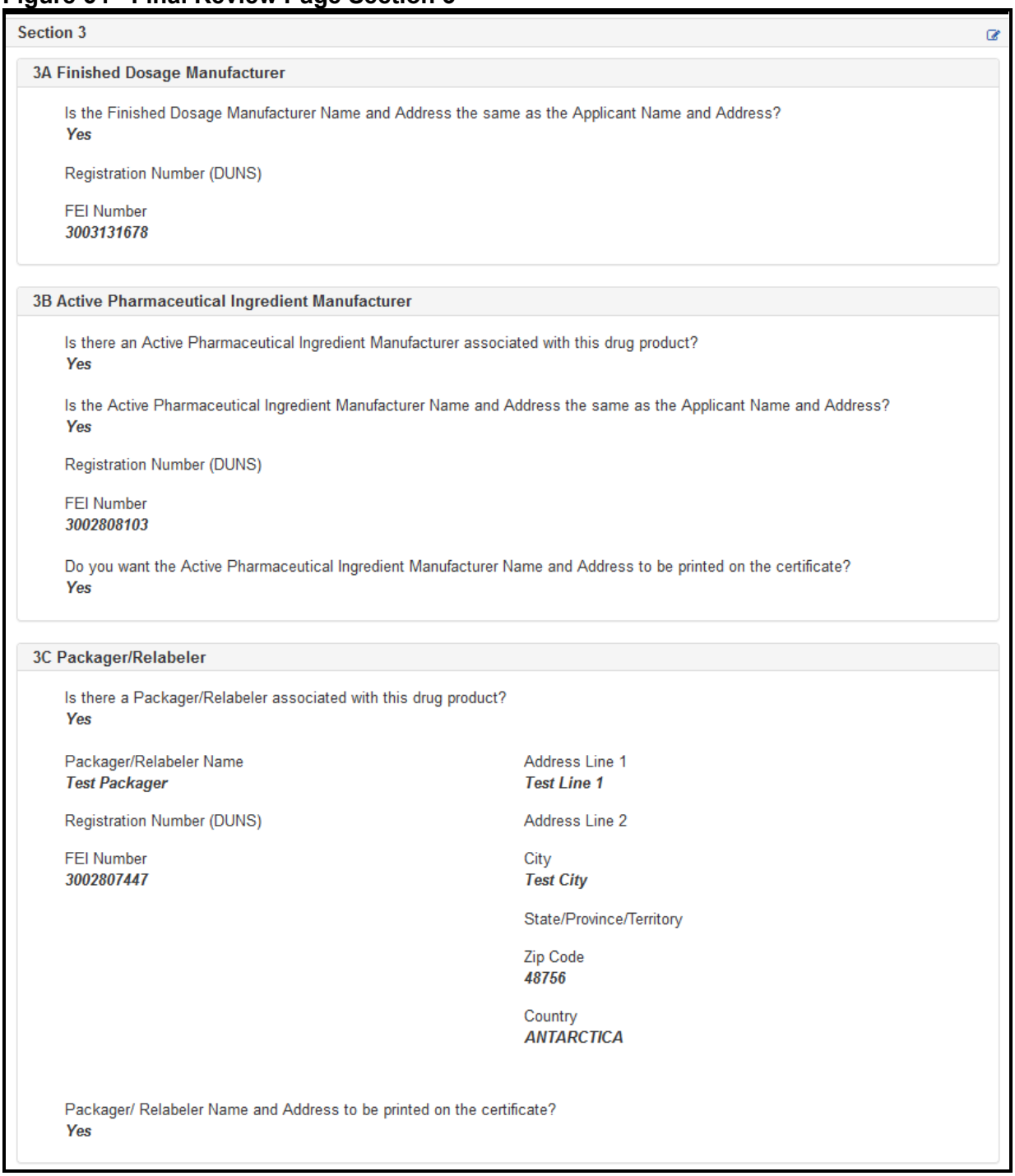
2D Product Characteristics

Proprietary Name (Drug, Trade or Brand Name)
Test

Dosage Form
Aerosol

Active Ingredient	Amount Per Unit Dosage
Test Ingr.	12.0 MCG

Figure 64 - Final Review Page Section 3



Section 3

3A Finished Dosage Manufacturer

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

Registration Number (DUNS)

FEI Number
3003131678

3B Active Pharmaceutical Ingredient Manufacturer

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

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

Registration Number (DUNS)

FEI Number
3002808103

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

3C Packager/Relabeler

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

Packager/Relabeler Name
Test Packager

Registration Number (DUNS)

FEI Number
3002807447

Address Line 1
Test Line 1

Address Line 2

City
Test City

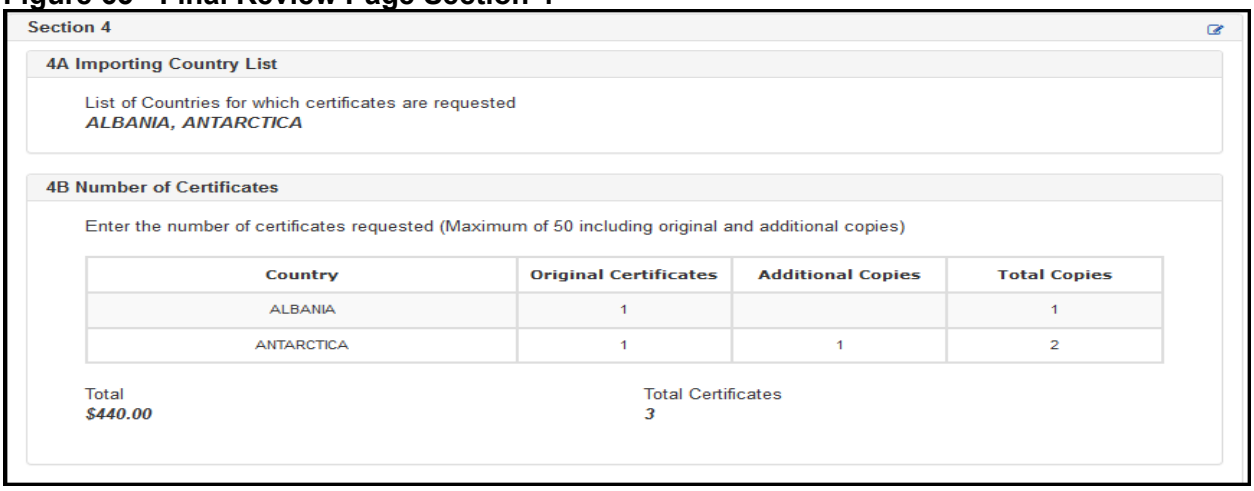
State/Province/Territory

Zip Code
48756

Country
ANTARCTICA

Packager/ Relabeler Name and Address to be printed on the certificate?
Yes

Figure 65 - Final Review Page Section 4



Section 4

4A Importing Country List

List of Countries for which certificates are requested
ALBANIA, ANTARCTICA

4B Number of Certificates

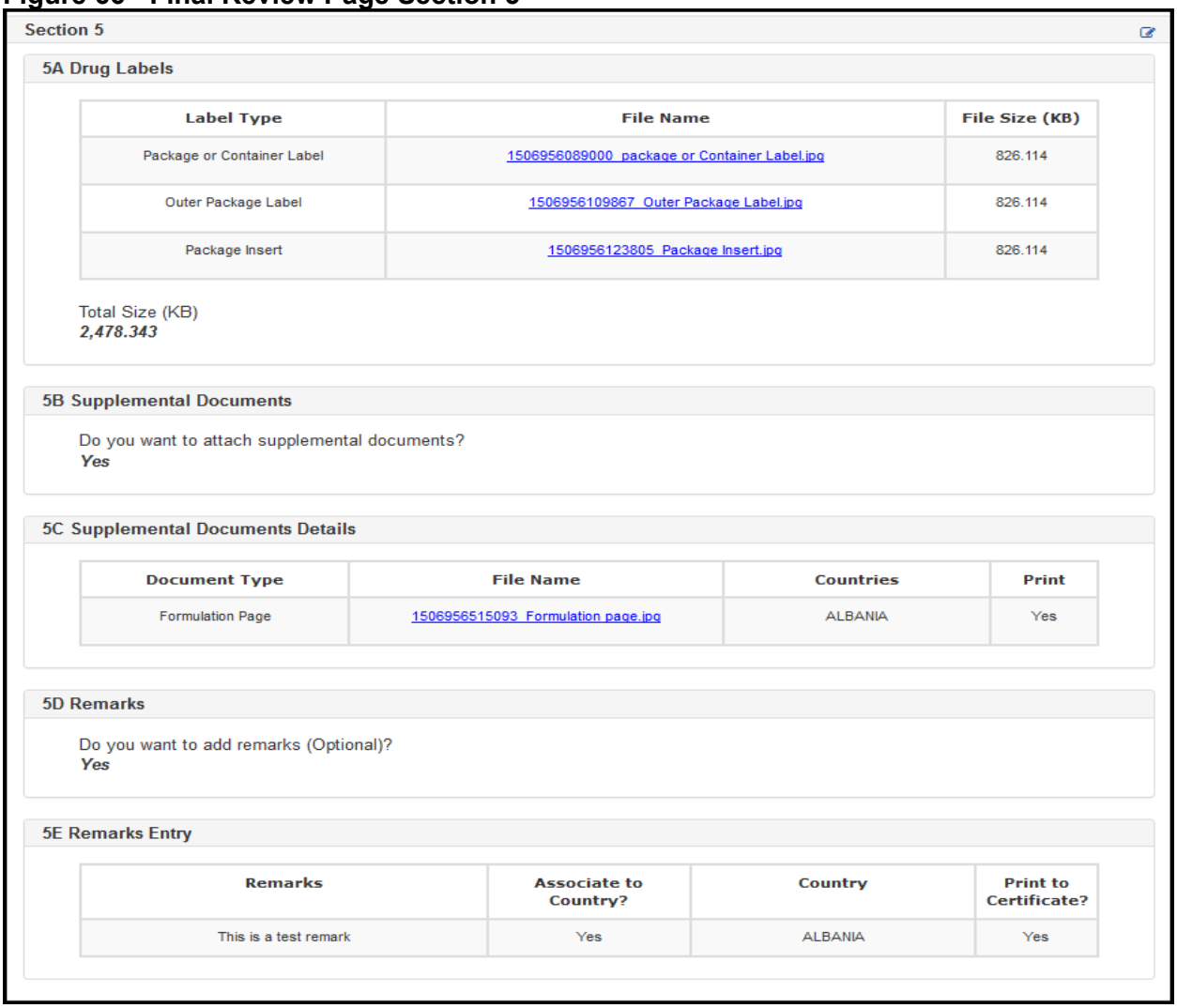
Enter the number of certificates requested (Maximum of 50 including original and additional copies)

Country	Original Certificates	Additional Copies	Total Copies
ALBANIA	1		1
ANTARCTICA	1	1	2

Total
$440.00

Total Certificates
3

Figure 66 - Final Review Page Section 5



Section 5

5A Drug Labels

Label Type	File Name	File Size (KB)
Package or Container Label	1506956089000_package or Container Label.jpg	826.114
Outer Package Label	1506956109867_Outer Package Label.jpg	826.114
Package Insert	1506956123805_Package Insert.jpg	826.114

Total Size (KB)
2,478.343

5B Supplemental Documents

Do you want to attach supplemental documents?
Yes

5C Supplemental Documents Details

Document Type	File Name	Countries	Print
Formulation Page	1506956515093_Formulation page.jpg	ALBANIA	Yes

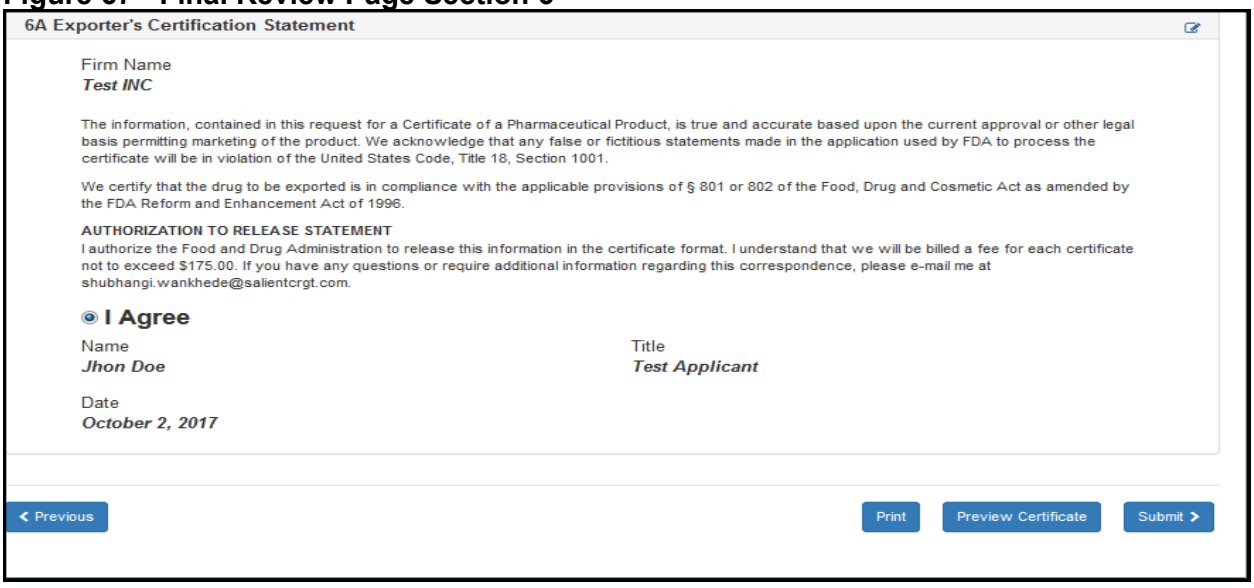
5D Remarks

Do you want to add remarks (Optional)?
Yes

5E Remarks Entry

Remarks	Associate to Country?	Country	Print to Certificate?
This is a test remark	Yes	ALBANIA	Yes

Figure 67 - Final Review Page Section 6

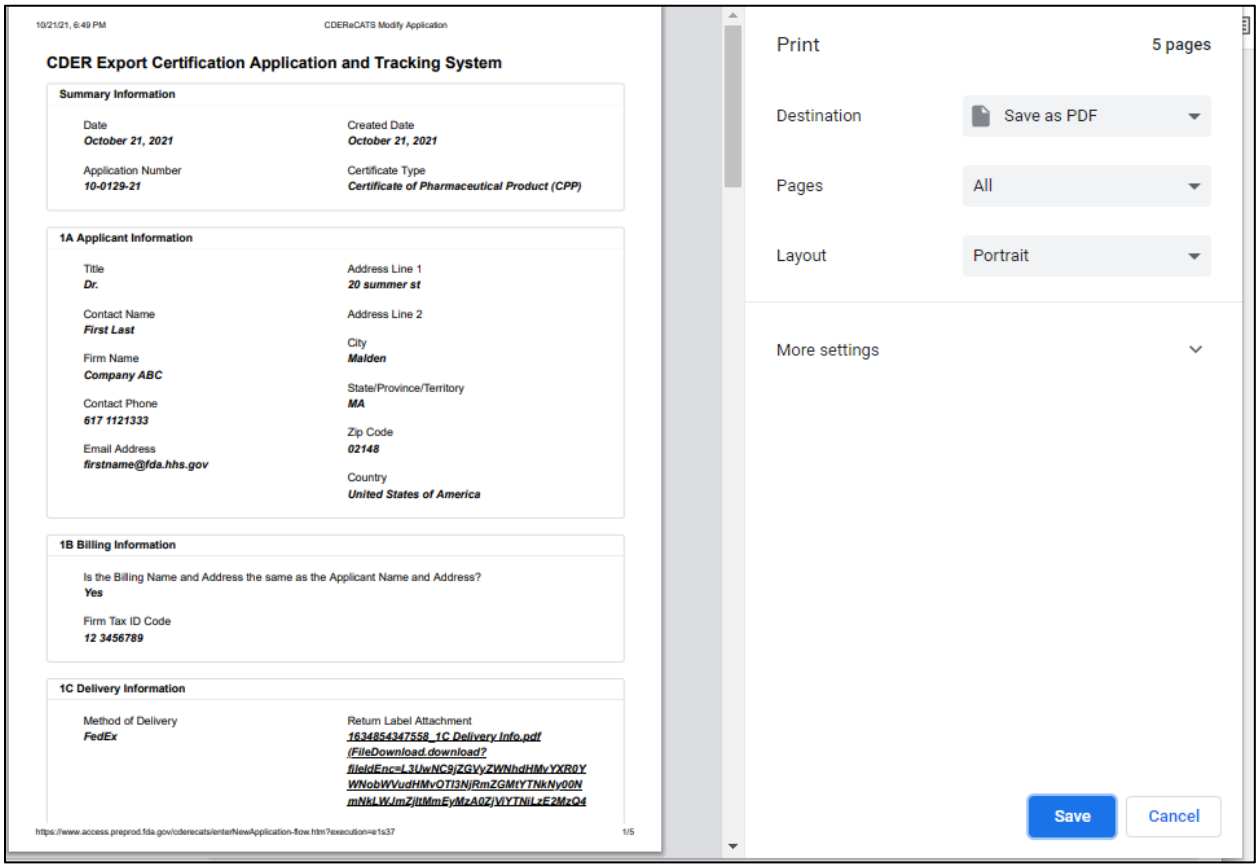


4.22 Print the Application

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, as shown in Figure 68 (below).

