U.S. Food and Drug Administration

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

June 2024

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1 Overview of CDER eCATS

The U.S. Food and Drug Administration (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)

FIS is an electronic portal that facilitates and provides general entry to a series of systems which enable electronic submissions to FDA. Examples of submissions that can be entered via FIS are registration, listing, and export certification applications. 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 access.fda.gov website for a list of approved browsers and browser versions, found in the lower right-hand corner of the page.

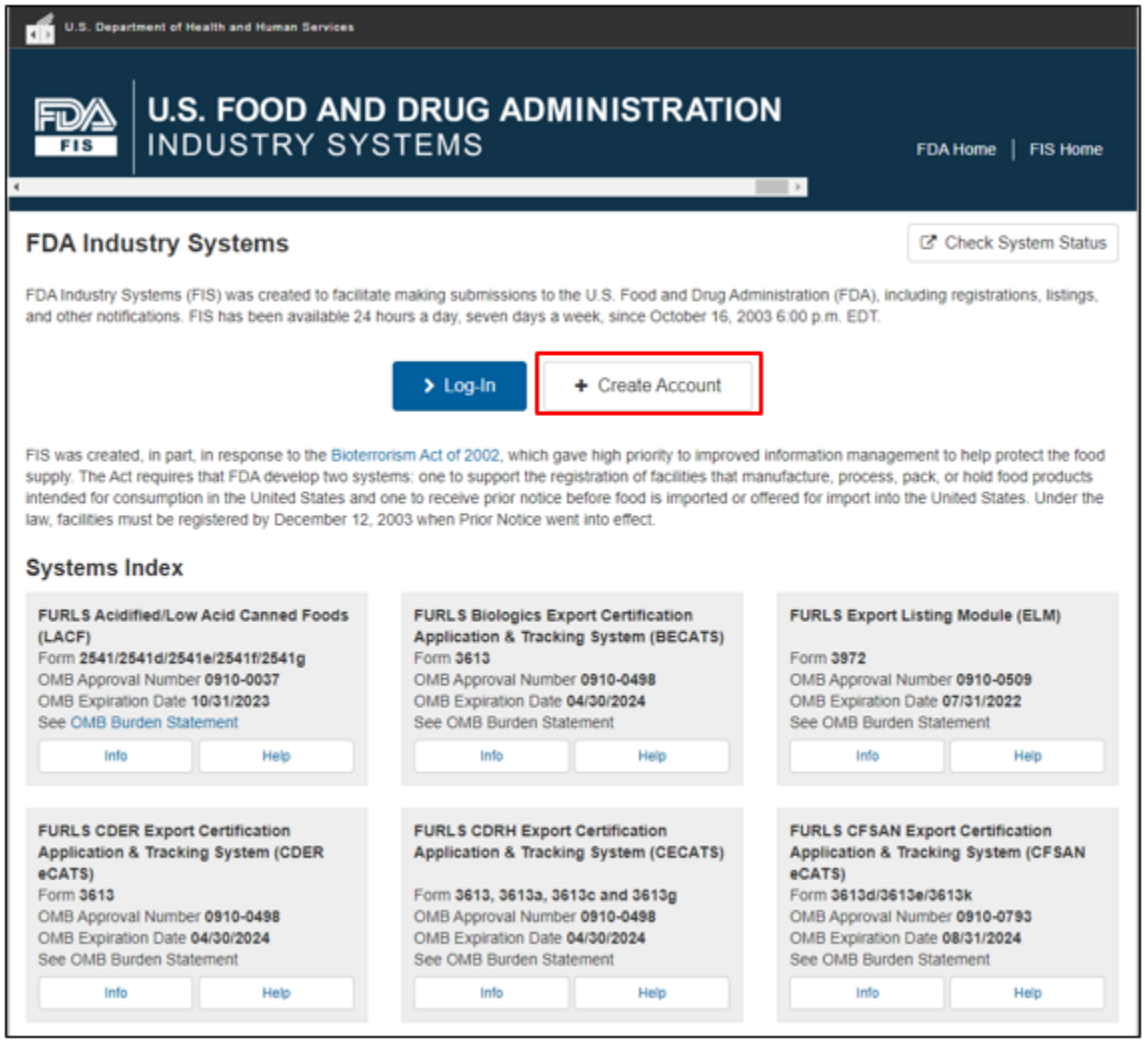
2 Creating a New Account and Accessing CDER eCATS via FIS

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:

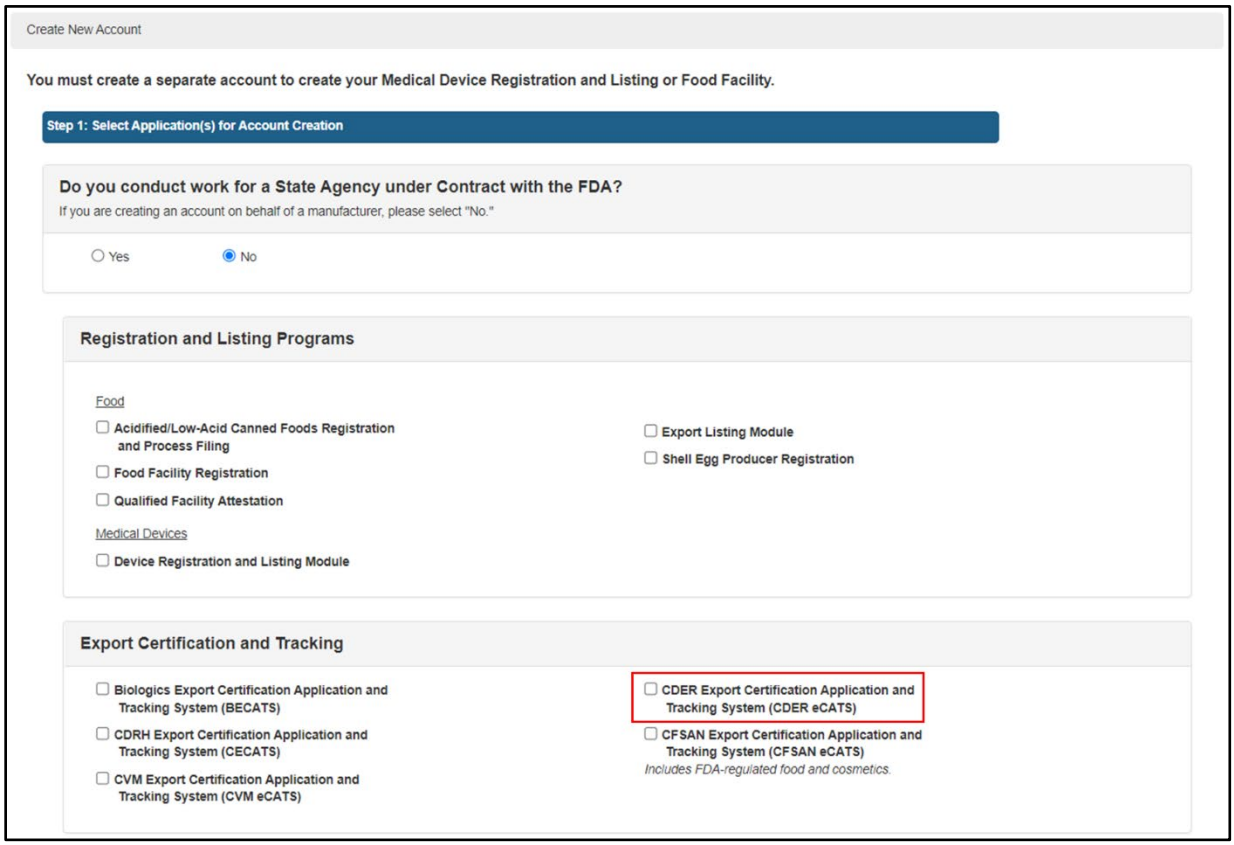
To access the FIS electronic portal, go to the access.fda.gov website. Click the "Create New Account" button, as shown in Figure 1 (below).

Figure 1 - Create New Account in FDA FIS Electronic Portal



1. Select “CDER Export Certification Application and Tracking System”.
2. Select a response to the question “Do you conduct work for a State Agency under Contract with the FDA?”
3. 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.