Figure 68 - Print Application



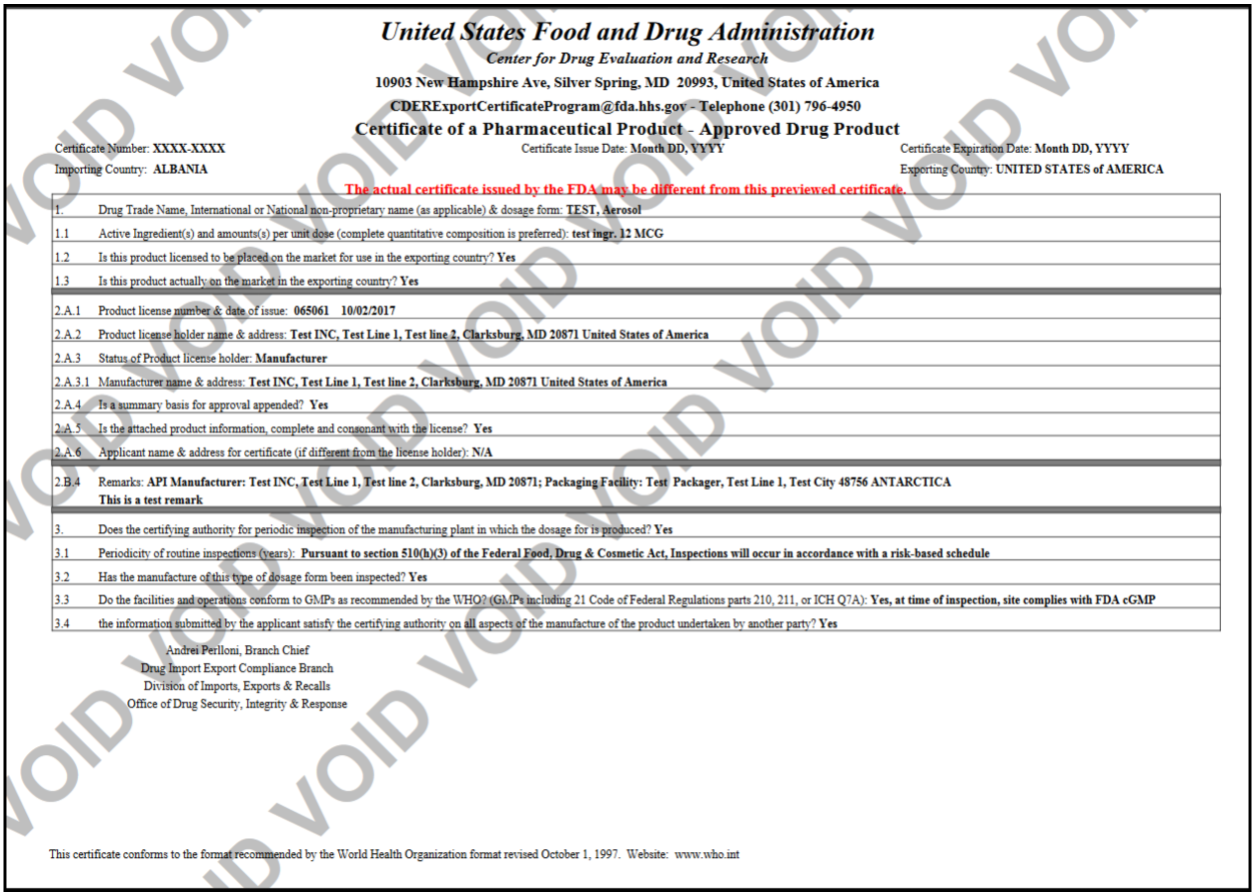
4.23 Preview Certificate

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 FDA approves your application).

You will be able to view the certificate draft and, if necessary, make modifications to your application prior to submission.

Below is an example of previewing a certificate, as shown in Figure 69.

Figure 69 - 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: **ALBANIA** Exporting Country: **UNITED STATES of AMERICA**

The actual certificate issued by the FDA may be different from this previewed certificate.

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **TEST, Aerosol**
1.1	Active Ingredient(s) and amounts(s) per unit dose (complete quantitative composition is preferred): **test ingr. 12 MCG**
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: **065061 10/02/2017**
2.A.2	Product license holder name & address: **Test INC, Test Line 1, Test line 2, Clarksburg, MD 20871 United States of America**
2.A.3	Status of Product license holder: **Manufacturer**
2.A.3.1	Manufacturer name & address: **Test INC, Test Line 1, Test line 2, Clarksburg, MD 20871 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: **API Manufacturer: Test INC, Test Line 1, Test line 2, Clarksburg, MD 20871; Packaging Facility: Test Packager, Test Line 1, Test City 48756 ANTARCTICA** **This is a 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 a 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	the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? **Yes**

Andrei Perlloni, Branch Chief
Drug Import Export Compliance Branch
Division of Imports, Exports & Recalls
Office of Drug Security, Integrity & Response

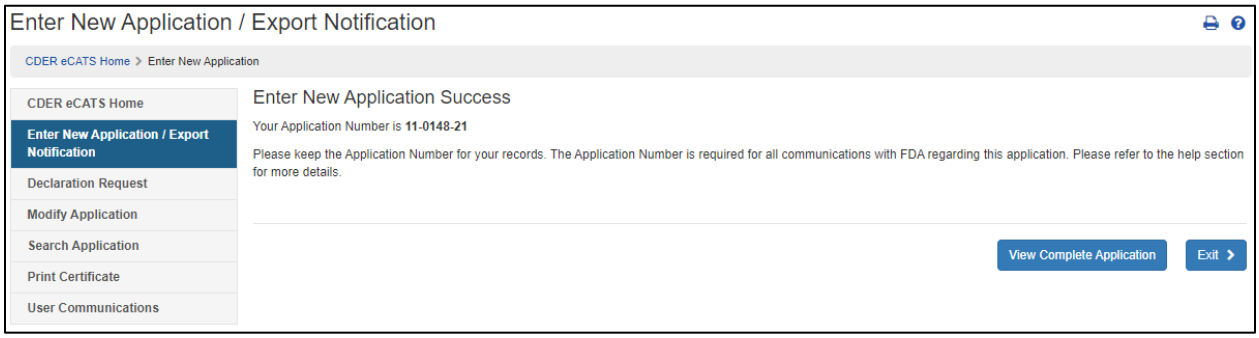
This certificate conforms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int

4.24 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 noting that your application was successfully submitted, as shown in Figure 70 (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 message stating your application was successfully received with the application number.

Figure 70 - Submission Page



5 Electronic Certificates Issued for Approved Applications

On December 3, 2021, CDER will begin issuing CPPs electronically (eCPPs) and will no longer issue or mail paper CPPs. CPP applications received prior to December 3, 2021, will be issued as paper certificates.

5.1 Notification of Application Approval

When an application has been reviewed and approved by the FDA, applicants will receive an email.

Subject: Export Certificate Application Approved: [Application Number]

Dear [Applicant First Name + Applicant Last Name],

Your application number [Application Number] was approved and you may print your certificate at this time.

To download and print your certificate package online, log in to FDA Industry System's CDER Export Certification Application and Tracking System (CDER eCATS). Navigate to the Print Certificate menu and select the Print icon from the dashboard.

The FDA Division of User Fees will send a billing invoice to the billing contact identified on your application. Invoices are sent on a quarterly basis.

Export certificates are issued by FDA solely for export purposes and may not be used for domestic advertising. You are responsible for ensuring that your product is manufactured in compliance with the FD&C Act and all other applicable U.S. laws and regulations. Issuance of this certificate does not suggest or imply that FDA approves or sanctions the labels and labeling of the firm's products or that the firm's products are in compliance with the requirements of the FD&C Act. Further, issuance of an export certificate does not preclude regulatory action by FDA, if warranted, against products covered by the certificate.

If you have any questions regarding your application, please contact the Center for Drug Evaluation and Research at cderexportcertificateprogram@fda.hhs.gov.

If you require the use of a Relay Service, please call the Federal Relay Services (1-800-877-8339). This is a toll-free relay service to call Federal agencies from TTY devices.

Thank you,

CDER Exports Compliance Branch

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

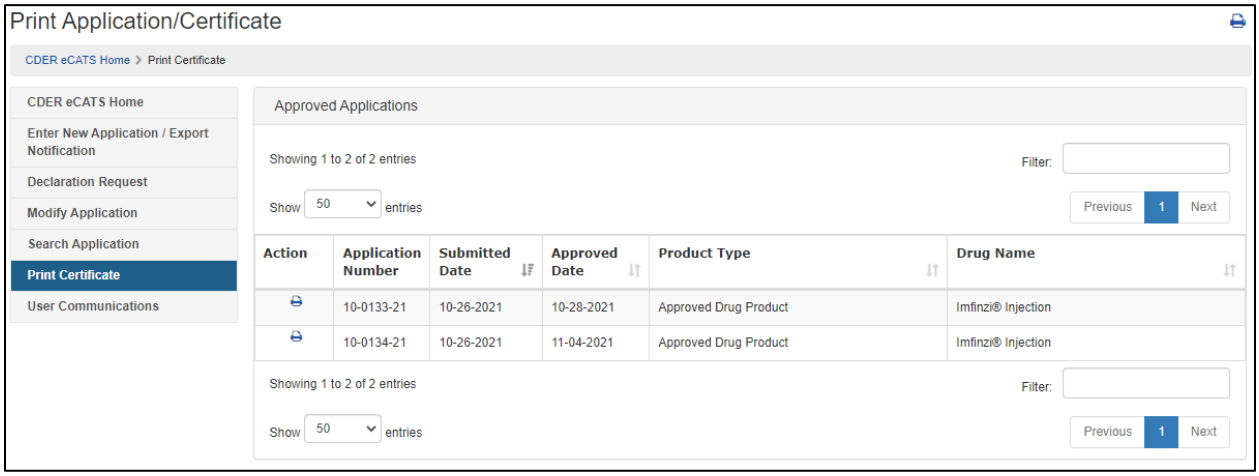
5.2 View and Print Electronic Certificate

To view your approve application and print the electronic certificate, select “Print Certificate” from the list of options on the CDER eCATS Main Menu page.

View Approved Applications:

The “Print Application/Certificate” dashboard (as shown in Figure 71 (below), displays your application(s) that have been approved and electronic certificate(s) issued.

Figure 71 - Print Certificate Dashboard



Print Electronic Certificate:

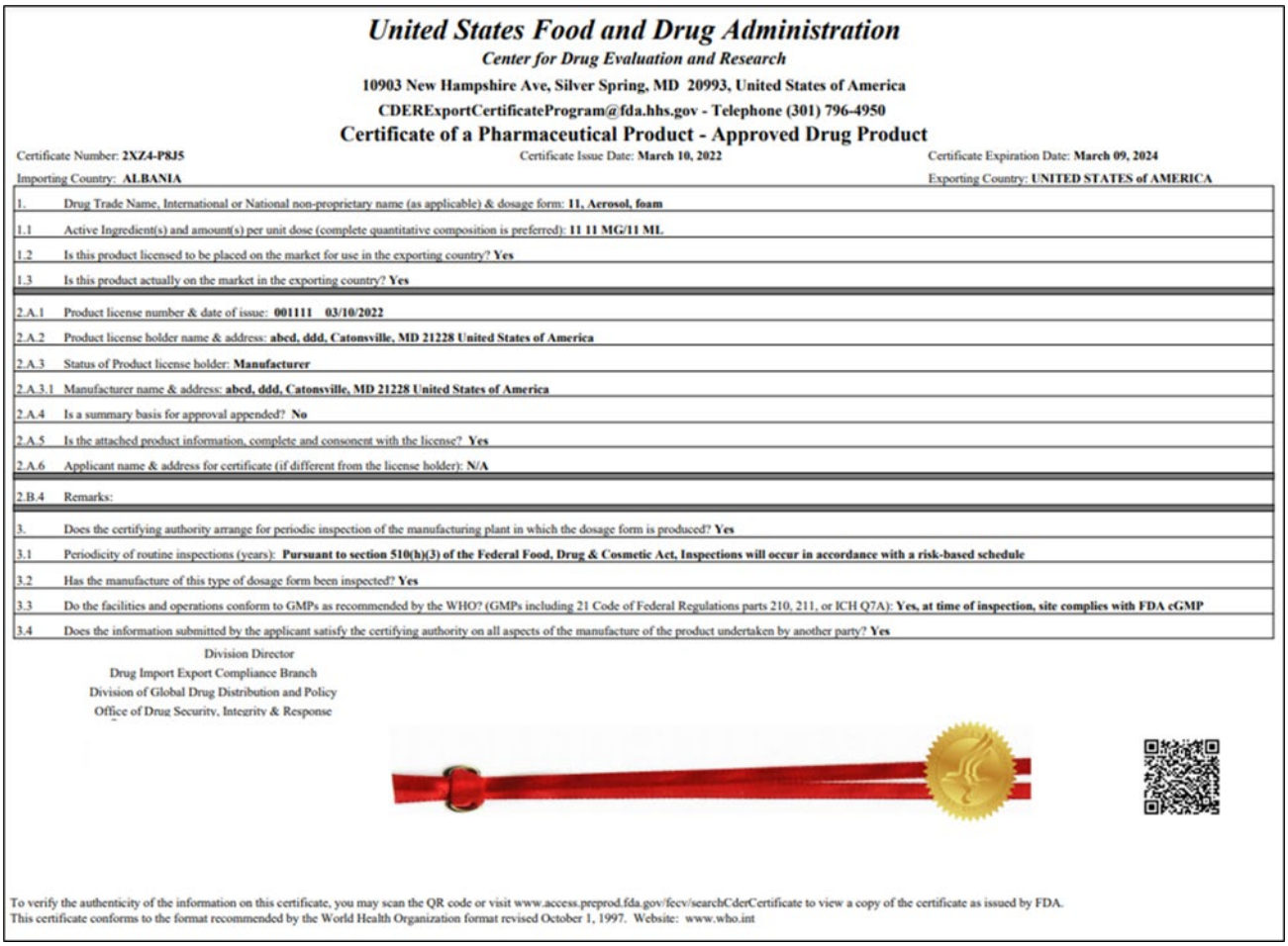
Click on the “Print” icon in the “Action” column. The generated certificate(s) will be displayed as a PDF. The electronic certificate(s) include(s) a unique ribbon/seal color based on the product type:

- Approved & OTC Products – Red Ribbon
- Unapproved Products – Blue Ribbon
- API – Orange Ribbon

Also included in the footer is a QR Code that can be used to authenticate the certificate.

Use your browser's print settings to print the certificate(s). Figure 72 - Figure 74 illustrate examples of the electronic certificates issued.

Figure 72 - Electronic Certificate – Approved Drug Product



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: **2XZ4-P8J5** Certificate Issue Date: **March 10, 2022** Certificate Expiration Date: **March 09, 2024**

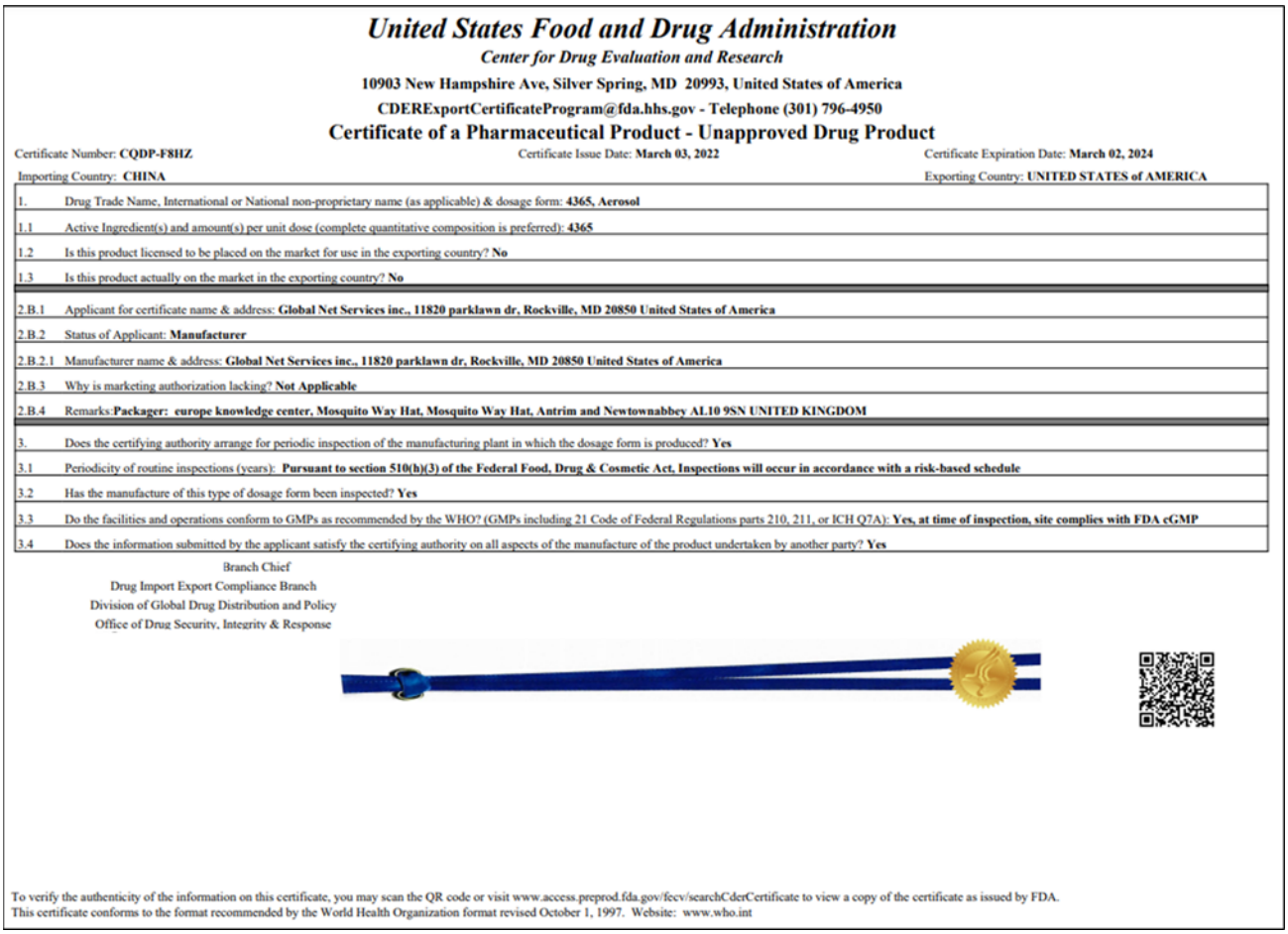
Importing Country: **ALBANIA** Exporting Country: **UNITED STATES of AMERICA**

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **11, Aerosol, foam**
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **11 11 MG/11 ML**
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: **001111 03/10/2022**
2.A.2	Product license holder name & address: **abcd, ddd, Catonsville, MD 21228 United States of America**
2.A.3	Status of Product license holder: **Manufacturer**
2.A.3.1	Manufacturer name & address: **abcd, ddd, Catonsville, MD 21228 United States of America**
2.A.4	Is a summary basis for approval appended? **No**
2.A.5	Is the attached product information, complete and consonent with the license? **Yes**
2.A.6	Applicant name & address for certificate (if different from the license holder): **N/A**
2.B.4	Remarks:
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form 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 a 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**

Division Director
Drug Import Export Compliance Branch
Division of Global Drug Distribution and Policy
Office of Drug Security, Integrity & Response

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.preprod.fda.gov/fecv/searchCderCertificate to view a copy of the certificate as issued by FDA.
This certificate conforms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int

Figure 73 - Electronic Certificate – Unapproved Drug Product



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 - Unapproved Drug Product

Certificate Number: **CQDP-F8HZ** Certificate Issue Date: **March 03, 2022** Certificate Expiration Date: **March 02, 2024**