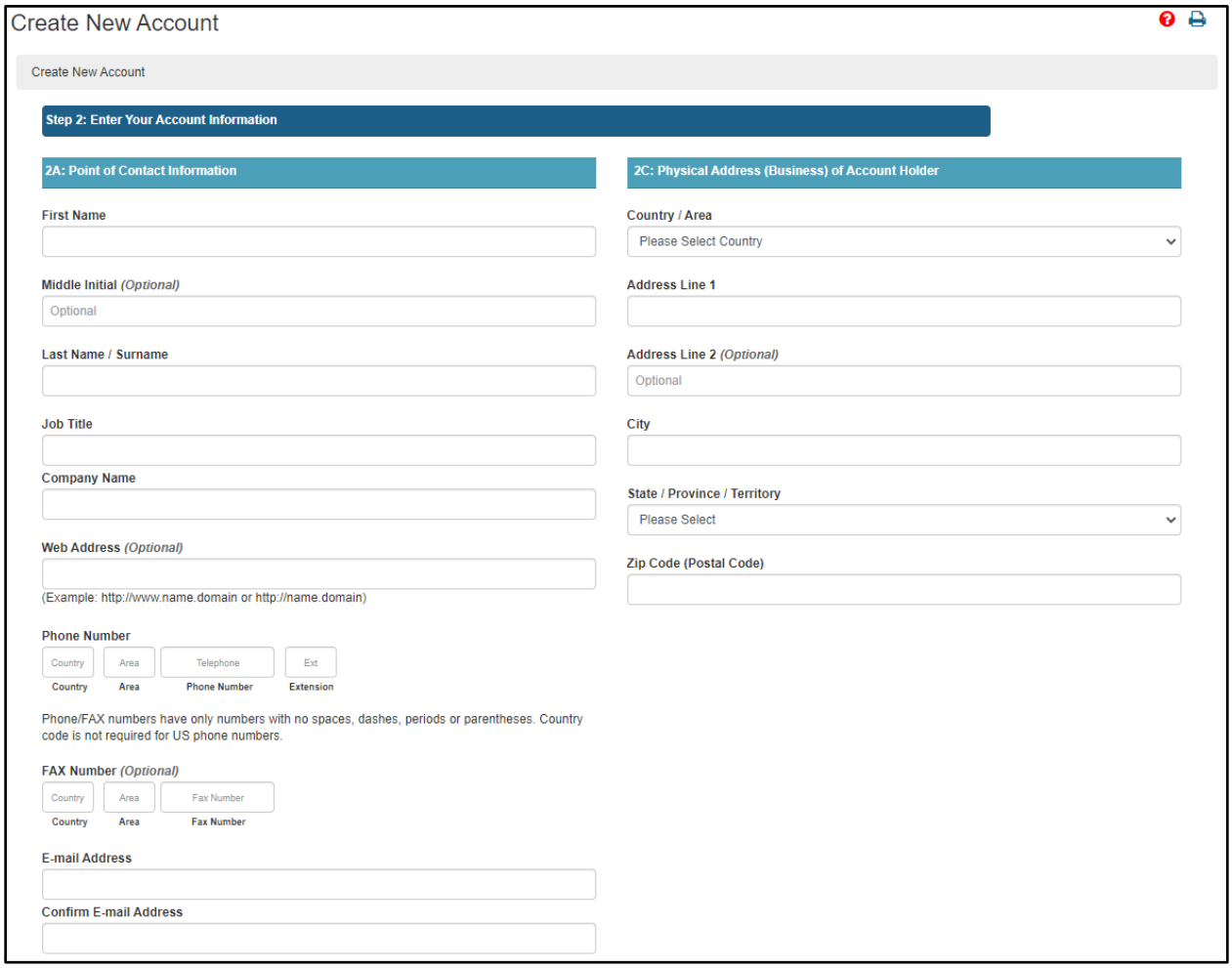
Figure 2 - CDER eCATS Checkbox in FIS Electronic Portal



4. Complete the Contact Information: Enter the contact information, including the point of contact's name, address, phone number, and email address – as shown in Figure 3 (below).

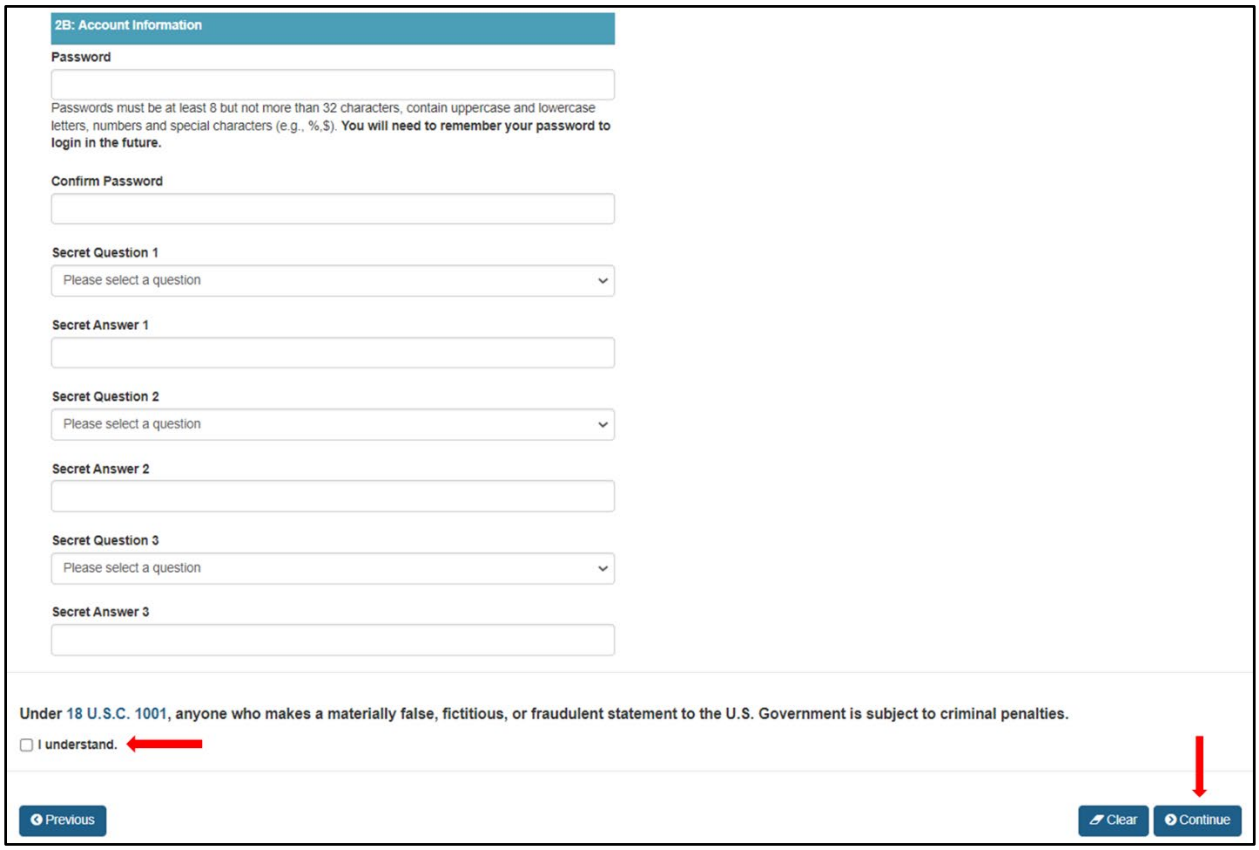
Note: FURLS uses the email address for all communication purposes including notifications about your export certification application.

Figure 3 - Contact Information in FIS Electronic Portal



5. Enter the Security Information.
6. 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 - Contact Information in FIS Electronic Portal



7. After you click the “Continue” button, the system will ask you to review your contact information.
8. Complete the submission by clicking 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.

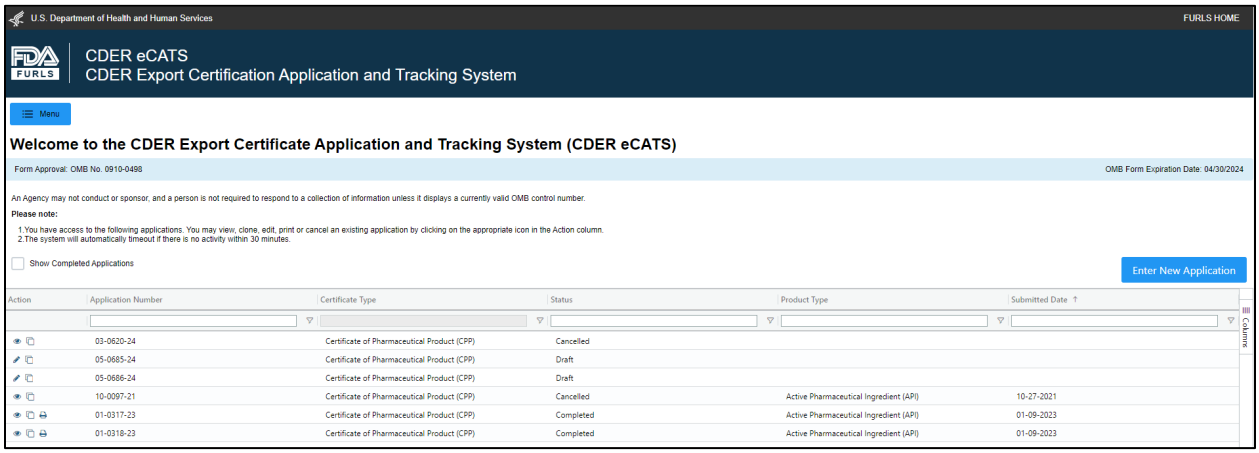
3 Accessing CDER eCATS

1. 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

2. Once you have selected “CDER Export Certification Application & Tracking System”, the system will direct you to the CDER eCATS Home dashboard, as shown in Figure 6 (below).