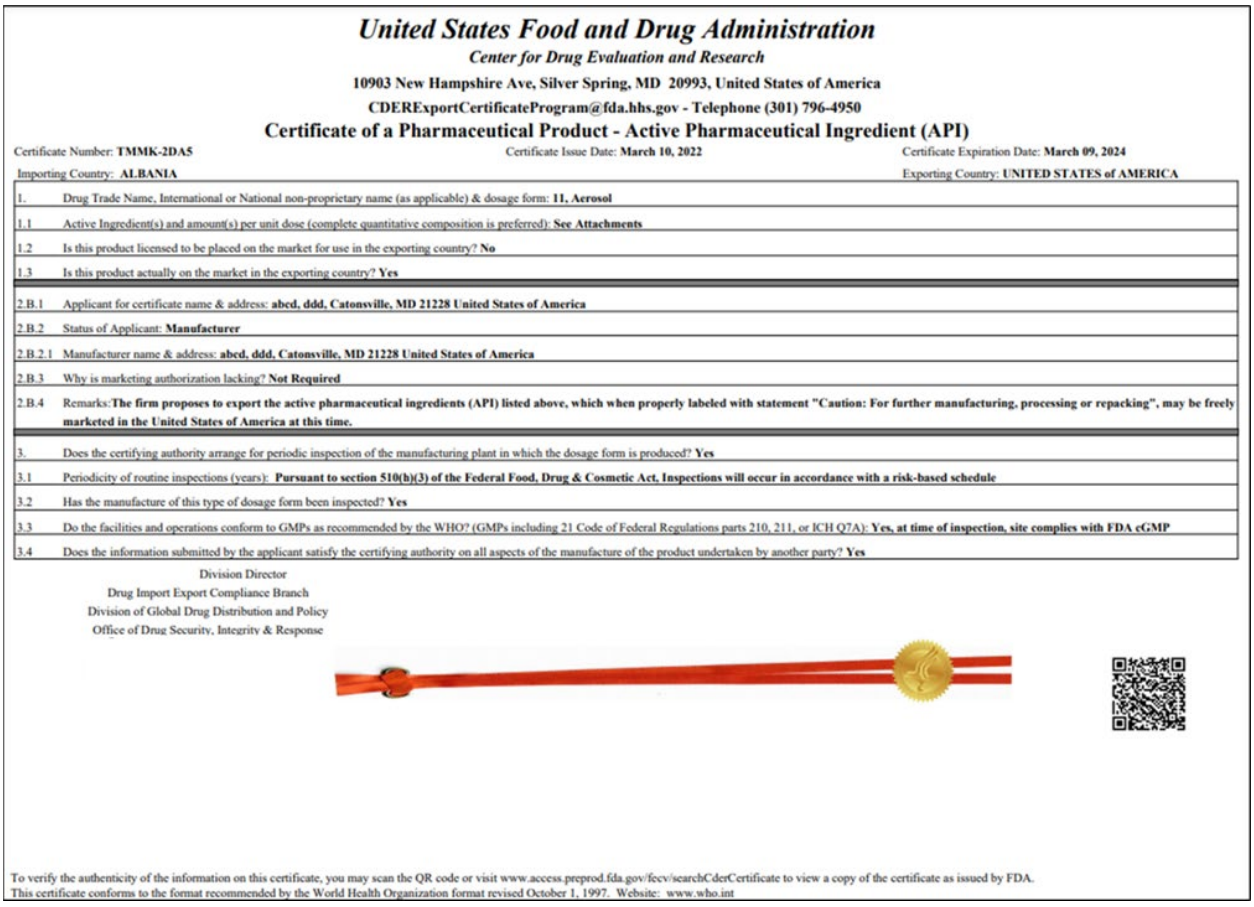
Importing Country: **CHINA** Exporting Country: **UNITED STATES of AMERICA**

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **4365, Aerosol**
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **4365**
1.2	Is this product licensed to be placed on the market for use in the exporting country? **No**
1.3	Is this product actually on the market in the exporting country? **No**
2.B.1	Applicant for certificate name & address: **Global Net Services inc., 11820 parklawn dr, Rockville, MD 20850 United States of America**
2.B.2	Status of Applicant: **Manufacturer**
2.B.2.1	Manufacturer name & address: **Global Net Services inc., 11820 parklawn dr, Rockville, MD 20850 United States of America**
2.B.3	Why is marketing authorization lacking? **Not Applicable**
2.B.4	Remarks:**Packager: europe knowledge center, Mosquito Way Hat, Mosquito Way Hat, Antrim and Newtownabbey AL10 9SN UNITED KINGDOM**
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form 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 a 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**

Branch Chief
Drug Import Export Compliance Branch
Division of Global Drug Distribution and Policy
Office of Drug Security, Integrity & Response

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.preprod.fda.gov/fecv/searchCderCertificate to view a copy of the certificate as issued by FDA.
This certificate conforms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int

Figure 74 - Electronic Certificate – Active Pharmaceutical Ingredient (API)



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 - Active Pharmaceutical Ingredient (API)

Certificate Number: **TMMK-2DA5** Certificate Issue Date: **March 10, 2022** Certificate Expiration Date: **March 09, 2024**

Importing Country: **ALBANIA** Exporting Country: **UNITED STATES of AMERICA**

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **11, Aerosol**
1.1	Active Ingredient(s) and amount(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? **No**
1.3	Is this product actually on the market in the exporting country? **Yes**
2.B.1	Applicant for certificate name & address: **abcd, ddd, Catonsville, MD 21228 United States of America**
2.B.2	Status of Applicant: **Manufacturer**
2.B.2.1	Manufacturer name & address: **abcd, ddd, Catonsville, MD 21228 United States of America**
2.B.3	Why is marketing authorization lacking? **Not Required**
2.B.4	Remarks:**The firm proposes to export the active pharmaceutical ingredients (API) listed above, which when properly labeled with statement "Caution: For further manufacturing, processing or repacking", may be freely marketed in the United States of America at this time.**
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form 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 a 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**

Division Director
Drug Import Export Compliance Branch
Division of Global Drug Distribution and Policy
Office of Drug Security, Integrity & Response

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.preprod.fda.gov/fecv/searchCderCertificate to view a copy of the certificate as issued by FDA.
This certificate conforms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int

6 Responding to Return for Action

FDA reviewers may return the application back to the applicant to modify.

Review the Email Notification:

If your application is incomplete, the system will send you an email notification informing you that your application has been “Returned for Action”. Review the notification to understand what change(s) you need to make to your application.

Make the requested change and submit:

Locate the application that has the status of “Returned for Action”. See Section 7: Modify Application section for detailed steps on modifying the application.

Make the required change(s) described in the email notification. Next, resubmit the application after filling out the “Attestation” section.

NOTE: *You must complete and submit your return-for-action application within three business days of receipt*. A Return-for-Action (RFA) application is automatically canceled if it is not corrected and resubmitted within three business days from the time it is returned for action by the FDA reviewer to the applicant.

7 Modify Application

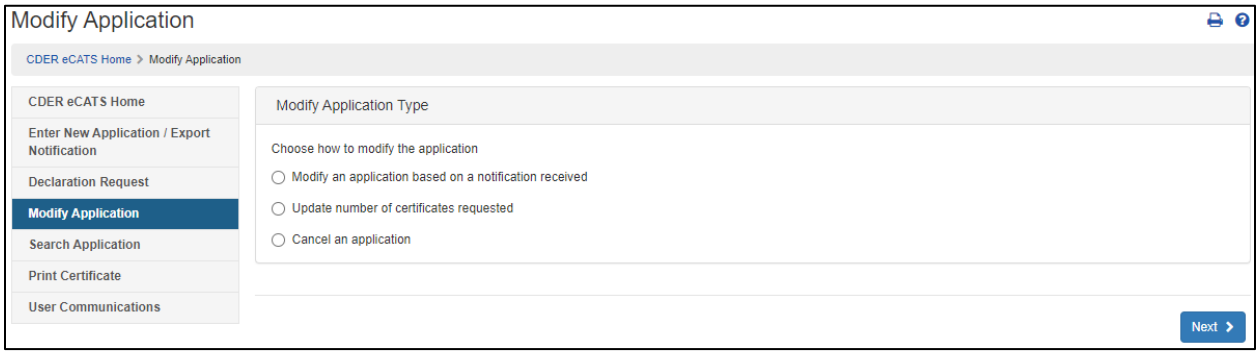
To modify an application, choose “Modify Application” from the list of options on the CDER eCATS Main Menu page.

Modify Application:

If there is an issue with an application, it will be returned for action.

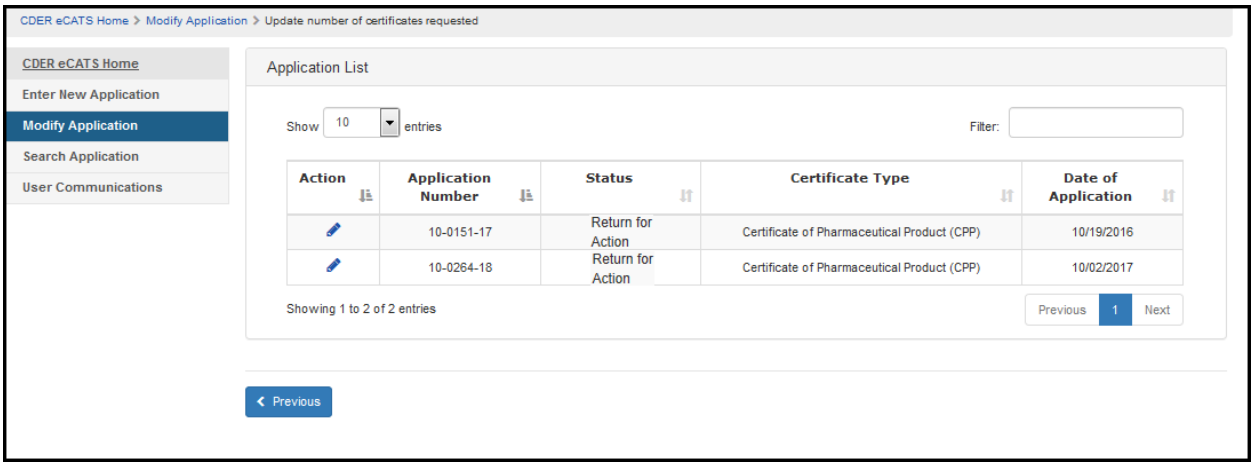
Select the “Modify Application” option from the main menu and then select “Modify an application based on a notification received”, as shown in Figure 75 (below).

Figure 75 - Modify Application Options



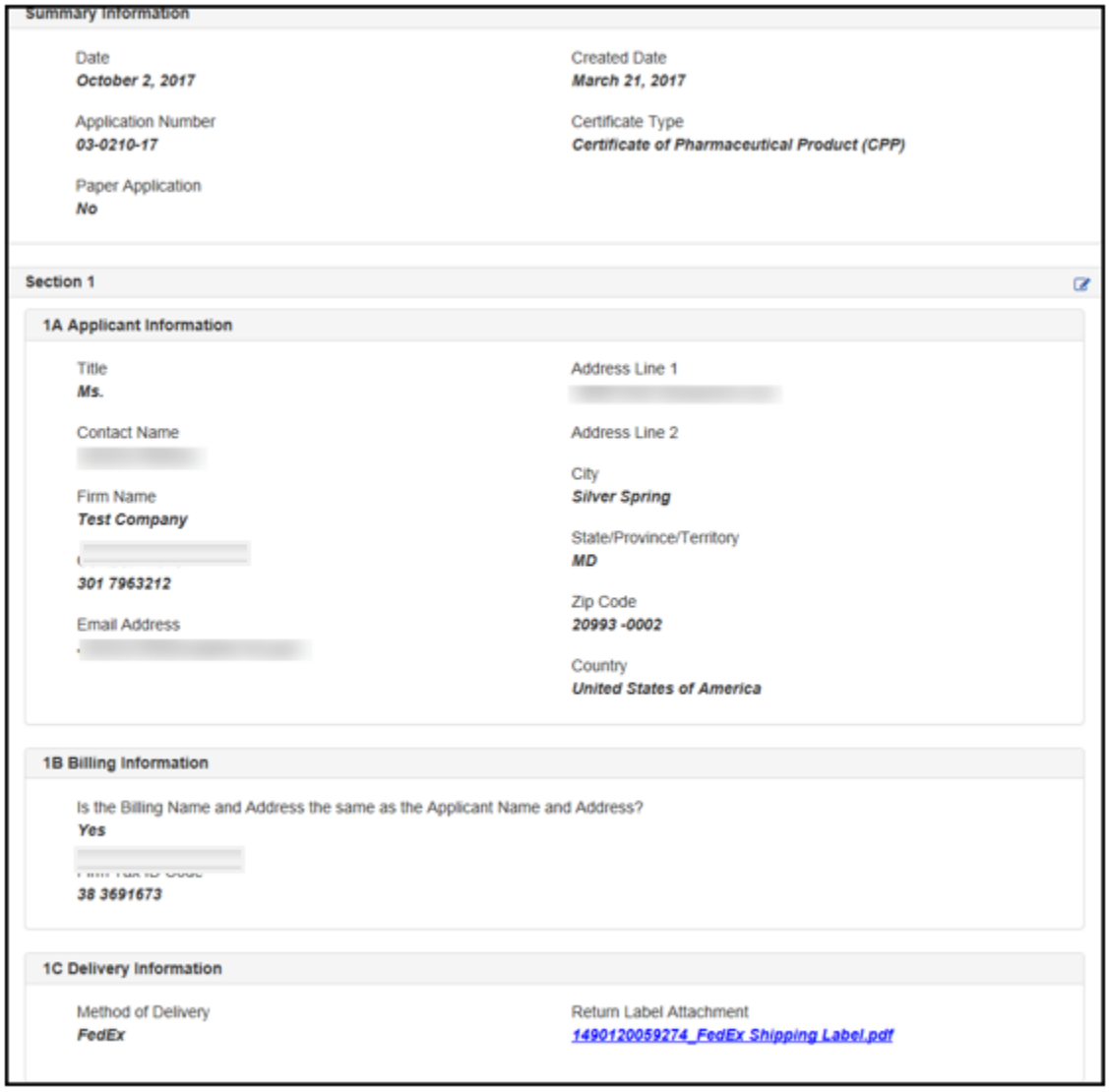
The system will display all applications that can be modified, as shown in Figure 76 (below).

Figure 76 - Applications that can be Modified



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” (pencil) icon next to each section, as shown in Figure 77 - Figure 82 (below).

Figure 77 - Final Review Page Section 1



Summary Information

Date
October 2, 2017

Created Date
March 21, 2017

Application Number
03-0210-17

Certificate Type
Certificate of Pharmaceutical Product (CPP)

Paper Application
No

Section 1

1A Applicant Information

Title
Ms.

Address Line 1

Contact Name

Address Line 2

Firm Name
Test Company

City
Silver Spring

State/Province/Territory
MD

301 7963212

Zip Code
20993 -0002

Email Address

Country
United States of America

1B Billing Information

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

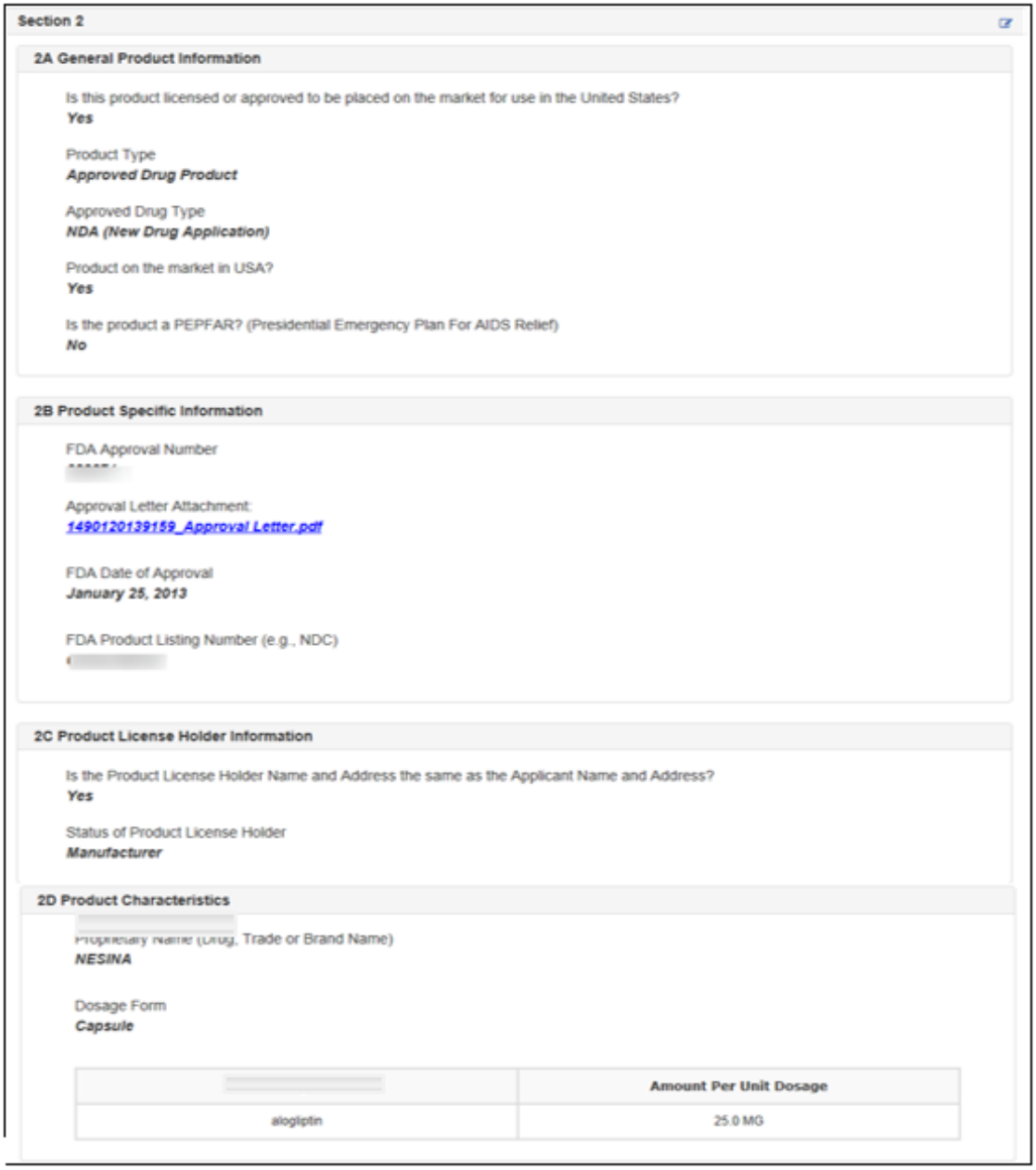
38 3691673

1C Delivery Information

Method of Delivery
FedEx

Return Label Attachment
1490120059274_FedEx Shipping Label.pdf

Figure 78 - Final Review Page Section 2



Section 2

2A General Product Information

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

Product Type
Approved Drug Product

Approved Drug Type
NDA (New Drug Application)

Product on the market in USA?
Yes

Is the product a PEPFAR? (Presidential Emergency Plan For AIDS Relief)
No

2B Product Specific Information

FDA Approval Number

Approval Letter Attachment:
1490120139159_Approval Letter.pdf

FDA Date of Approval
January 25, 2013

FDA Product Listing Number (e.g., NDC)

2C Product License Holder Information

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

Status of Product License Holder
Manufacturer

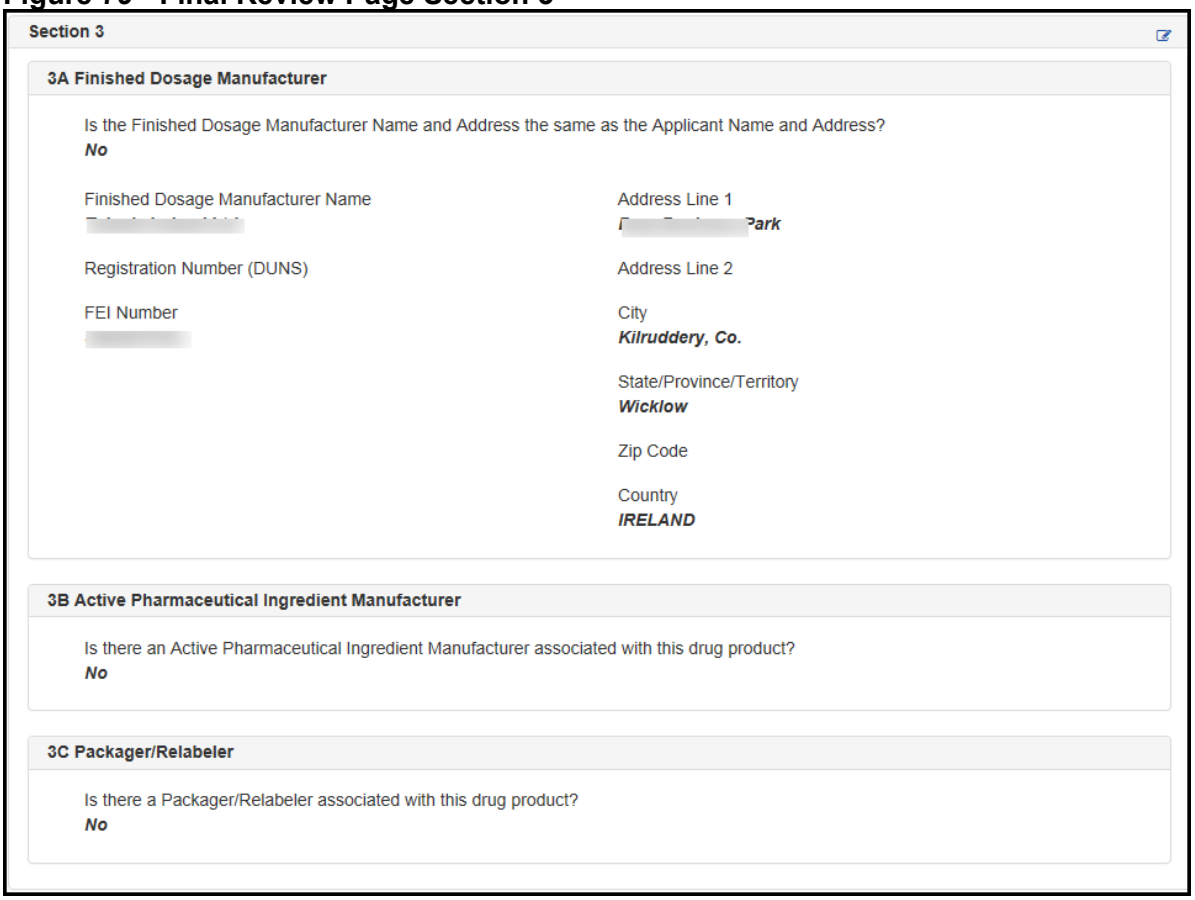
2D Product Characteristics

Proprietary Name (Drug, Trade or Brand Name)
NESINA

Dosage Form
Capsule

	Amount Per Unit Dosage
alogliptin	25.0 MG

Figure 79 - Final Review Page Section 3



Section 3

3A Finished Dosage Manufacturer

Is the Finished Dosage Manufacturer Name and Address the same as the Applicant Name and Address?
No

Finished Dosage Manufacturer Name

Registration Number (DUNS)

FEI Number

Address Line 1
Park

Address Line 2

City
Kilruddery, Co.

State/Province/Territory
Wicklow

Zip Code

Country
IRELAND

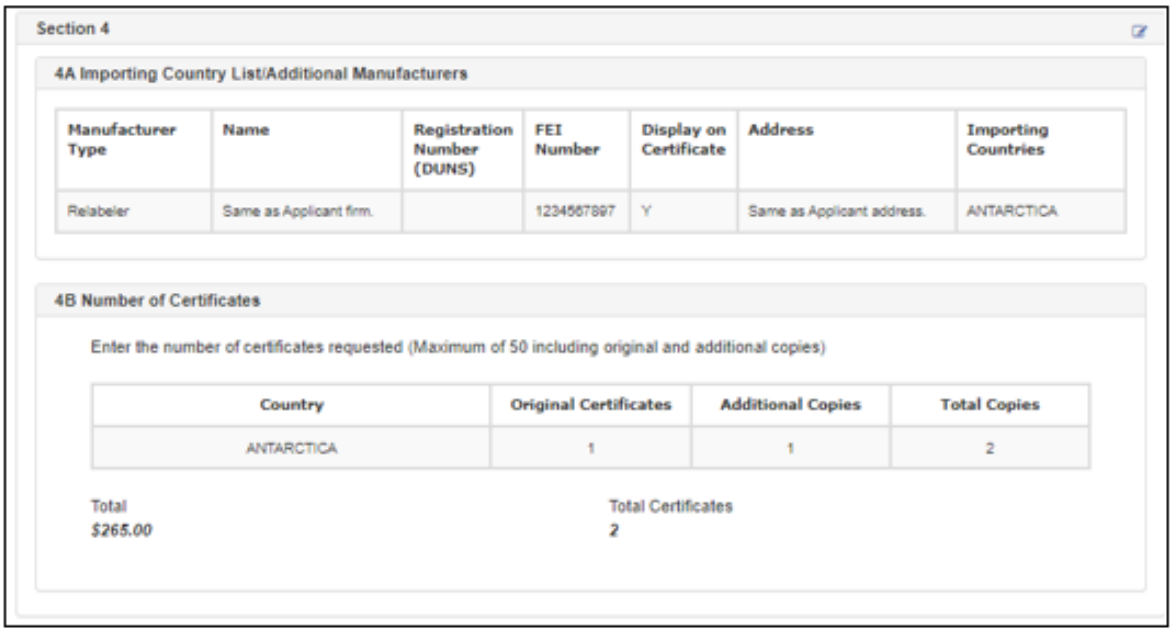
3B Active Pharmaceutical Ingredient Manufacturer

Is there an Active Pharmaceutical Ingredient Manufacturer associated with this drug product?
No

3C Packager/Relabeler

Is there a Packager/Relabeler associated with this drug product?
No

Figure 80 - Final Review Page Section 4



Section 4

4A Importing Country List/Additional Manufacturers

Manufacturer Type	Name	Registration Number (DUNS)	FEI Number	Display on Certificate	Address	Importing Countries
Relabeler	Same as Applicant firm.		1234567897	Y	Same as Applicant address.	ANTARCTICA

4B Number of Certificates

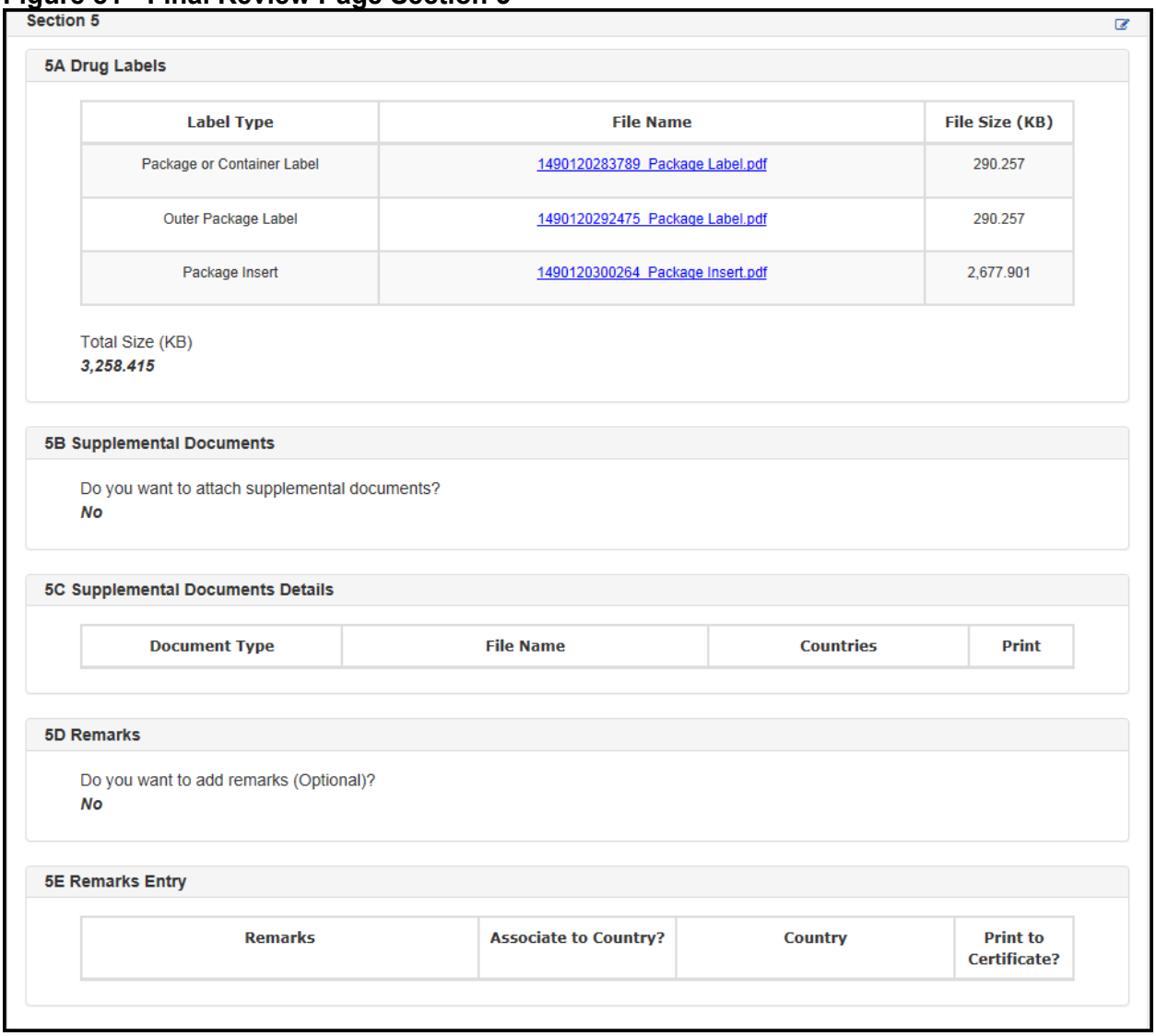
Enter the number of certificates requested (Maximum of 50 including original and additional copies)

Country	Original Certificates	Additional Copies	Total Copies
ANTARCTICA	1	1	2

Total
$265.00

Total Certificates
2

Figure 81 - Final Review Page Section 5



Section 5

5A Drug Labels

Label Type	File Name	File Size (KB)
Package or Container Label	1490120283789_Package Label.pdf	290.257
Outer Package Label	1490120292475_Package Label.pdf	290.257
Package Insert	1490120300264_Package Insert.pdf	2,677.901

Total Size (KB)
3,258.415

5B Supplemental Documents

Do you want to attach supplemental documents?
No

5C Supplemental Documents Details

Document Type	File Name	Countries	Print

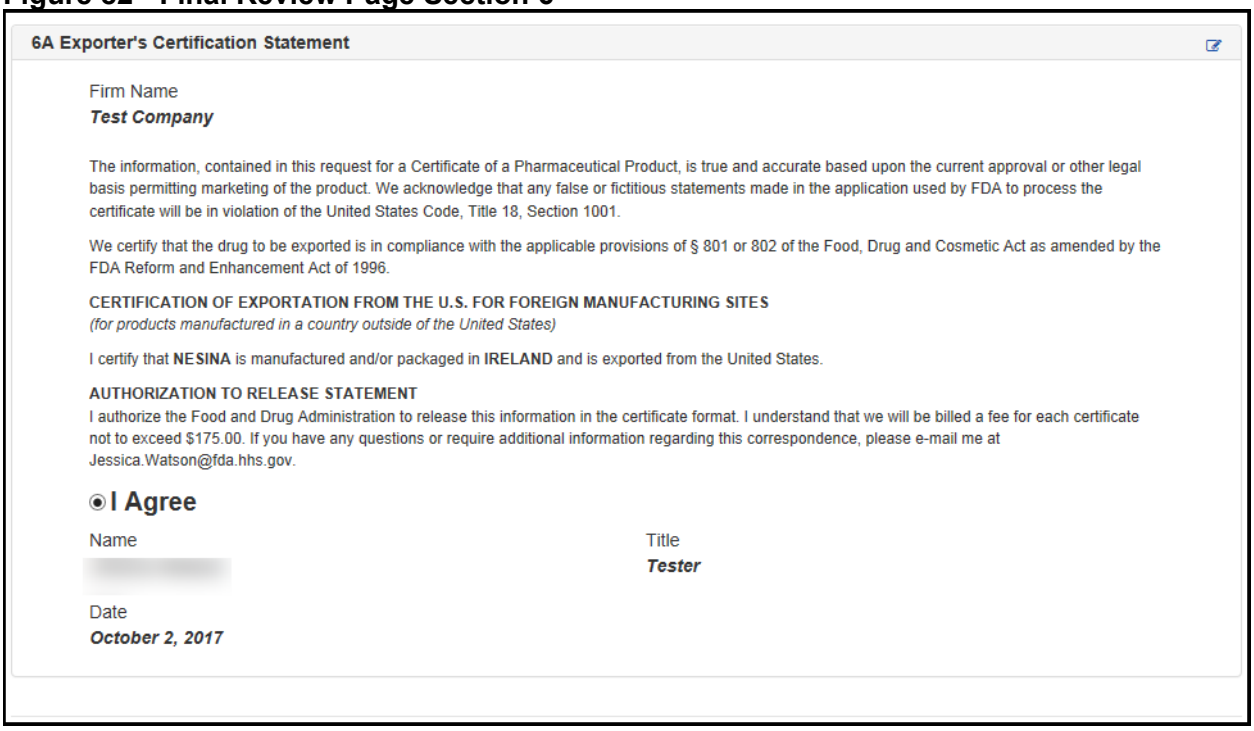
5D Remarks

Do you want to add remarks (Optional)?
No

5E Remarks Entry

Remarks	Associate to Country?	Country	Print to Certificate?

Figure 82 - Final Review Page Section 6



Click on the “Edit” icon 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 the 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 stating the application has been successfully updated
- Send a confirmation email

7.1 Request Additional Certificates

This option allows you to request additional certificates after your initial application has been submitted.

NOTE: The application must be in one of the following statuses in order to update the number of certificates requested:

- Received
- Ready to Review

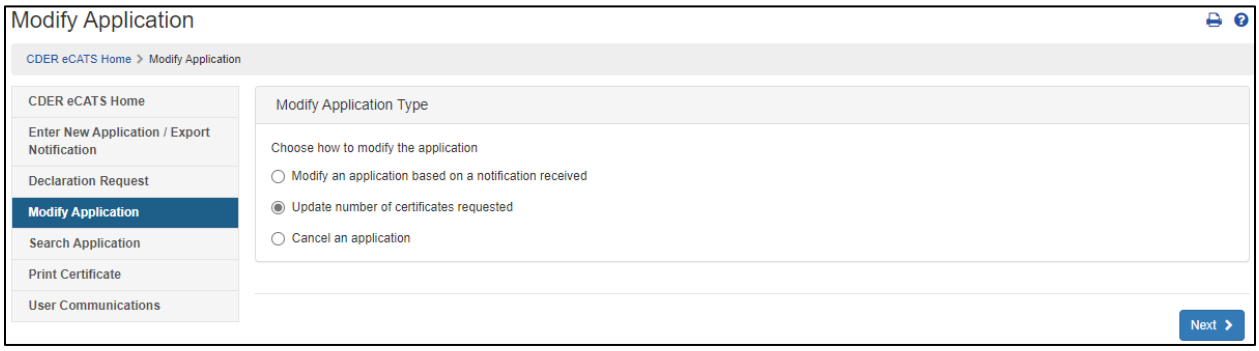
- Under Review
- Return for Action

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.

Select the “Update number of certificates requested” option, as shown in Figure 83 (below).