Figure 6 - CDER eCATS Home Dashboard



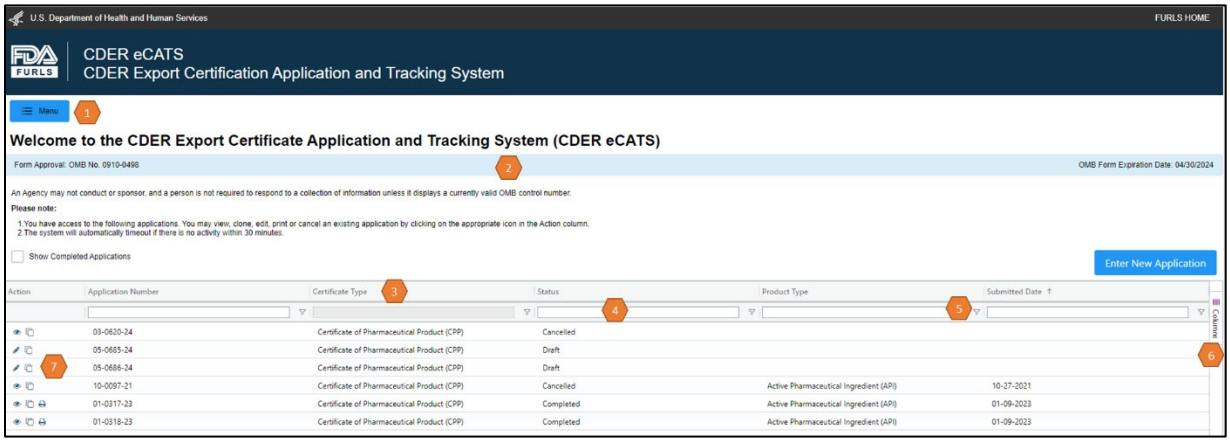
A Get Help (“question mark”) icon (located at the top right) will provide page-specific help. For an overview of all the help files available, please refer to the FIS Index Help page.

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”.

3.1 Home Dashboard

After you click on the **CDER Export Certification and Tracking System** link, the Home Dashboard will display, as illustrated in Figure 7 (below).

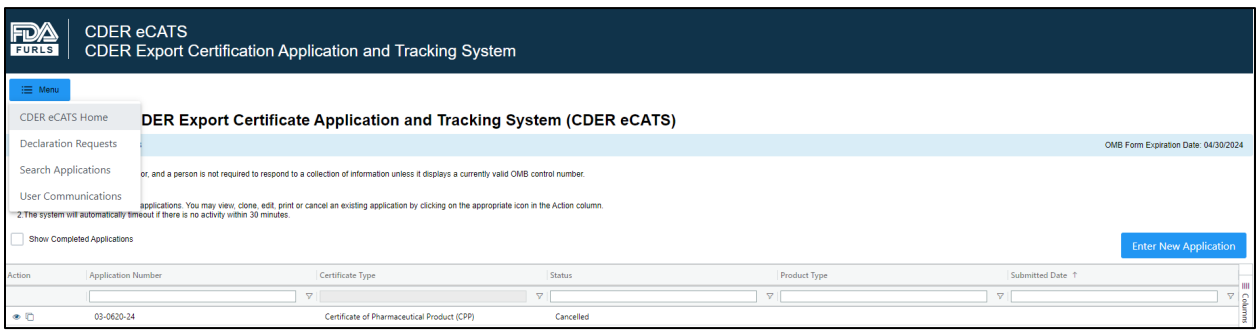
Figure 7 - CDER eCATS Home Dashboard Features



Below is a summary for each of the numbers indicated on the above figure. Each of the functions is described in later sections of the user guide.

1. **Menu** – Initially, CDER eCATS will display the menu in a collapsed format. Click the Menu hamburger icon again to collapse the menu. When you click on the menu's hamburger icon (Figure 8), the menu will expand and display the following options:
    a. CDER eCATS Home – Returns users to the Home dashboard.
    b. Declaration Requests – See Declaration Requests for details.
    c. Search Applications – See Search for details.
    d. User Communications – See User Communications for details.

Figure 8 – Main Menu Hamburger



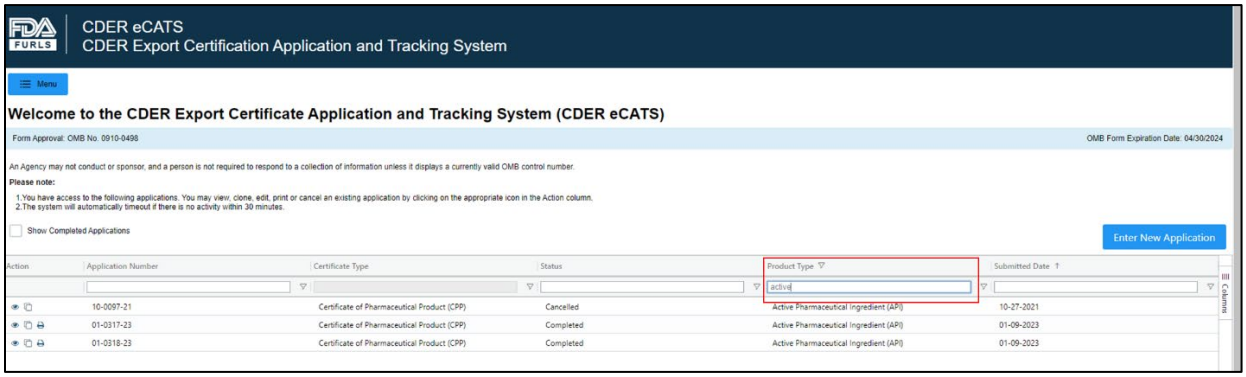
2. **Home Dashboard** – Once you have logged into CDER eCATS, this dashboard is the landing page. The system will display all of the applications created by the logged in user. To filter the dashboard to only display Completed Applications, select the “Show Completed Applications” checkbox. Use each of the column headings on the dashboard to filter or locate applications to act on.

   Note: Applications that are saved, but not submitted, will be in “Draft” status until the application is submitted. After 30 days, applications still in “Draft” status will be changed to “Cancelled” status.

3. **Column Heading** – For each column heading, click on the heading to sort the list in ascending or descending order.

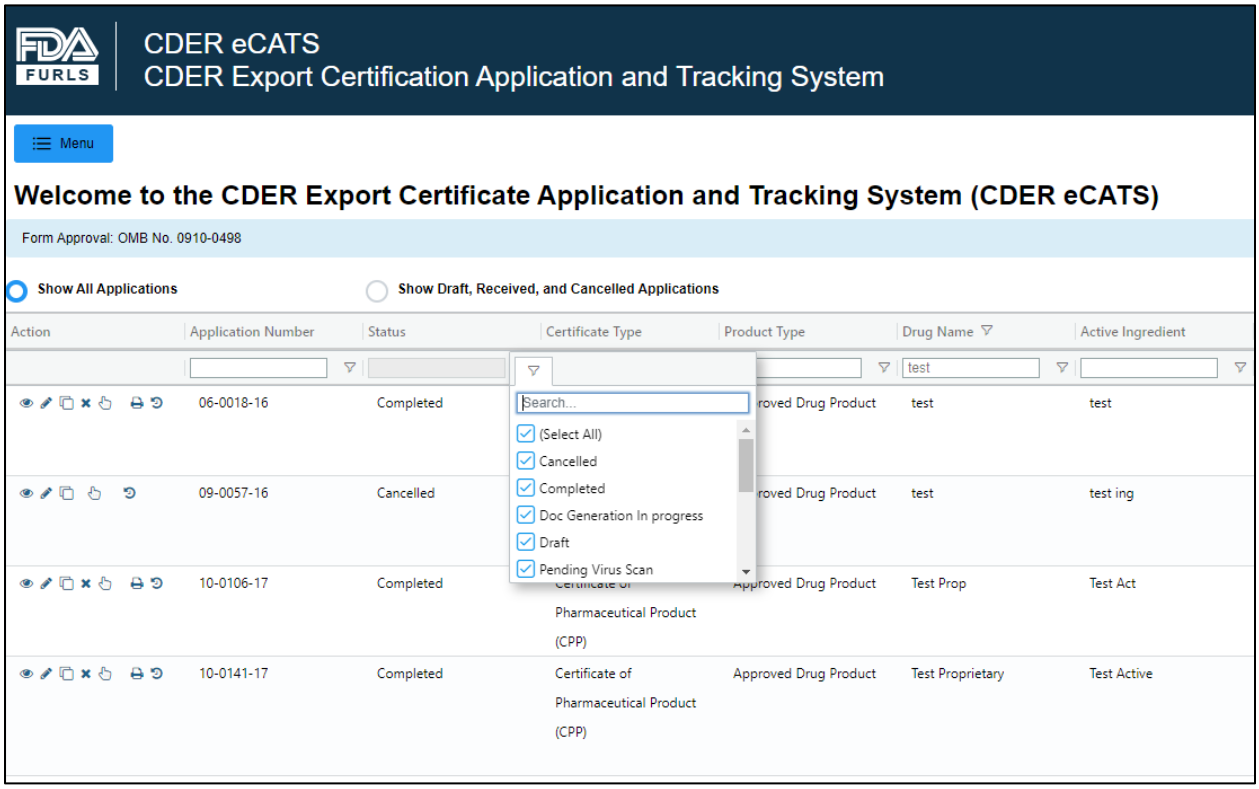
4. **Using the Basic Dashboard Filter** – For each of the column headings, enter partial text to filter the list according to the text values. See Figure 9 (below) for an example; notice the text on the “Product Type” column heading.