Figure 83 - Update Number of Certificates Requested

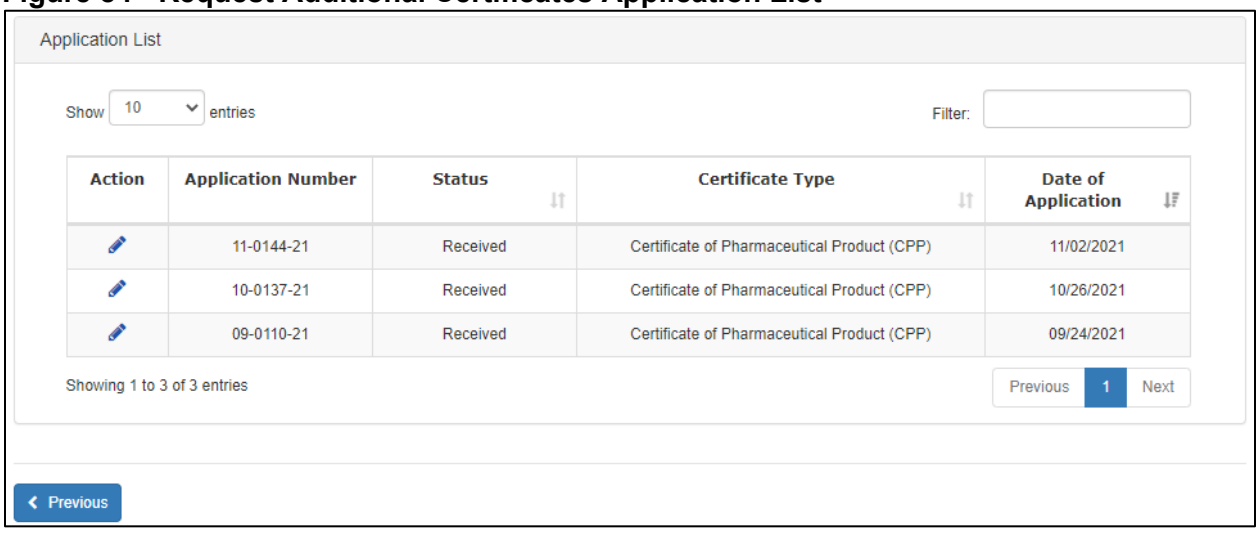


The system will only display those applications in the following status, as shown in Figure 84 (below):

Received:

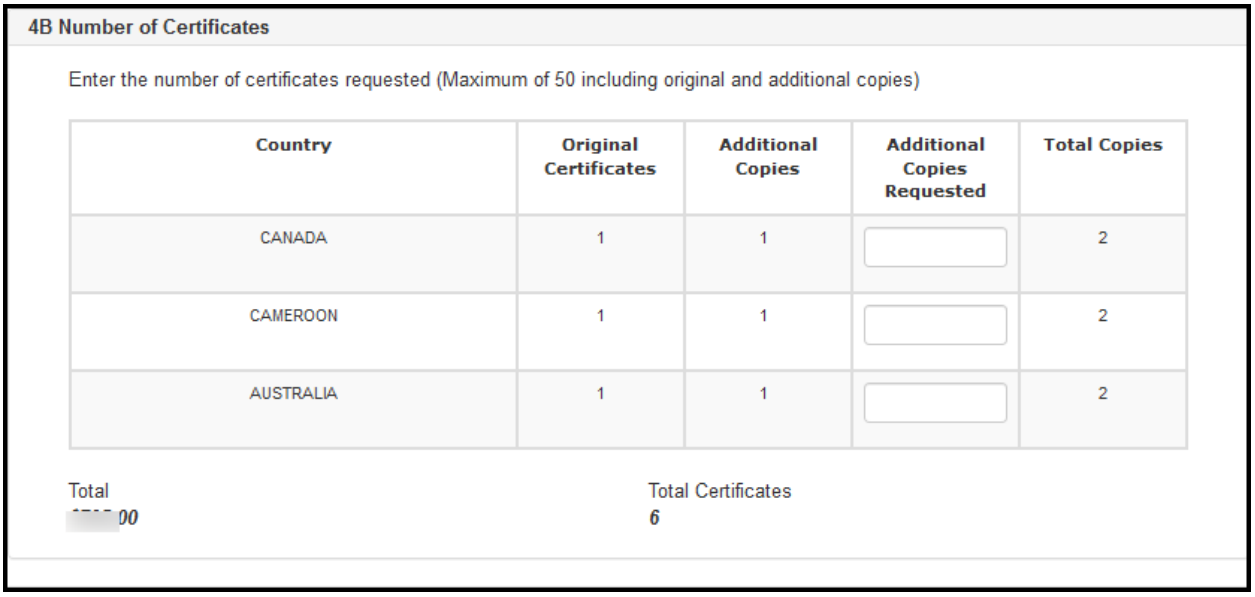
- Ready to Review
- Under Review
- Return for Action

Figure 84 - Request Additional Certificates Application List



Select the application for which you are requesting additional certificates and click “Next”. The system will navigate you to the Final Review page, as shown in Figure 85 (below). The system will display the column “Additional Copies requested”, prompting you to enter the additional copies in Section 4B - Number of Certificates.

Figure 85 - Final Review Page with Edit Option Only for Section 4B Number of Certificates



Enter the additional copies in the “Additional Copies Requested” field(s) based on the number of countries you entered in the application.

Enter the number of additional copies in the “Request Additional Copies field”. Once you have entered the number click on “Submit”.

The system will perform the following:

- Display the application number and a message that the application has been successfully updated
- Send a confirmation email

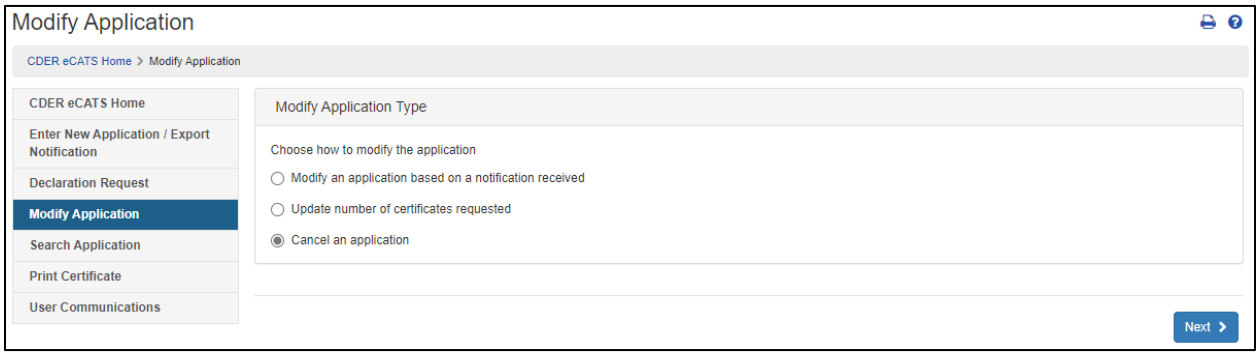
7.2 Cancel an Application

This option allows you to cancel an application. In order to cancel an application however, 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. Next, select the “Cancel the Application” option, as shown in Figure 86 (below).

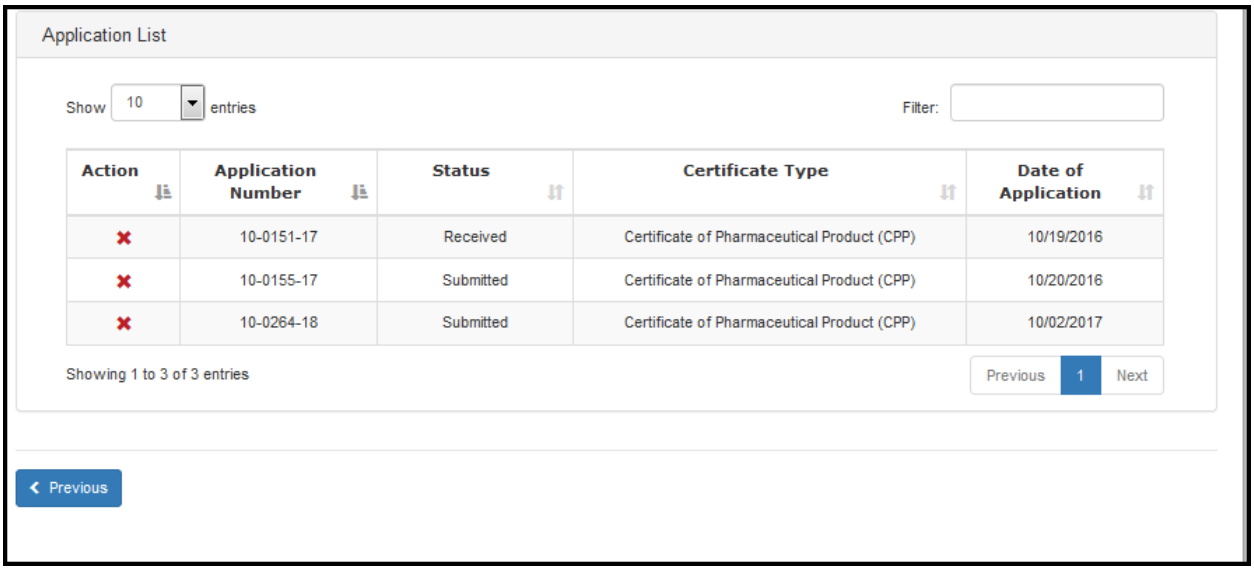
Figure 86 - Cancel the Application



NOTE: If the application is in any status other 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 for the issuance of the certificate requested. Please contact FDA at CDERExportCertificateProgram@fda.hhs.gov if you have any questions.

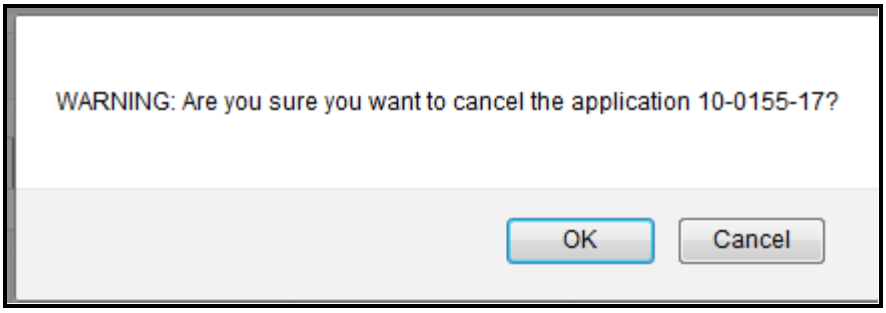
The system will display all applications that can be cancelled, as shown in Figure 87 (below).

Figure 87 - Selecting an Application for Cancellation



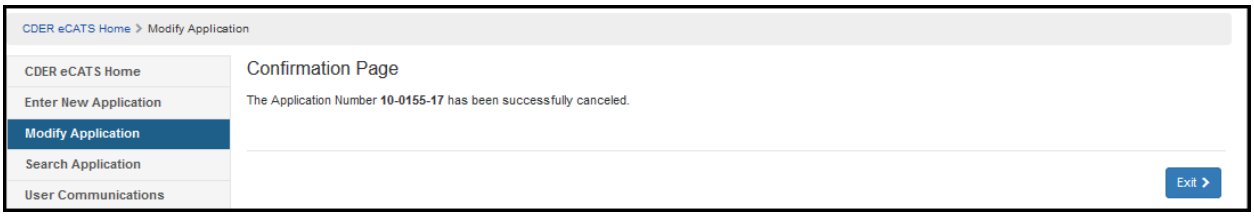
Once you have selected the application, the system will display a warning message prior to cancelling an application, as shown in Figure 88 (below).

Figure 88 - 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 89 (below). The application remains in your list of applications with the status “Cancelled”.

Figure 89 - Application Successfully Cancelled Message Displayed

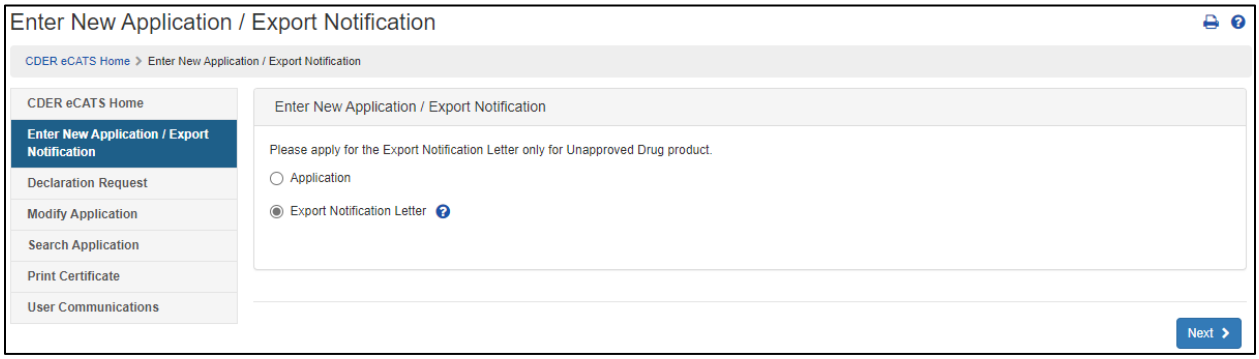


8 Submitting an Export Notification Letter

Once you have selected “CDER Export Certification Application & Tracking System”, the system will navigate you to the CDER eCATS Main Menu page.

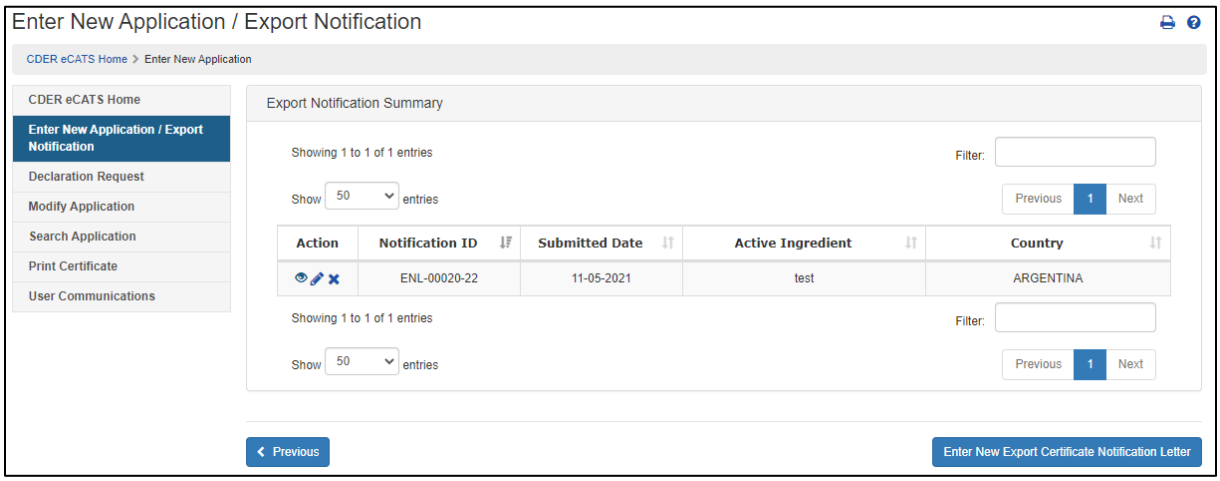
Select “Enter New Application / Export Notification” from the list of options. The system will display a screen allowing you to apply for an Export Notification letter, as shown in Figure 90 (below).

Figure 90 - Export Notification Letter



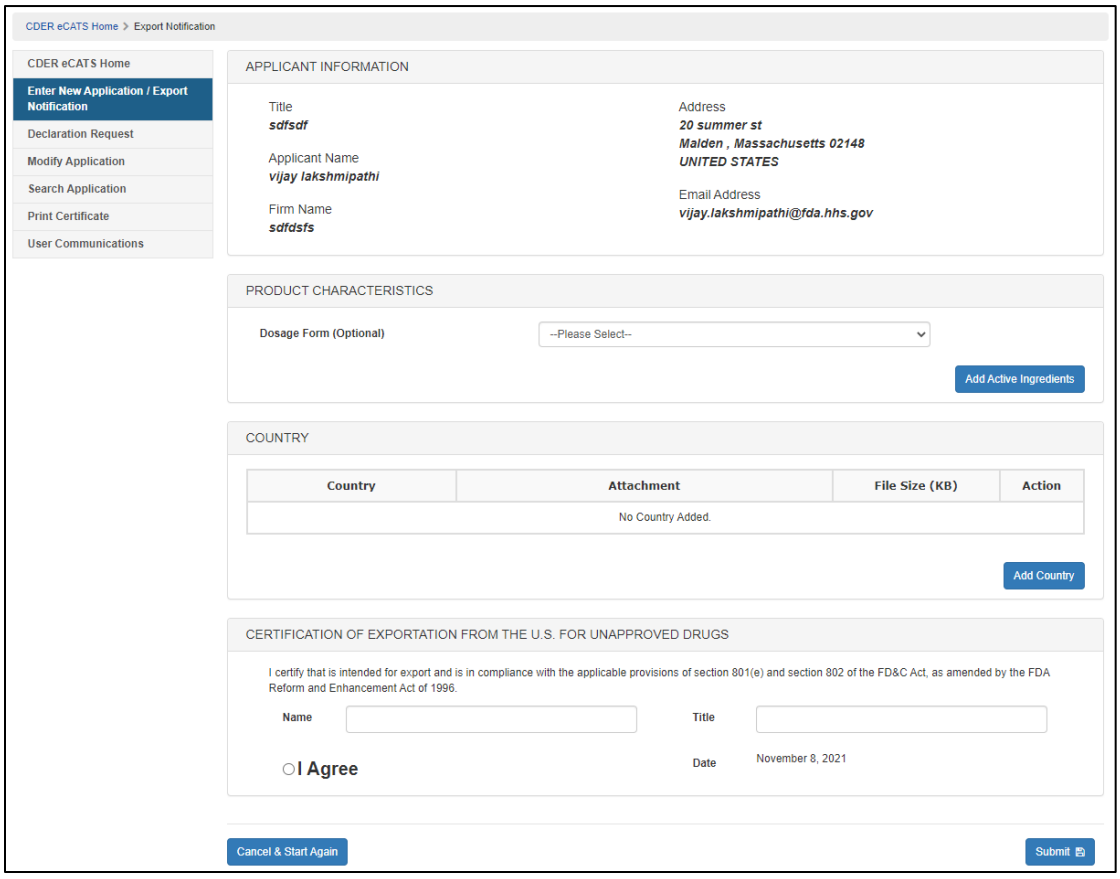
Select “Export Notification Letter”. All the export notification letters you have submitted will be displayed, as shown in Figure 91 (below).

Figure 91 - Account Export Notification Letters



Click the “Enter New Export Certificate Notification Letter” button to submit a new letter. The export notification letter will be displayed, as shown in Figure 92 (below).

Figure 92 - Create New Export Notification Letter



Applicant Information:

The applicant is the owner of the account from which the application is filed, and the point of contact requesting the export notification letter. The applicant is responsible for completing and signing the export notification letter form. The fields in this section 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.