Figure 9 – Using the Dashboard Filter - Basic



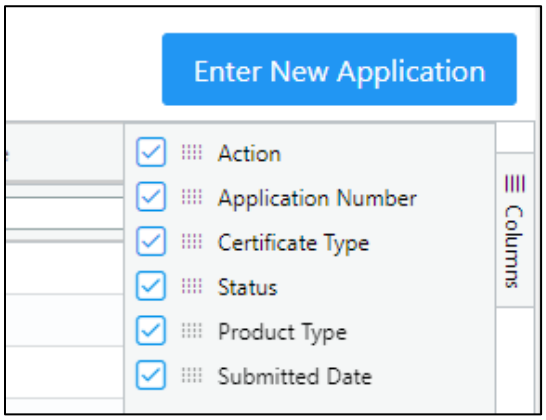
5. **Using the Advanced Dashboard Filter** – The “Filter” icon can be used to perform more advance filtering, as shown in Figure 10 (below):

Figure 10 – Using the Dashboard Filter - Advanced



6. **Enabling and Disabling of Dashboard's Column** – By default, CDER eCATS displays all the columns available on the Dashboard. To remove a particular column, customize the display by activating the **Columns** hamburger icon located to the right after the last column. When the hamburger icon is clicked, CDER eCATS displays the list of columns. Select or deselect the column(s) to display, as shown in Figure 11 (below).

Figure 11 – Dashboard Columns Hamburger



7. **Dashboard Action Icons** – For each of the application entries, CDER eCATS displays the available action(s) respective to each application. Figure 12 shows all of the available icons.

   Each of the icons' actions are described (below):

Figure 12 – Action Icons

a. **View ("eye") icon** – The View icon is available for all applications except those in "Draft" status. View details of the application in read-only mode. If the application was cloned from an existing application, CDER eCATS also displays the original application number.

b. **Modify ("pencil") icon** – The Modify icon is available for all applications except those in "Cancelled" or "Completed" status. Review each section of the application and update its details. Select this icon to continue working on an application that has been saved as "Draft".

c. **Clone ("double book") icon** – The Clone icon is available for all applications. Create a new application with the same information as the original application.

d. **Cancel Application ("x") icon** – The Cancel icon is only available for applications in "Submitted", "Ready to Review" or "Return for Action" status. The cancel application icon allows you to cancel and change the application status to "Canceled". Detailed information can be found in the Cancel an Application section.

e. **Print ("printer") icon** – The Print icon is only available for all applications in "Completed" status. A Print Certificate/Attachments window is displayed. Detailed information can be found in the View and Print Electronic Certificate section.

3.2 Navigation

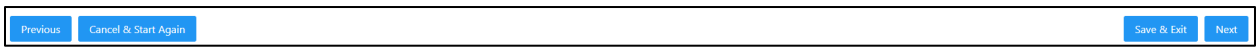
At the top of every page of the “Enter New Application” section, a status bar will track your progress through each step of the online application process, as shown in Figure 13 (below).

Figure 13 - Navigation Bar

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.

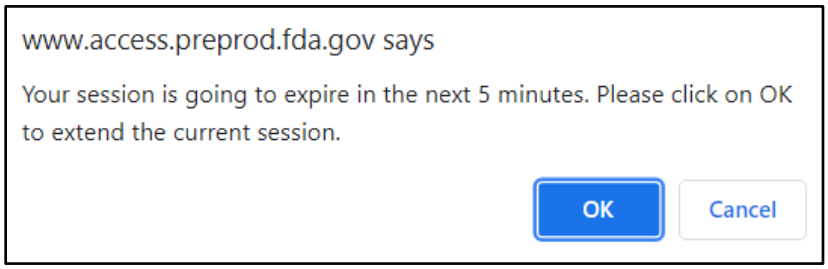
Figure 14 - General Navigation Buttons



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

To begin the application process:

1. Select the “Enter New Application” button from the Home dashboard. The system will display a screen with options to create a new application or an export notification letter, as shown in Figure 16 (below).

Figure 16 - Select New Application or Export Notification Letter

2. Select “Application” and click “Next”. The General/Contact Information page is displayed.

4.1 General/Contact Information

1. Please read and review the “General Information” and guidelines regarding exporting drug products, as shown in Figure 17 and Figure 18 (below). If you have any questions, please refer to the links provided.

Figure 17 - General/Contact Information

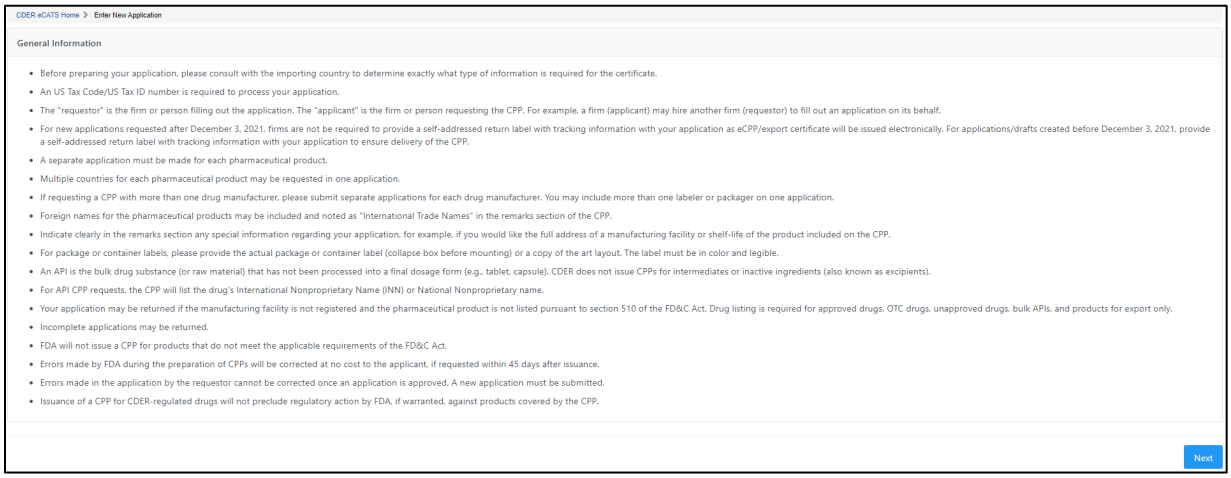
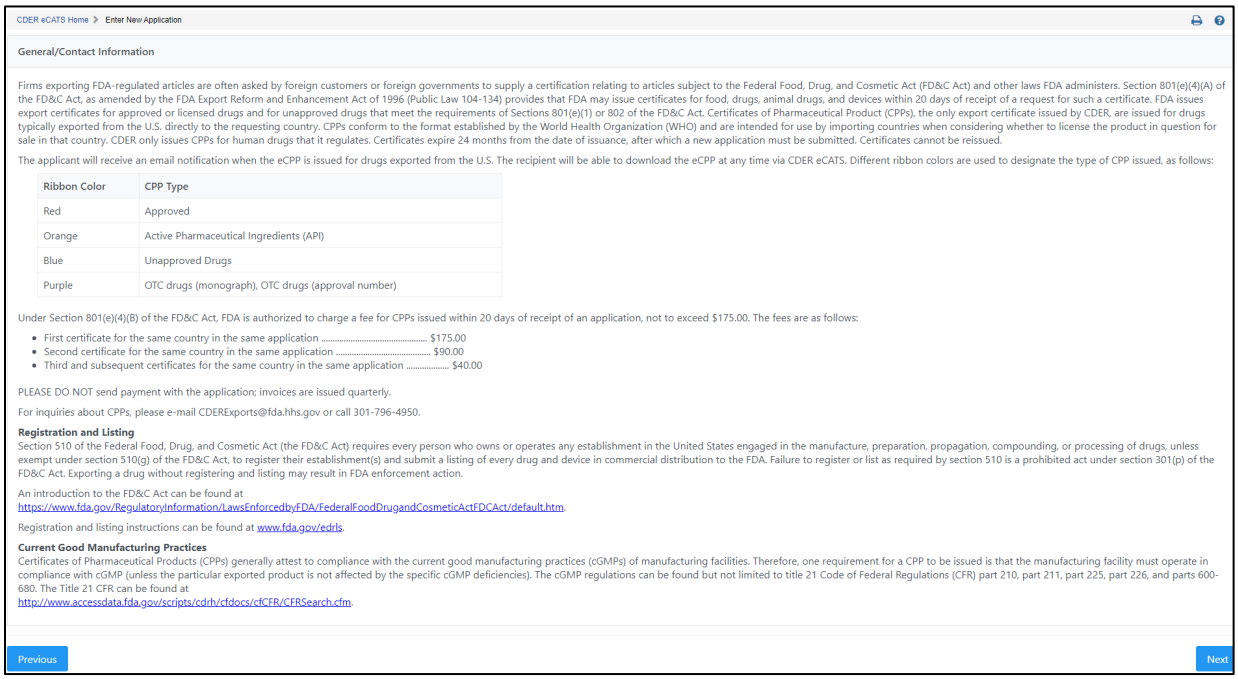


Figure 18 - General/Contact Information (cont.)



2. Click “Next” to continue creating an application.
3. 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 19 (below).

Figure 19 - Certificate Types

Certificate of Pharmaceutical Product (CPP):

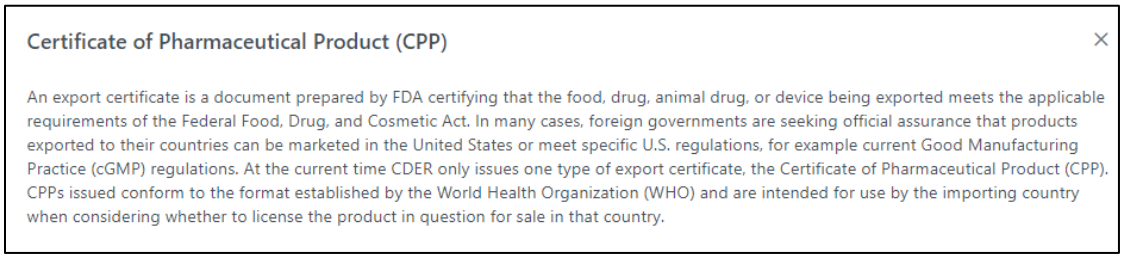
The following section provides an overview of the CPPs and Simple Notifications generated within the application:

- CPP 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 Help ("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 20 (below).

Note: At this time the CPP is the only certificate type that can be requested online. Export Notifications can also be submitted electronically in the CDER eCATS application.

Figure 20 - Certificate of Pharmaceutical Product (CPP)

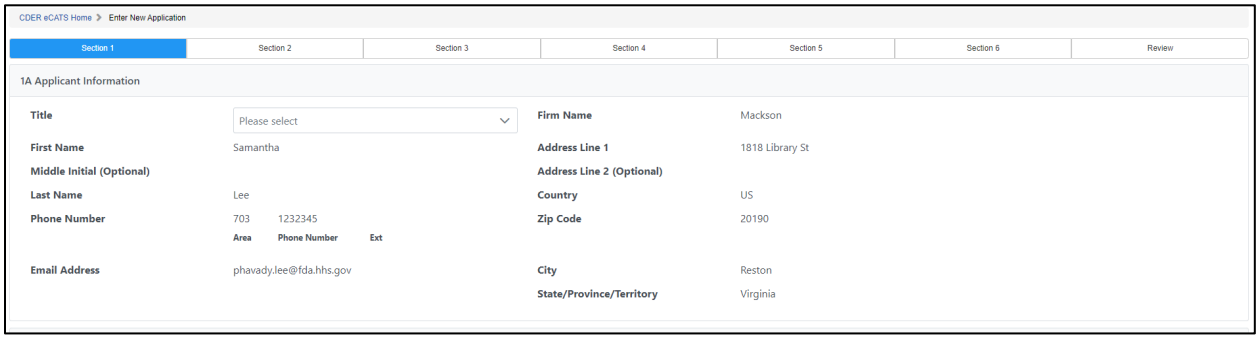


4.2 Section 1A – Applicant Information

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.

1. 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, as shown in Figure 21 (below).

Figure 21 - Applicant Information



If the information is incorrect, you will need to update your OAA Account profile.

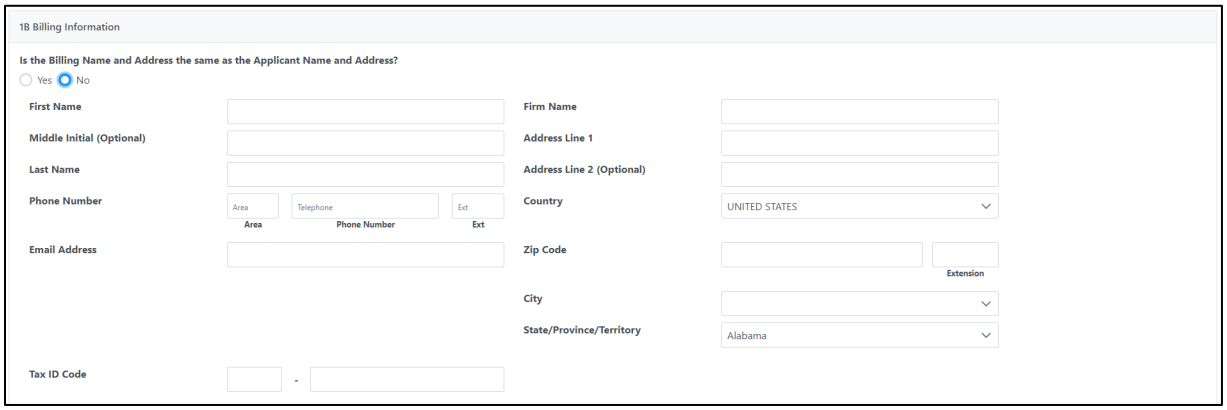
2. Click on the “FURLS Home” link (located in the top right-hand corner), select “Edit Account Profile” (on the left-hand side), and update your account profile accordingly.
3. Once you have updated your account, navigate back to the CDER eCATS application to restart the application and verify your changes. Note: Fields marked with “(Optional)” are not mandatory.
4. Select a “Title”.
5. Once you have completed this section, continue to section 1B.

4.3 Section 1B – Billing Information

Billing Address

1. 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 information.
2. Enter the “Tax ID Code”, as shown in Figure 22 (below).

Figure 22 - Billing Address

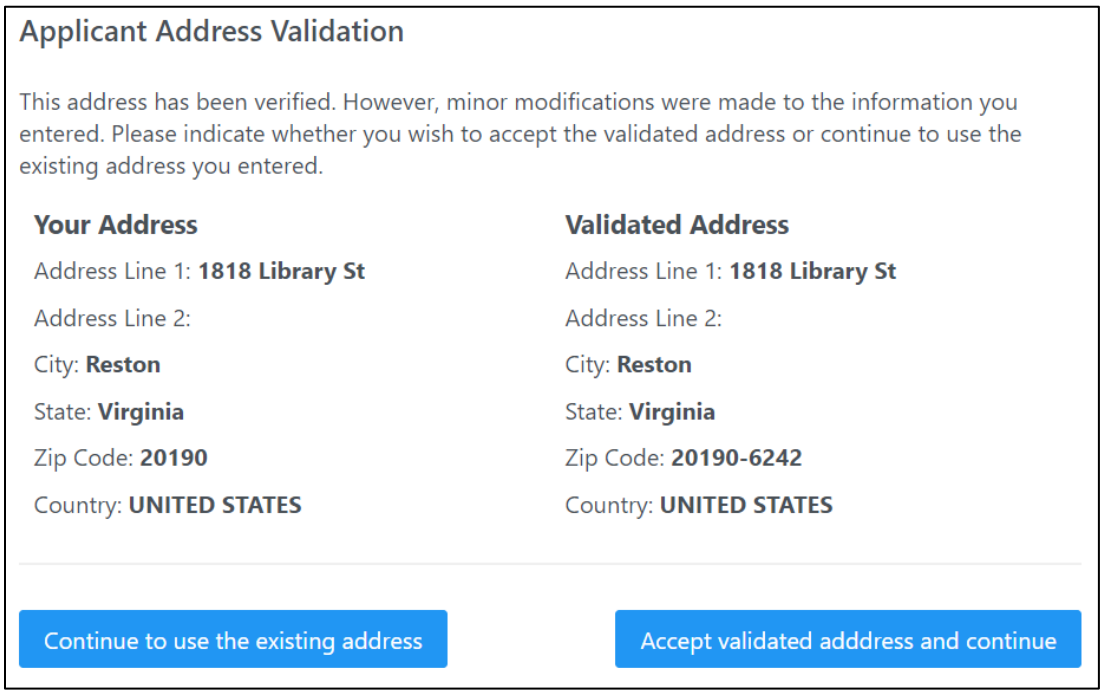


3. Once you have completed this section, click “Next”.

Address Validation

The system will perform an address validation. The system will display the “Validated Address” if there are minor differences to the Requestor’s 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. Otherwise, select the “Accept validated address and continue” radio button. See Figure 23 (below).