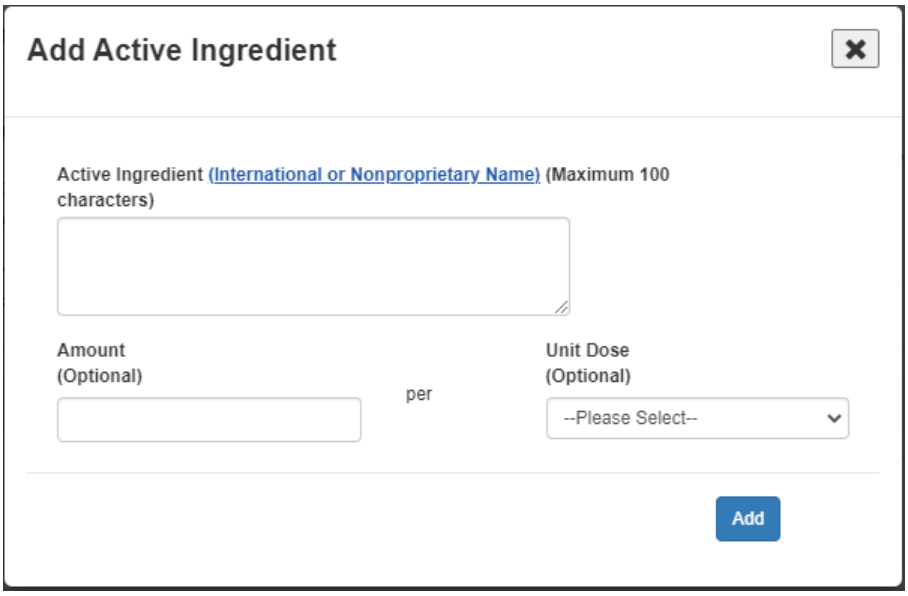
Product Characteristics:

Select the "Dosage Form", if applicable.

Select the "Add Active Ingredient" button to add an active ingredient; at least one must be added.

Enter the "Active Ingredient" and click the "Add" button, as shown in Figure 93 (below).

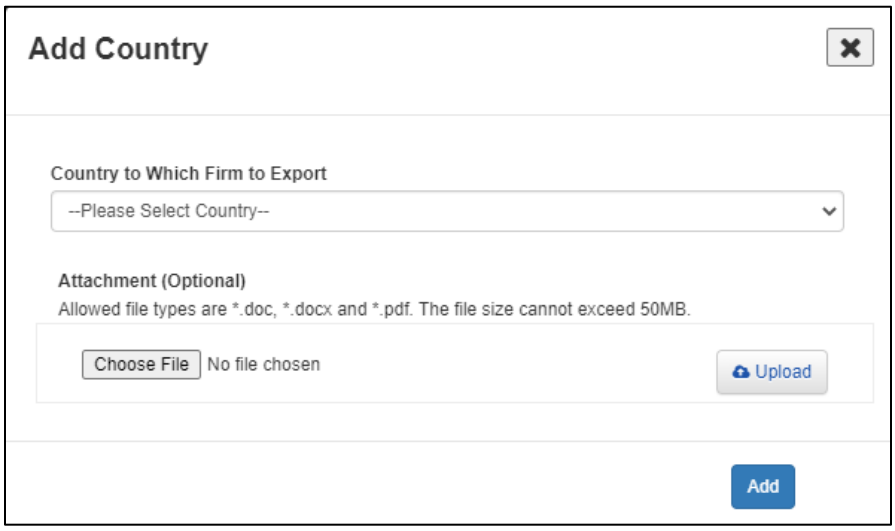
Figure 93 - Add Active Ingredient



Country:

Select the "Add Country" button to add country information, as shown in Figure 94 (below). Select a country, add attachment(s) (if applicable), and click the "Add" button.

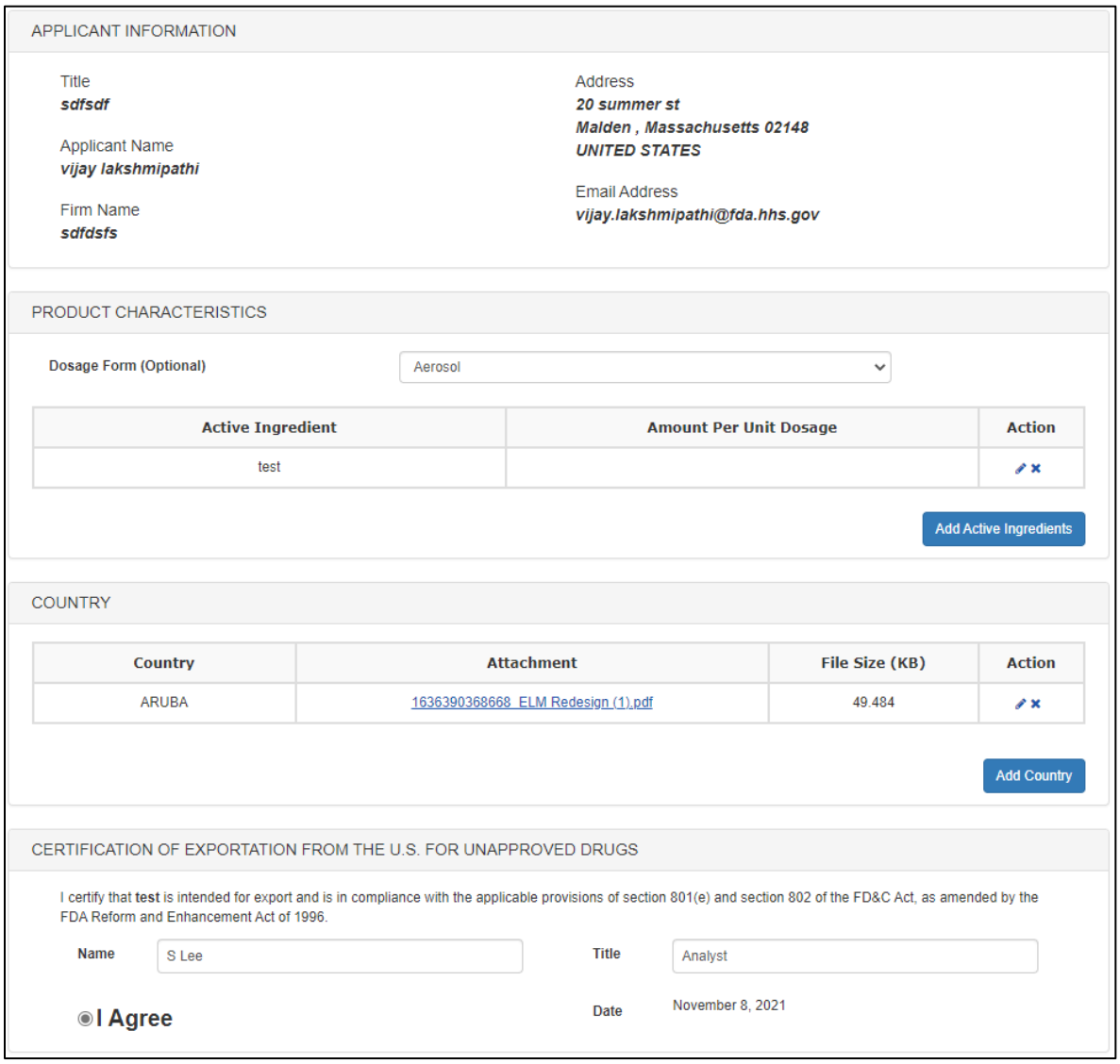
Figure 94 - Add Country



Submitting the Export Notification Letter:

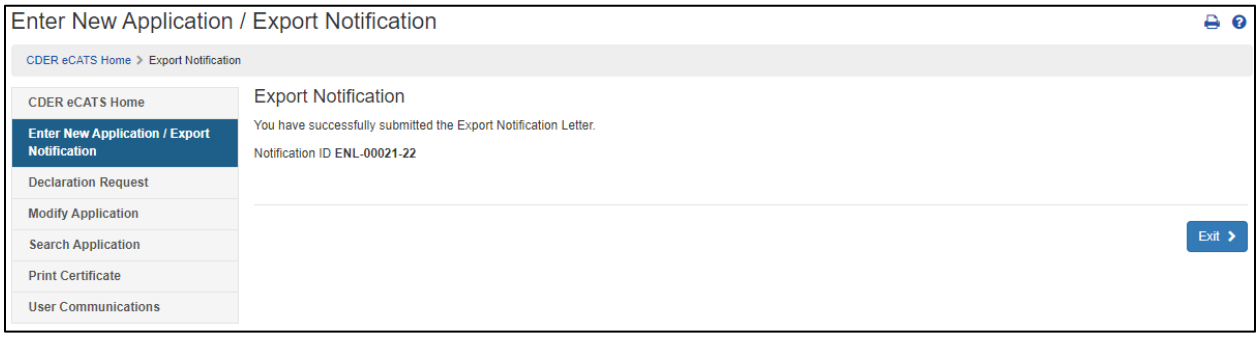
When your application is ready for submission, click on the “Submit” button located at the bottom of the page, as shown in Figure 95 (below).

Figure 95 - Review Export Notification Letter



The system will display a message stating that your export notification letter was successfully submitted, as shown in Figure 96 (below). The system will provide you with a “Notification ID” number. **Please save this number for future reference**.

Figure 96 - Submission Page

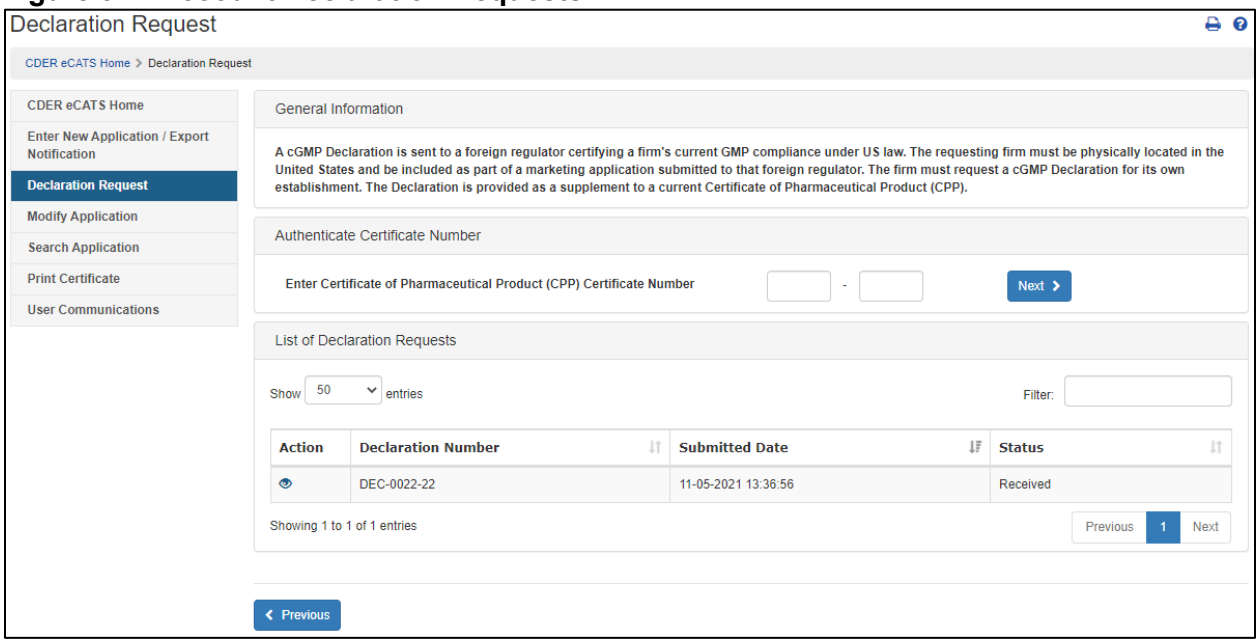


9 Declaration Request

Once you have selected “CDER Export Certification Application & Tracking System”, the system will navigate you to the CDER eCATS Main Menu page.

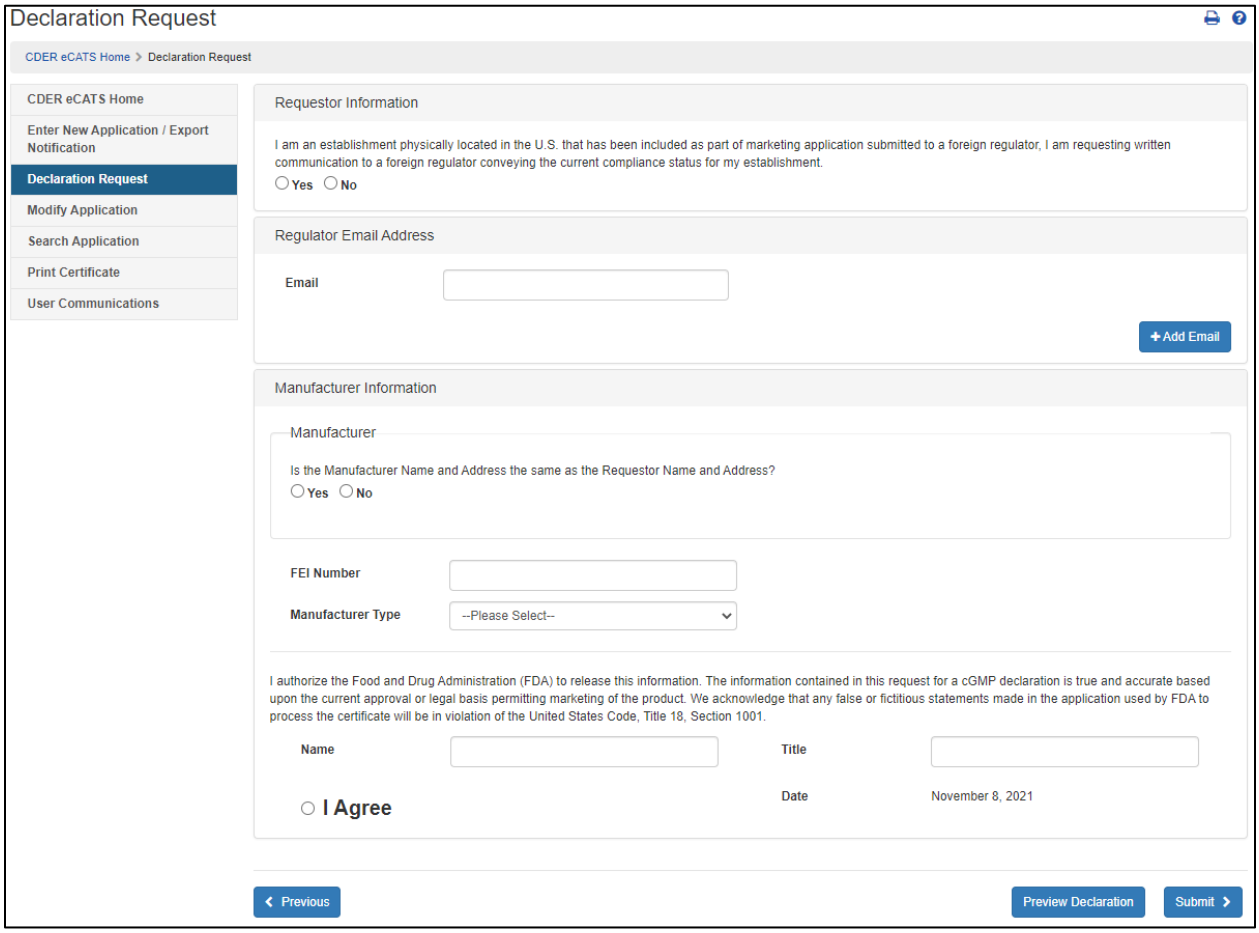
Select the “Declaration Request” option and all Declaration Requests you have submitted will be displayed, as shown in Figure 97. below.

Figure 97 - Account Declaration Requests



Enter a CPP Certification Number and click “Next”. The Declaration Request will be displayed, as shown in Figure 98 (below).

Figure 98 - Create New Declaration Request



Requestor Information:

Select “Yes” or “No”.

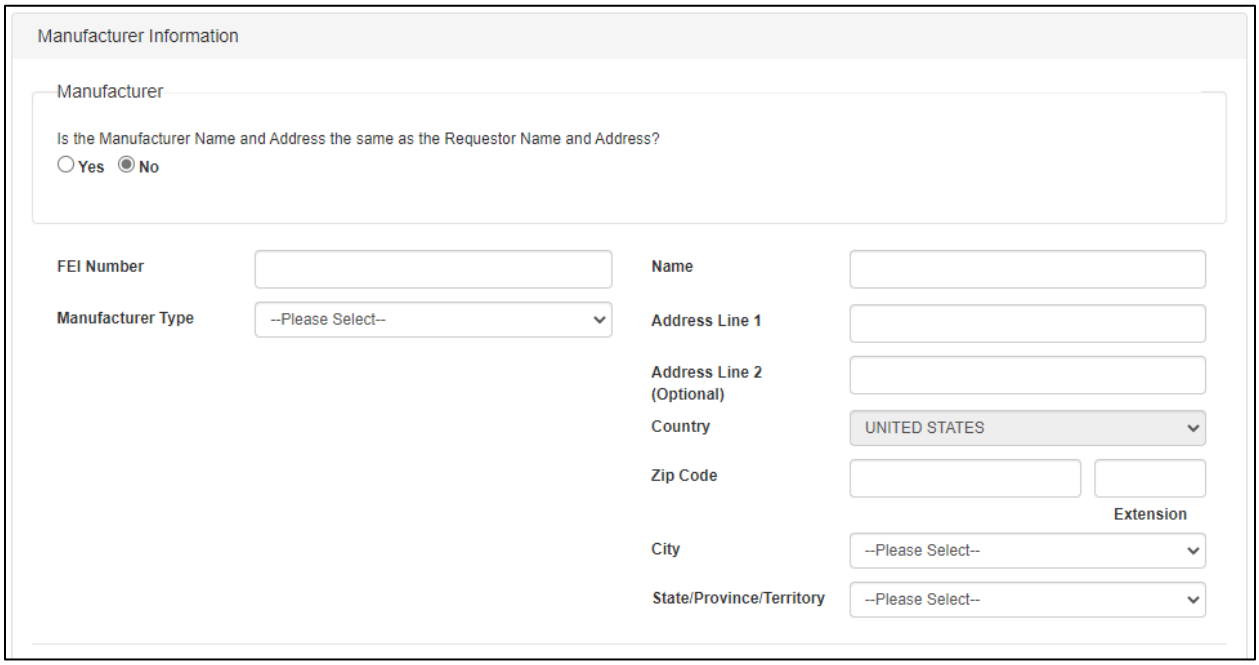
Regulator Email Address:

Enter an email address. Click the “Add Email” button to add additional email addresses.

Manufacturer Information:

Indicate if the Manufacturer Information is the same as the Requestor Information (from the application). If you answered “Yes” to the abovementioned prompt, the system will display the following to be filled out, as shown in Figure 99 (below).

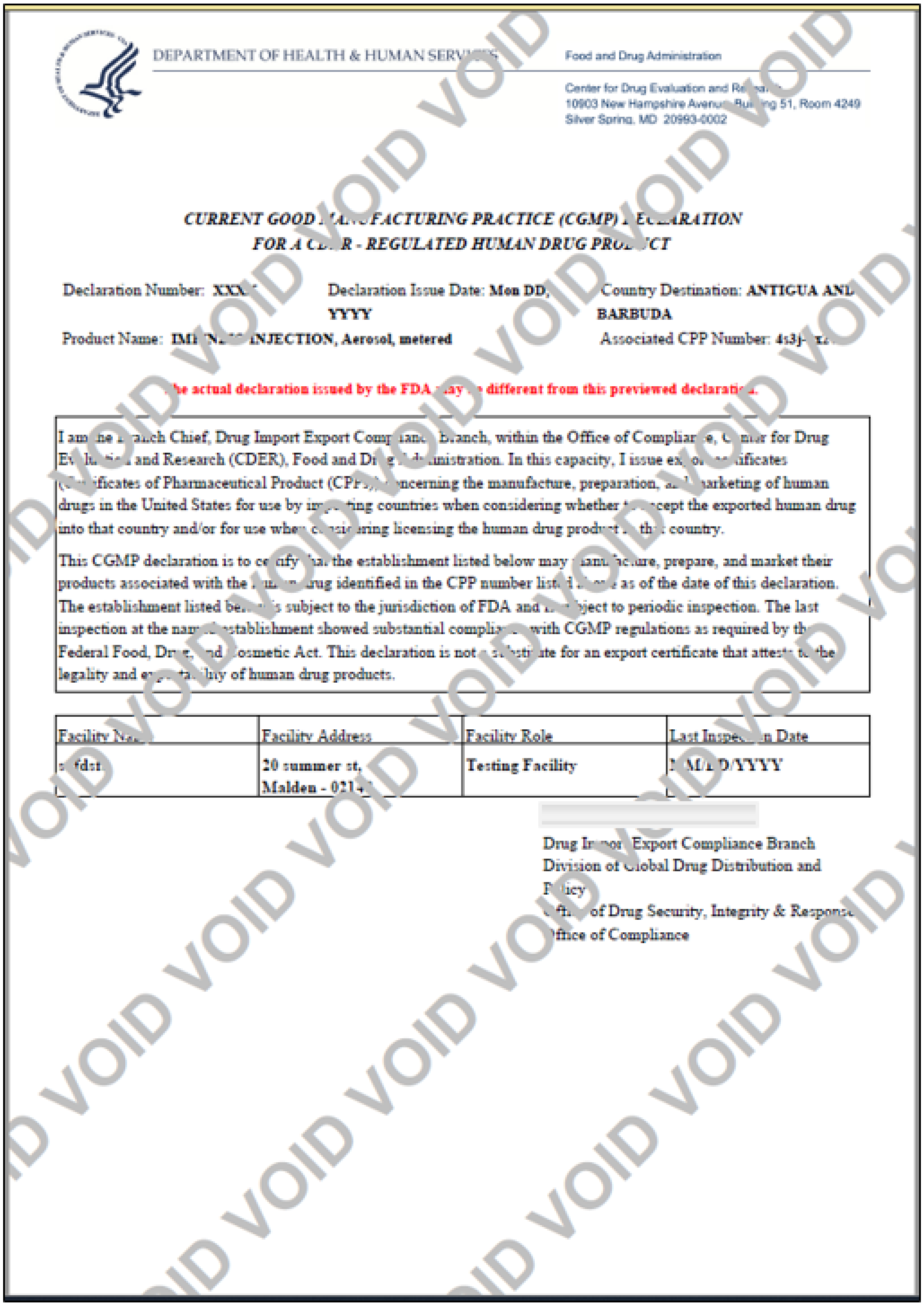
Figure 99 - Add Manufacturer Information



Previewing the Declaration Request:

To review the Declaration Request prior to submission, click the “Preview Certificate” button. This will save the request as a PDF; use your browser settings to view the PDF, as shown in Figure 100 (below).

Figure 100 - Declaration Request Preview



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

CURRENT GOOD MANUFACTURING PRACTICE (CGMP) DECLARATION FOR A CDER - REGULATED HUMAN DRUG PRODUCT

Declaration Number: **XXX[illegible]**
Declaration Issue Date: **Mon DD, YYYY**
Country Destination: **ANTIGUA AND BARBUDA**
Product Name: **IM[illegible] INJECTION, Aerosol, metered**
Associated CPP Number: **4s3j-[illegible]**

The actual declaration issued by the FDA may be different from this previewed declaration.

I am the Branch Chief, Drug Import Export Compliance Branch, within the Office of Compliance, Center for Drug Evaluation and Research (CDER), Food and Drug Administration. In this capacity, I issue export certificates (Certificates of Pharmaceutical Product (CPPs)) concerning the manufacture, preparation, and marketing of human drugs in the United States for use by importing countries when considering whether to accept the exported human drug into that country and/or for use when considering licensing the human drug product in that country.

This CGMP declaration is to certify that the establishment listed below may manufacture, prepare, and market their products associated with the human drug identified in the CPP number listed above as of the date of this declaration. The establishment listed below is subject to the jurisdiction of FDA and is subject to periodic inspection. The last inspection at the named establishment showed substantial compliance with CGMP regulations as required by the Federal Food, Drug, and Cosmetic Act. This declaration is not a substitute for an export certificate that attests to the legality and exportability of human drug products.

Facility Name	Facility Address	Facility Role	Last Inspection Date
[illegible]fdst	20 summer st, Malden - 021[illegible]	Testing Facility	MM/DD/YYYY

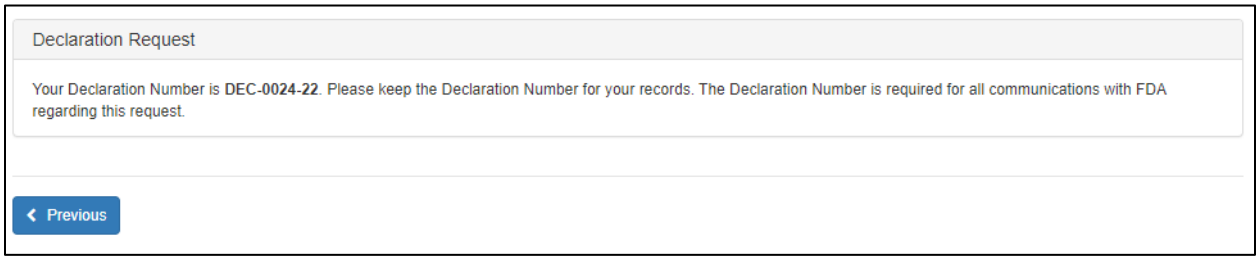
Drug Import Export Compliance Branch
Division of Global Drug Distribution and Policy
Office of Drug Security, Integrity & Response
Office of Compliance

Submitting the Declaration Request:

When your Declaration Request is ready for submission, click on the “Submit” button located at the bottom of the page.

The system will display a message confirming your declaration request was successfully submitted, as shown in Figure 101 (below). The system will provide you with a Declaration Number. **Please save this number for future reference**.

Figure 101 - Declaration Request Submission



10 Search

10.1 Search Applications

To search for applications, select “Search Application” from the CDER eCATS Main Menu page.

Select the “Application” option (as shown below in Figure 102 (below) 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.

Figure 102 - Search Application

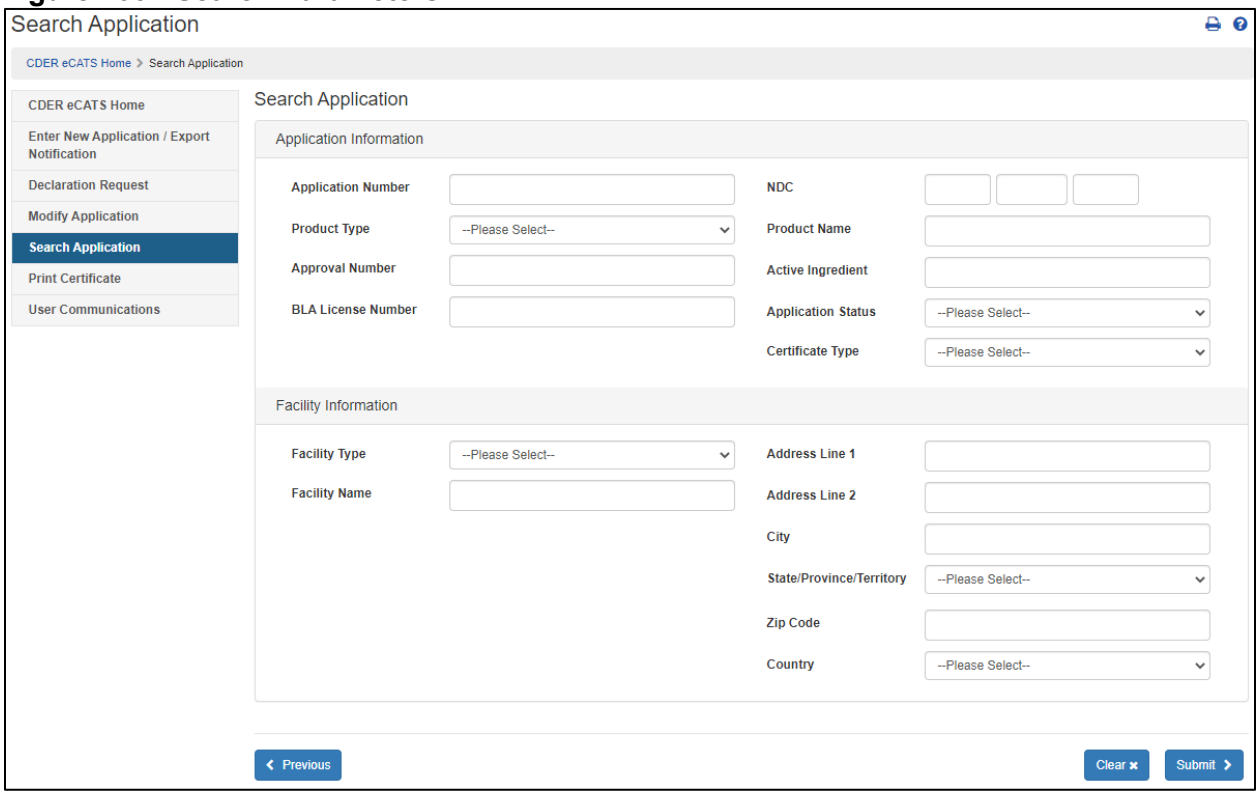
You can search using any or all of the following fields, as shown in Figure 103 (below):

You must enter at least one search criteria:

- Application Number
- Product Type (dropdown list)
- Approval Number
- BLA License Number
- NDC
- Product Name
- Active Ingredient
- 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)

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.

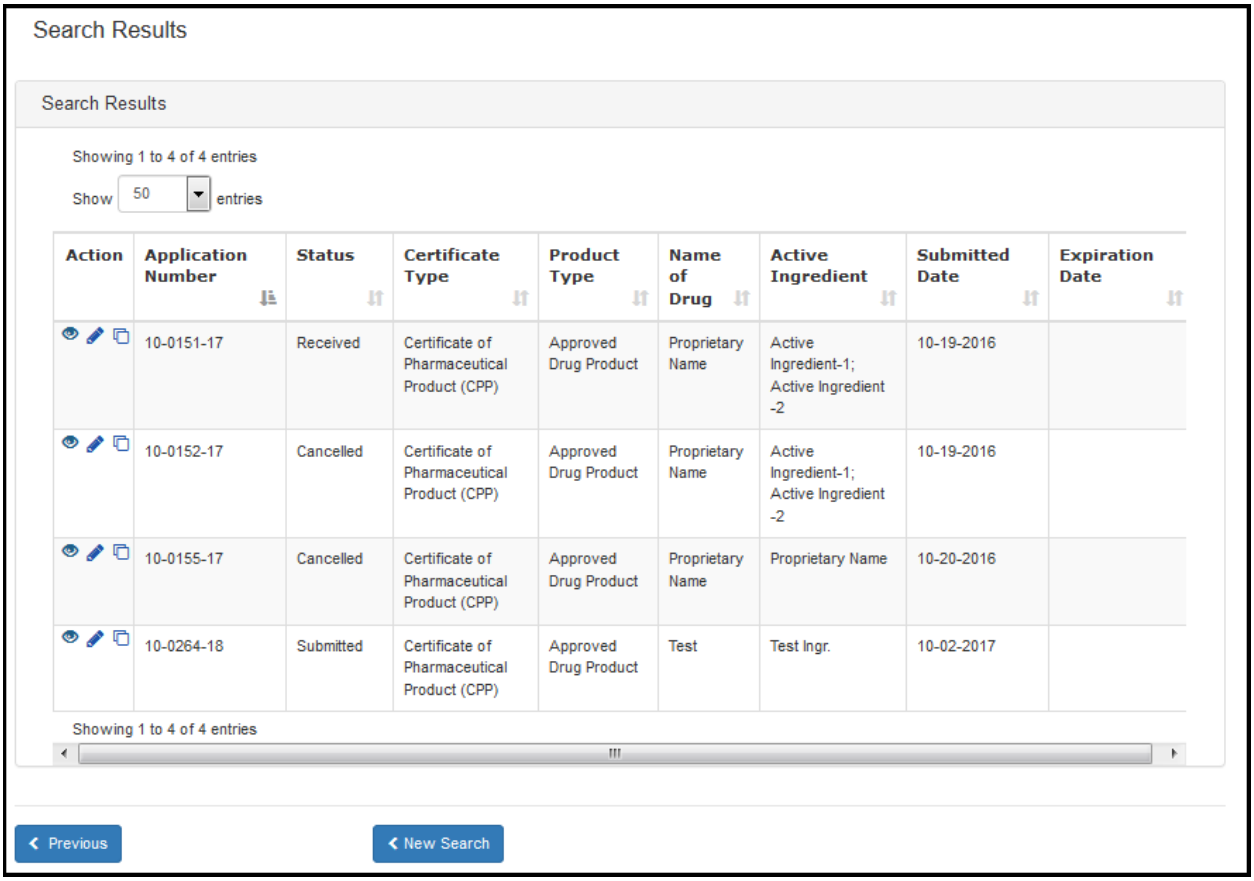
Figure 103 - Search Parameters



10.2 Search Results

The system will display the results which correspond to your search, as shown in Figure 104 (below).

Figure 104 - Search Results



The system will display the “Action”, “Application Number”, “Status”, “Certificate Type”, “Product Type”, “Name of Drug”, “Active Ingredient”, “Submitted Date”, and the “Expiration Date”. Use the up and down arrows in the column headings to sort the application list in ascending or descending order.

Features Available from Search Results:

The following features are available from the Search Results dashboard:

- View Application
- Modify Application
- Clone Application

View an Application:

To view an application, click on the “eye” icon from the Action column. Once the application is displayed, you can print a copy of the application.

Modify an Application:

To modify an application, select the “pencil” icon from the Action column.

NOTE: The application must be in a specific status in order to select the Modify option. Refer to 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 generate a copy of an existing submitted application. Next to the application number, select the “Double Book” option from the Action column. 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 any necessary edits prior to submitting the application.

10.3 Search Export Notification Letters

To search for export notification letters, select “Search Application” from the CDER eCATS Main Menu page.

Select the “Export Notification Letter” option (as shown below in Figure 105 (below) to search your letters by various criteria. Once you have found the letter, you can view, modify (if applicable), or delete it.

Figure 105 - Search Export Notification Letter

You can search using any or all of the following fields, as shown in Figure 106 (below):

You must enter at least one search criteria:

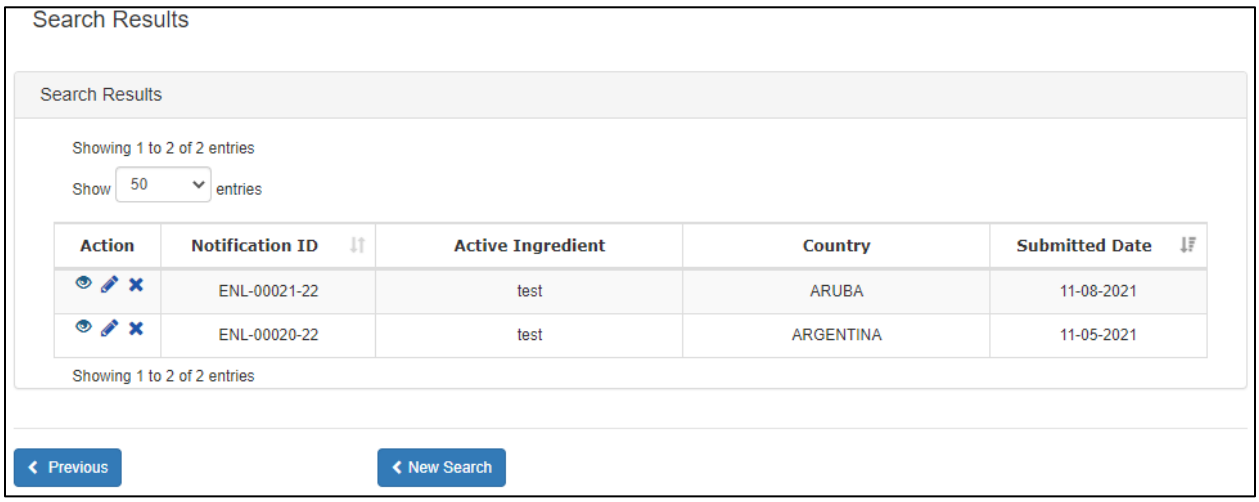
- Submission Date Range – Start Date and End Date
- Notification ID
- Country

Figure 106 - Search Parameters

Search Results:

The system will display the results which correspond to your search, as shown in Figure 107 (below).

Figure 107 - Search Results



The system will display the “Action”, “Notification ID”, “Active Ingredient”, “Country”, and “Submitted Date” columns. You can use the up and down arrows in the “Notification ID” and “Submitted Date” column headings to sort the letter list in ascending or descending order.

View an Export Notification Letter:

To view an Export Notification Letter, click on the “eye” icon from the Action column.

Modify an Export Notification Letter:

To modify an Export Notification Letter, select the “Pencil” icon from the Action column.

Cancel Export Notification Letter:

To delete an Export Notification Letter, select the “x” icon from the Action column. A confirmation message is displayed. Select “OK” to delete.

10.4 Search Declarations

To search for declarations, select “Search Application” from the CDER eCATS Main Menu page.