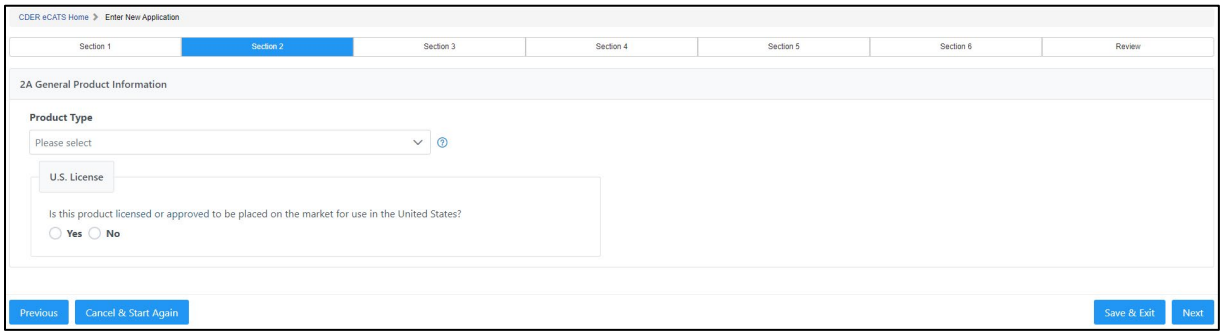
Figure 23 - Address Validation



4.4 Section 2A – General Product Information

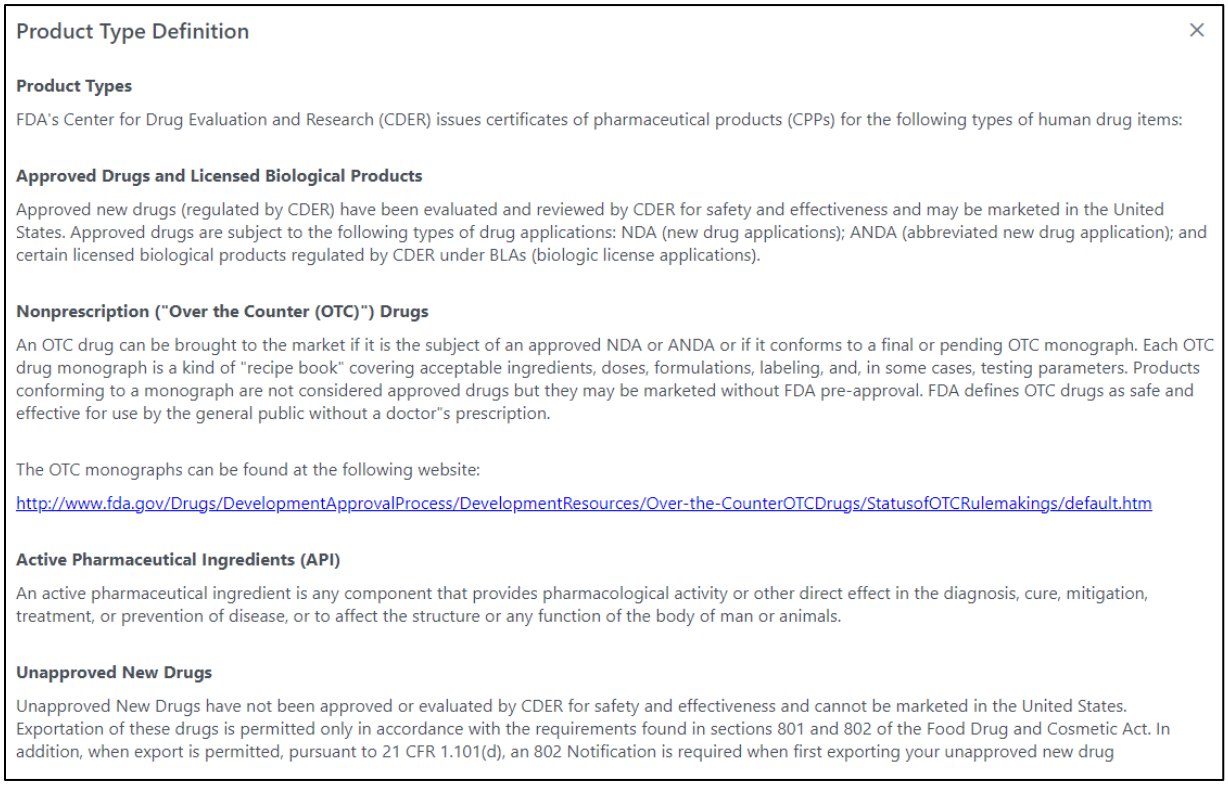
1. Select the product type from the following dropdown list, as shown in Figure 24 (below):
    - Approved Drug Product
    - Over-the-Counter (OTC)
    - Active Pharmaceutical Ingredient (API)
    - Unapproved Drug Product

Figure 24 - General Product Information



2. Click on the "?" icon to view the definition for each product type, as shown in Figure 25 (below).

Figure 25 - Product Type Definition



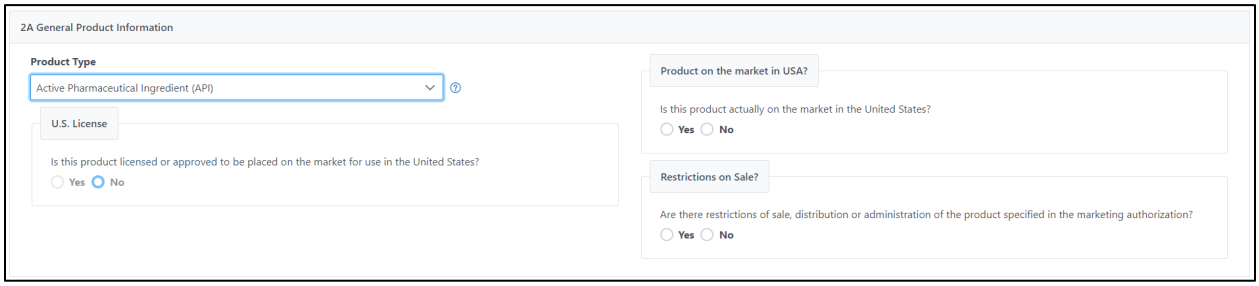
The below questions are applicable for all Product Types:

3. Select "Yes" or "No" – depending on whether the product is licensed or approved to be placed on the market in the United States. Note: Click the "licensed or approved" hyperlink to view the definition.
4. Select "Yes" or "No" based on whether the product is actually on the market in

the United States, as shown in Figure 26 (below).

5. Select “Yes” or “No” to indicate if there are any restrictions on the sale, distribution, or administration of the product – as shown in Figure 26 (below).

Figure 26 – General Product Information

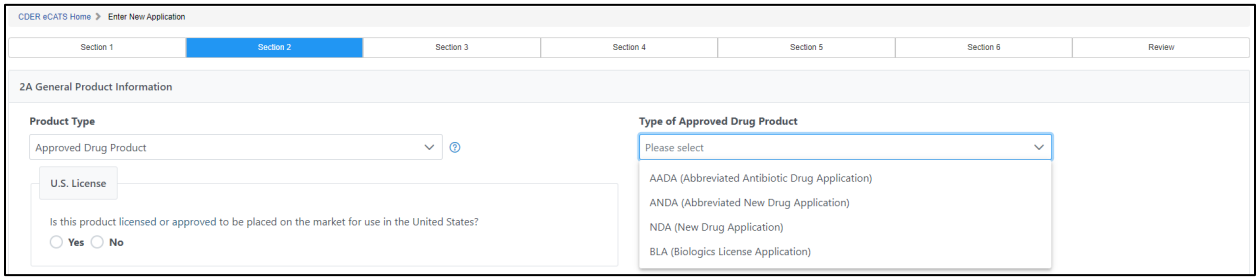


Approved Drug Product Flow Only:

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

1. Please select from the following, as shown in Figure 27 (below):
    - AADA (Abbreviated Antibiotic Drug Application)
    - ANDA (Abbreviated New Drug Application)
    - NDA (New Drug Application)
    - BLA (Biologics License Application)