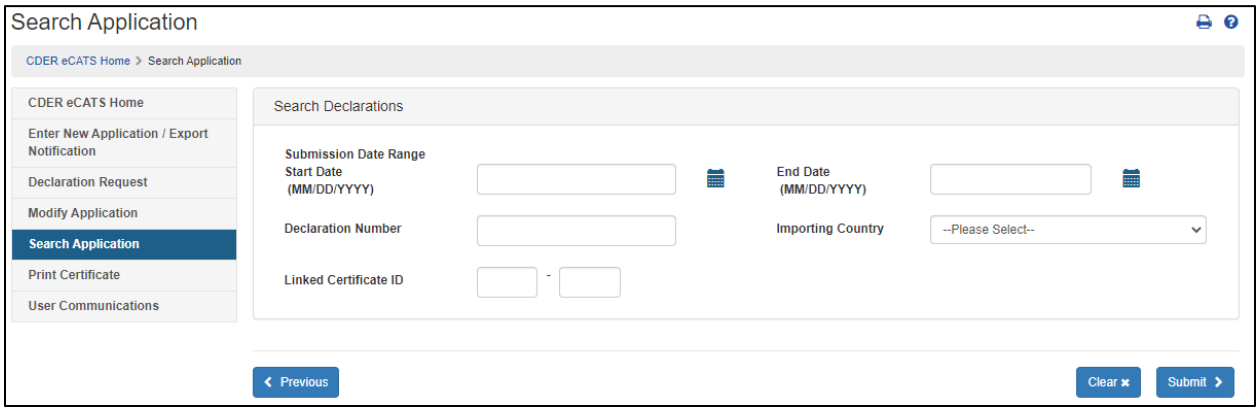
Select the “Declarations” option (as shown below in Figure 108) to search your declarations by various criteria. Once you have found the letter, you can view the declaration.

Figure 108 – Search Declarations

You can search using any or all of the following fields, as shown in Figure 109 below. You must enter at least one search criteria:

- Submission Date Range – Start Date and End Date
- Declaration Number
- Importing Country
- Linked Certificate ID

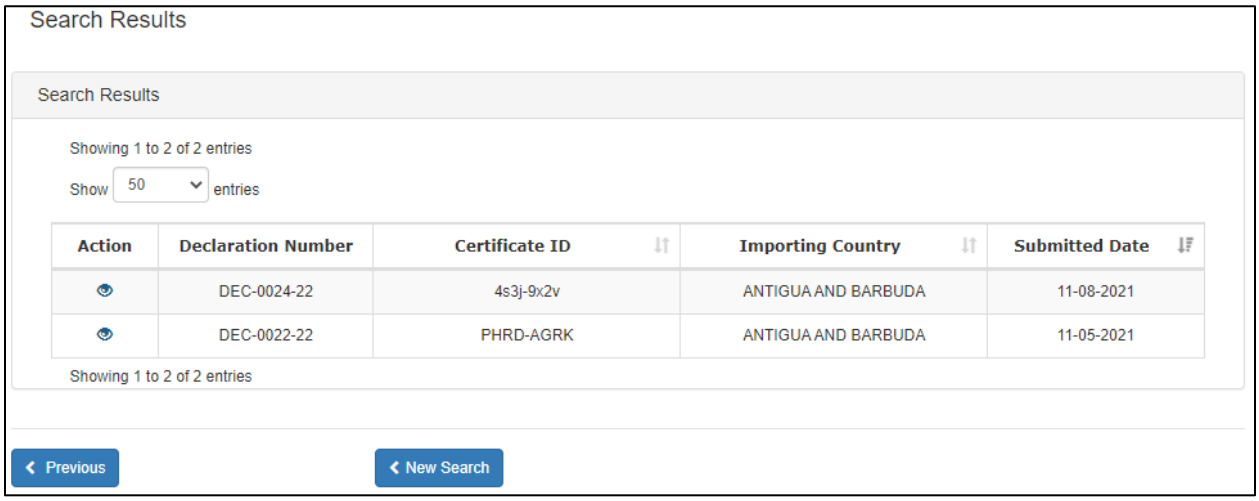
Figure 109 - Search Parameters



Search Results:

The system will display the results which correspond to your search, as shown in Figure 110 (below).

Figure 110 - Search Results



The system will display the “Action”, “Declaration Number”, “Certificate ID”, “Importing Country”, and “Submitted Date”. You can use the up and down arrows in the “Certificate ID” and “Submitted Date” column headings to sort the declaration list in ascending or descending order.

View a Declaration Request:

To view a Declaration Request, click on the “eye” icon from the Action column.

11 User Communication

During the application process, applications may require additional clarification between the roles of FDA reviewer and requester. The “User Communications” workflow consolidates the correspondence between requestor and FDA reviewers in the CDER eCATS application.

To send and respond to the communication related to your application, export notification letter or declaration request, click on the “User Communications” from the CDER eCATS Main Menu page.

For communications regarding your application, select the “Application” option and the system will provide an option to “Enter the Application Number”, as shown in Figure 111 (below). Click “Next “.

Figure 111 - Enter Application Number

For communications regarding your export notification letter, select the “Export Notification Letter” option and the system will provide an option to enter the “Export Certificate Notification Letter ID”, as shown in Figure 112.

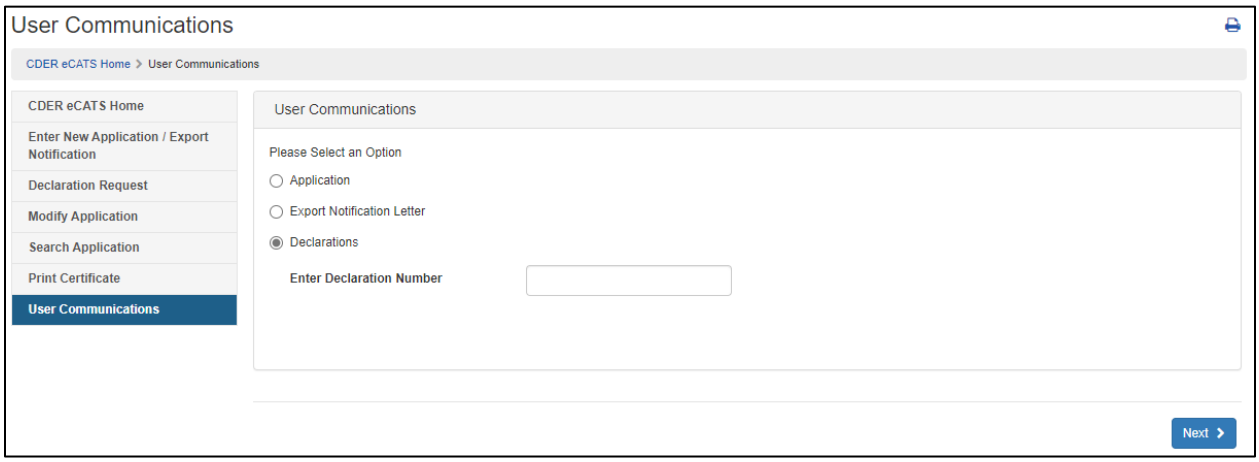
Click “Next “.

Figure 112 - Enter Notification ID

For communications regarding your declaration request, select the “Declarations” option and the system will provide an option to “Enter the Declaration Number”, as shown in Figure 113.

Click “Next “.

Figure 113 - Enter Declaration Number



The system will display the option to enter the user comments. If there are previous inquires, those inquires will be displayed in the data table, as shown in Figure 114 (below). Users can submit the comments via this workflow for applications in all statuses – except “Submitted”, “Canceled”, “Pending virus scan”, “Processing and Draft” – as well as any export notification letters and declaration requests.

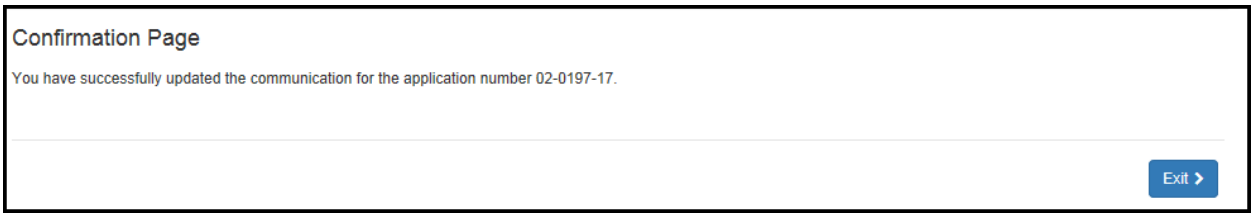
The data table will display the following fields:

- Comments
- Entered By
- Created Date

Figure 114 - Enter User Comments

Enter any user comments and click “Submit”. The system will display the confirmation message, as shown in Figure 115 (below)**.**

Figure 115 - User Communications Confirmation Message



When an FDA user submits communication on any application via “User Communications” workflow, the system will send the notification to the Requestor email address associated with the application.

When an industry user submits communication on any application via “User Communications” workflow, the system will send the email notification to the FDA CDER Exports Compliance Branch.

NOTE: For the inquires requested on your application, export notification letter, or declaration request(s), please do not reply to email notifications. Enter your response via the “User Communications” workflow.

12 Obtaining and Responding to Notifications

The system provides automated notifications to the Requestor email address whenever:

- You save an application to draft prior to submittal
- You submit your application
- Your submitted application is under review by the FDA
- You cancel your application
- You modify and re-submit your application based on a Return for Action request from FDA
- Your application is approved by FDA
- Your application is cancelled by FDA
- Your application is cancelled because it has been in “Incomplete” status for more than 30 days
- Your application is cancelled because it has been in “Return for Action” status for more than three business days

13 Validating the Authenticity of CDER-Issued Export Certificate

Foreign Government Officials (FGO) can validate the authenticity of CDER-issued certificates by using FDA’s Online Portal for Verification of Export Certificates for Drugs.

There are two ways to access this online portal:

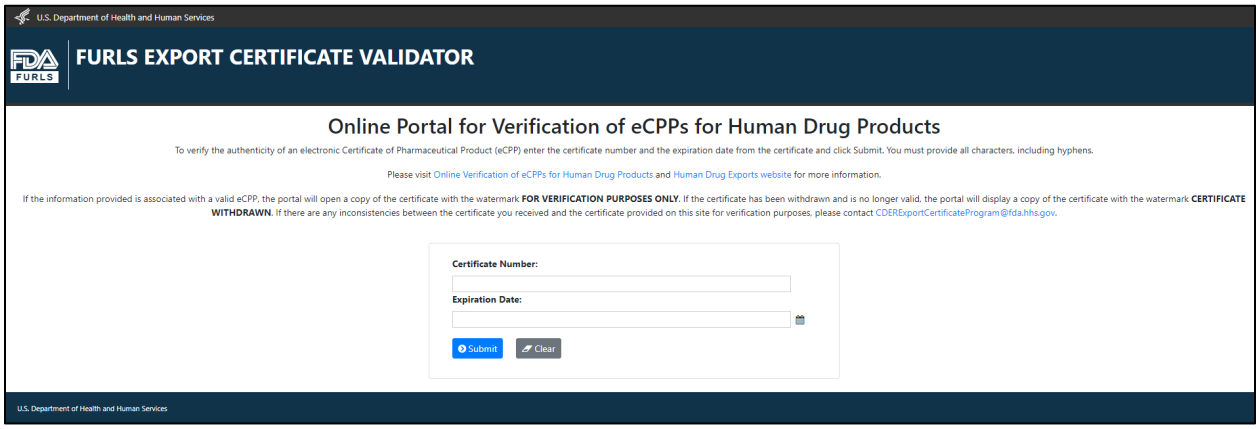
- Visit FDA’s Online Portal for Verification of Export Certificates for Drugs. This link is also included in the footer of each electronic certificate issued.

- Scan the QR code included at the bottom of each electronic certificate issued

Online Portal

The FGO must have the Certificate Number and Expiration Date of the certificate to verify it. Enter the information, and click the “Submit” button, as shown in Figure 116 (below).

Figure 116 - FDA Online Portal for Verification of Export Certificates for Drugs



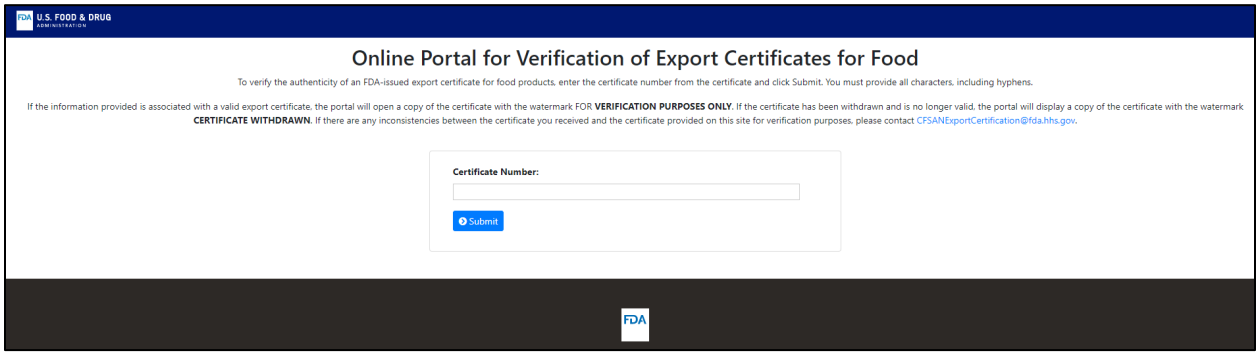
QR Code

Use a QR Reader to scan the QR Code displayed on FDA's issued electronic certificates as shown in Figure 117.

Figure 117 – QR Code on eCPPs

The FGO will enter the Certificate Number and click the "Submit" button, as shown in Figure 118.

Figure 118 – Certificate Verification using QR Code



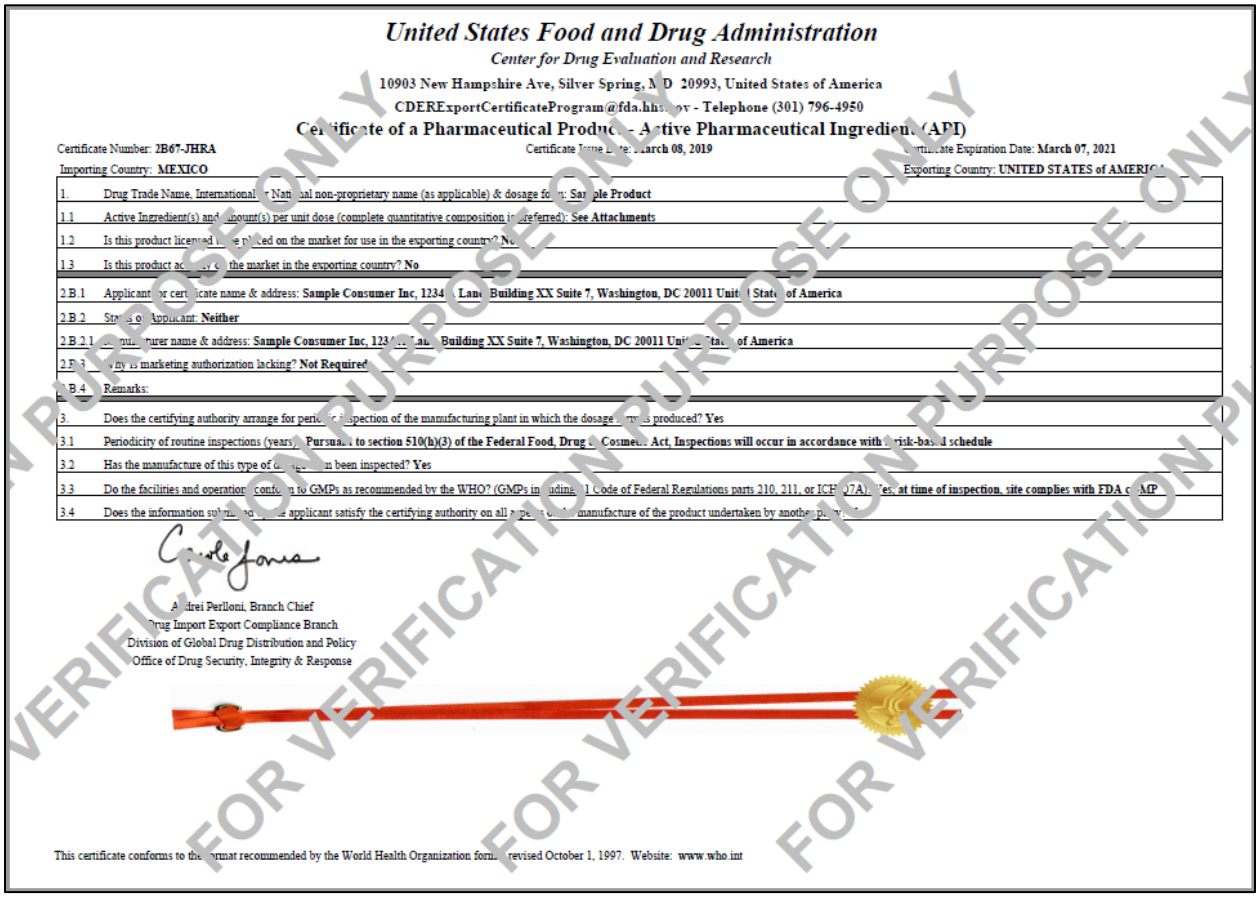
If a certificate is not found, (i.e., the certificate expired or is no longer valid) an error

message will be displayed.

If the provided information is correct, a PDF will be generated. The certificate will display a “For Verification Purposes Only” watermark. The certificate will display a “Withdrawn” watermark if the certificate has been withdrawn.

Use your browser settings to view the PDF, as shown in Figure 119 (below). Using the data displayed, you can verify the information based on the certificate a U.S. Exporter has provided.

Figure 119 - Authenticate 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 - Active Pharmaceutical Ingredient (API)

Certificate Number: **2B67-JHRA** Certificate Issue Date: **March 08, 2019** Certificate Expiration Date: **March 07, 2021**

Importing Country: **MEXICO** Exporting Country: **UNITED STATES of AMERICA**

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **Sample Product**
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition if preferred): **See Attachments**
1.2	Is this product licensed and placed on the market for use in the exporting country? **No**
1.3	Is this product actually on the market in the exporting country? **No**
2.B.1	Applicant for certificate name & address: **Sample Consumer Inc, 1234 Lane Building XX Suite 7, Washington, DC 20011 United States of America**
2.B.2	Status of Applicant: **Neither**
2.B.2.1	Manufacturer name & address: **Sample Consumer Inc, 1234 Lane Building XX Suite 7, Washington, DC 20011 United States of America**
2.B.3	Why is marketing authorization lacking? **Not Required**
2.B.4	Remarks:
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form 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 a 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 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?

Andrei Perlloni, Branch Chief
Drug Import Export Compliance Branch
Division of Global Drug Distribution and Policy
Office of Drug Security, Integrity & Response

This certificate conforms to the format recommended by the World Health Organization formulated revised October 1, 1997. Website: www.who.int