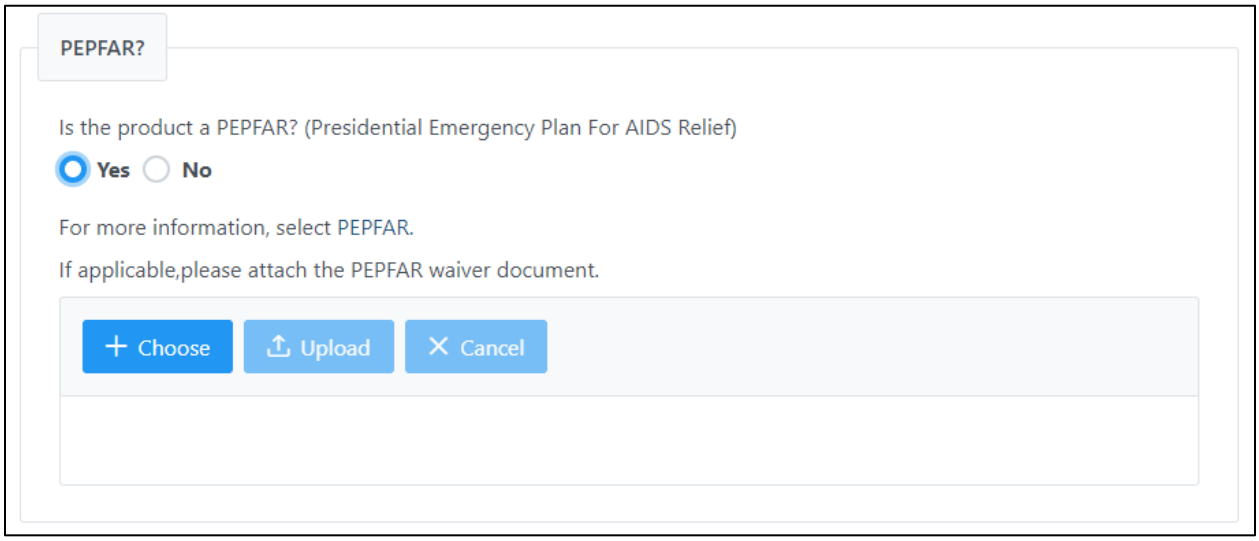
Figure 27 - Type of Approved Drug Product List



2. 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 28 (below).

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

Figure 28 - PEPFAR Waiver Document



4.5 Section 2B – Product Specific Information

4.5.1 Approved Drug Product

Applies to AADA, ANDA, or NDA if:

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

OR

The approved drug product is a PEPFAR and you did NOT upload a waiver document: Enter/upload the following information, as shown in Figure 29 (below):

- FDA Approval Number – If the approved drug product is NOT a PEPFAR

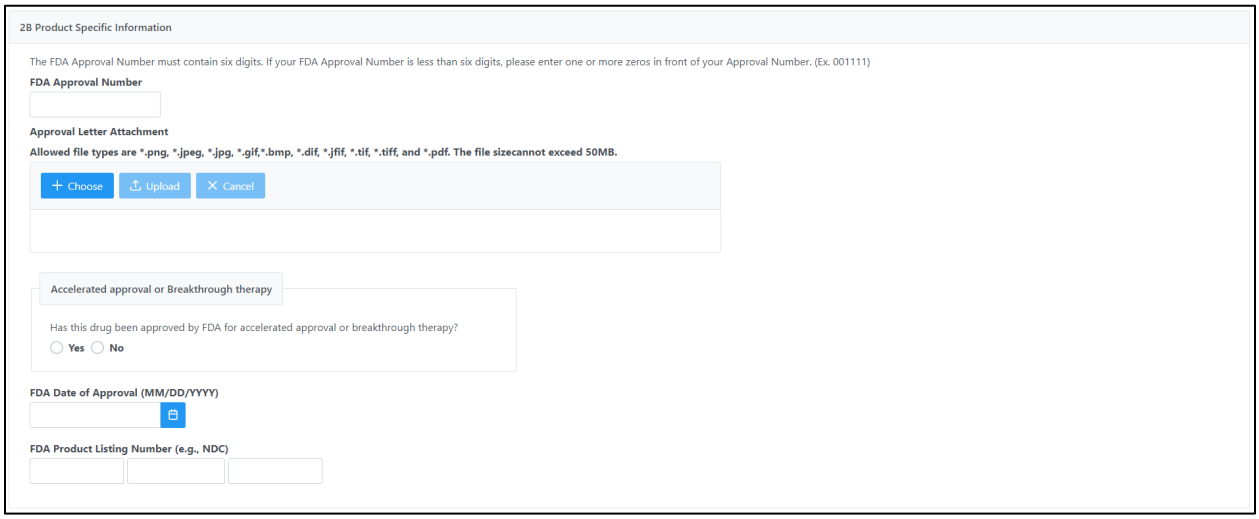
  OR

- FDA Approval Number or Tentative Approval Number – If the approved drug product is a PEPFAR and no waiver document uploaded
- Approval Letter Attachment – If the approved drug product is NOT a PEPFAR

  OR

- Approval Letter or Tentative Approval Letter/Approval Letter Attachment – If the approved drug product is a PEPFAR and no waiver document uploaded
- FDA Date of Approval (MM/DD/YYYY)
- FDA Product Listing Number

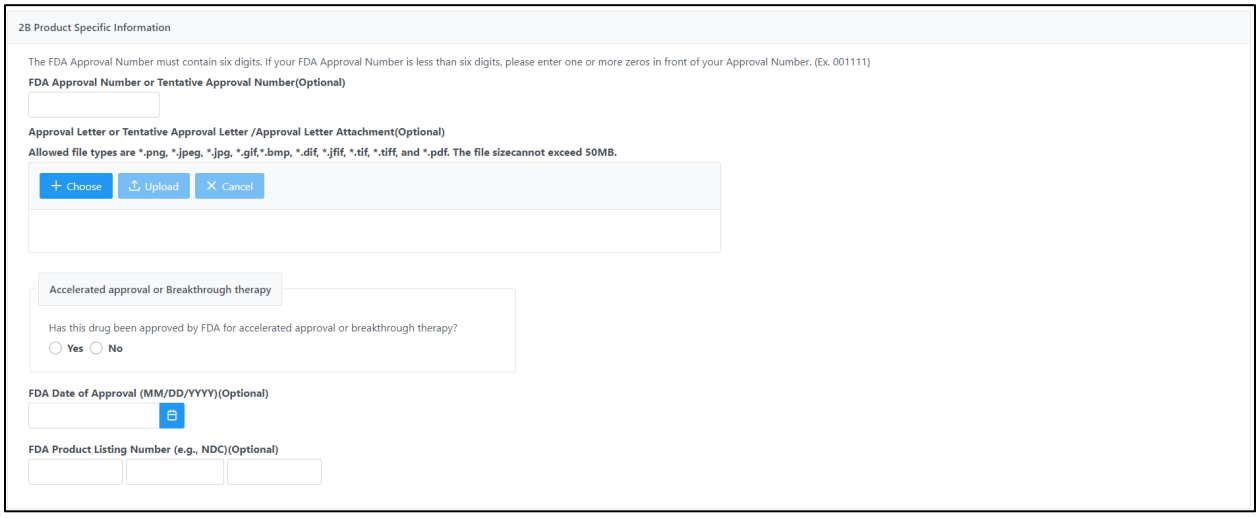
Figure 29 - Approved Drug not a PEPFAR



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 30 (below):

- FDA Approval Number (optional)
- Approval Letter or Tentative Approval Letter / Approval Letter Attachment (Optional) FDA Date of Approval (MM/DD/YYYY)
- FDA Product Listing Number

Figure 30 - Approved Drug is a PEPFAR with Waiver Document

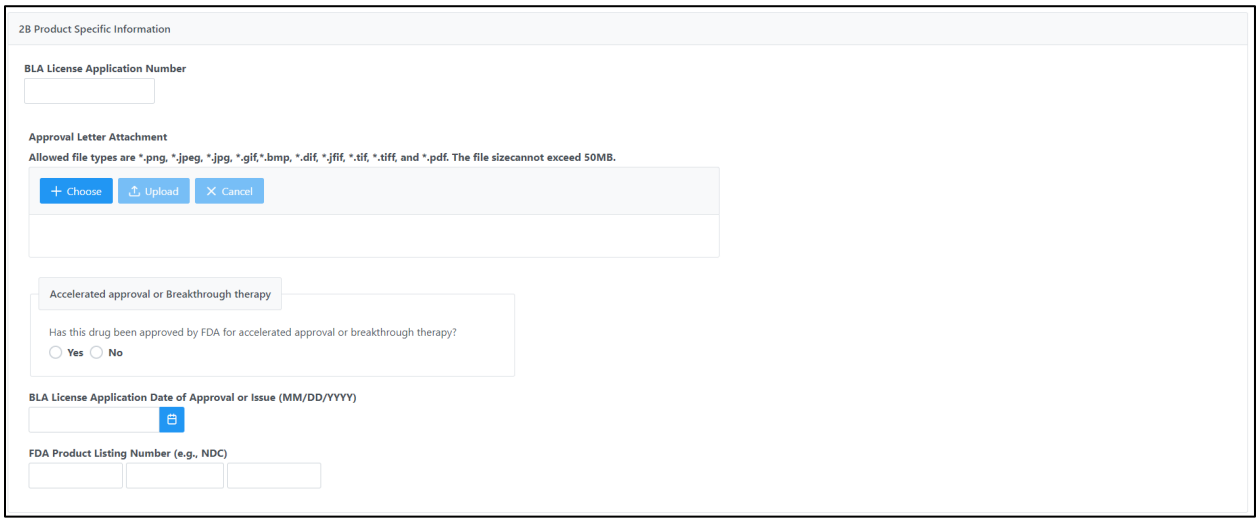


Applies to BLA:

If the approved drug product is a BLA, enter/upload the following information, as shown in Figure 31 (below):

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

Figure 31 - BLA with Approval Letter

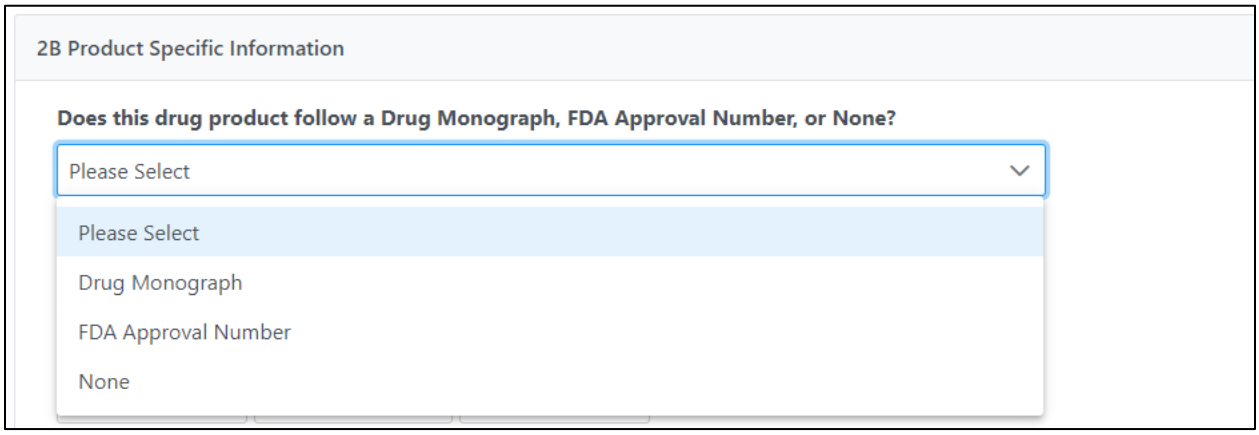


WARNING: Any FDA Approval Number entered in Section 2B must be a valid FDA Approval Number or you will not be able to continue with the application process.

4.5.2 Over-the-Counter Drug (OTC)

1. For OTC, select from the following options in dropdown list regarding which method the drug follows, as shown in Figure 32 (below):
    - Drug Monograph
    - FDA Approval Number
    - None

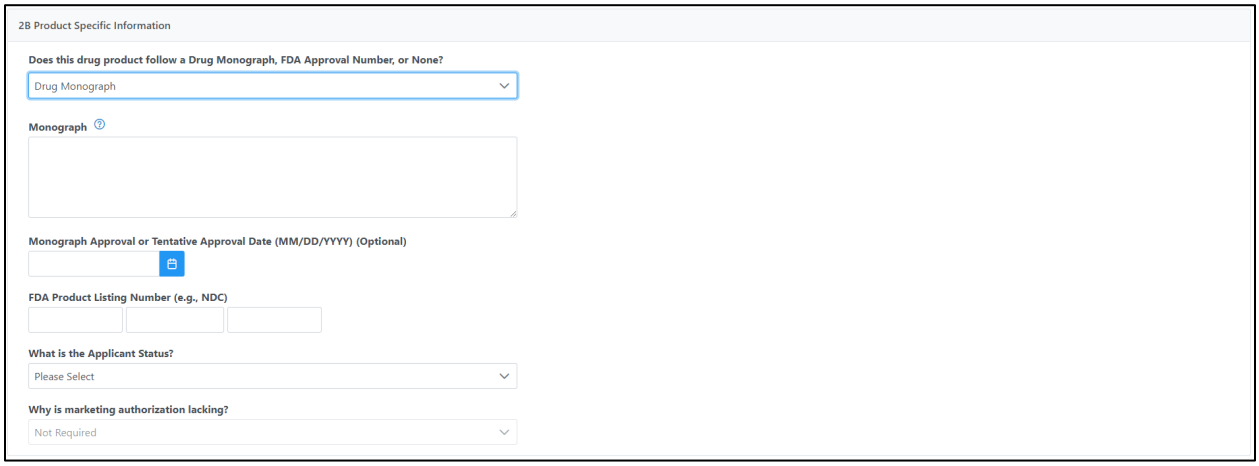
Figure 32 – OTC Type



2. 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?

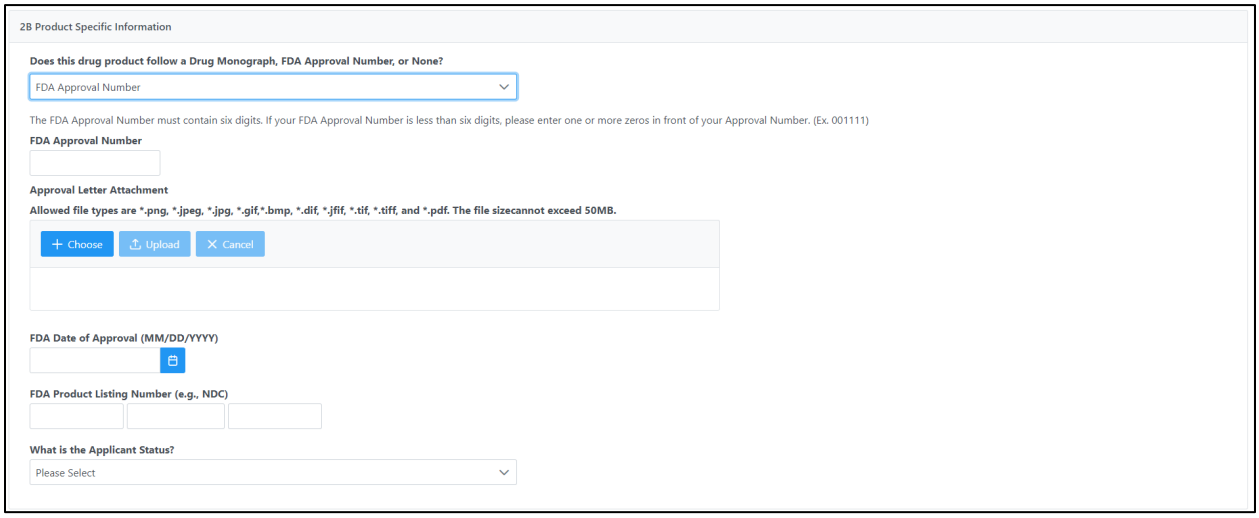
    Note: Click the "?" icon for more information regarding Monograph. If the drug does not follow a Drug Monograph or FDA Approval Number, you will not be able to continue with the application process.

Figure 33 - Drug Monograph Specifications



3. 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?

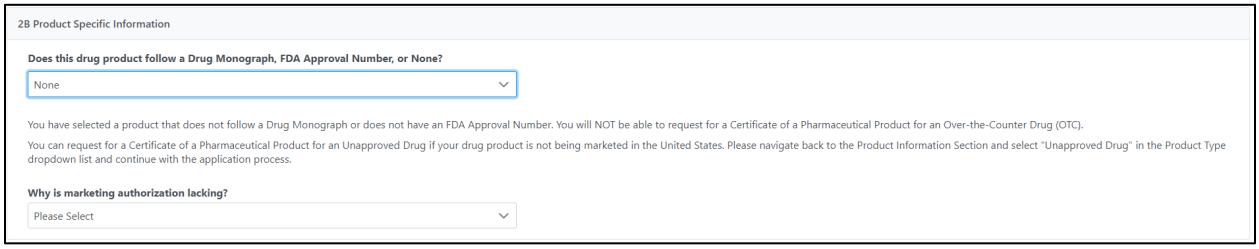
Figure 34 - Follow FDA Approval Number



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.

4. If the drug follows “None”, select a response to the question “Why is marketing authorization lacking?”, as shown in Figure 35 (below):

Figure 35 - Follow None



Note: Section 2C does not apply to an OTC product type.

4.5.3 Active Pharmaceutical Ingredient (API)

For the API, provide the following information – as shown in Figure 36 (below):

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

Figure 36 - Product Specific Information – API

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

4.5.4 Unapproved Drug Product

For Unapproved Drug Products, enter the following information, as shown in Figure 37 (below):

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

Figure 37 - Product Specific Information – Unapproved Drug

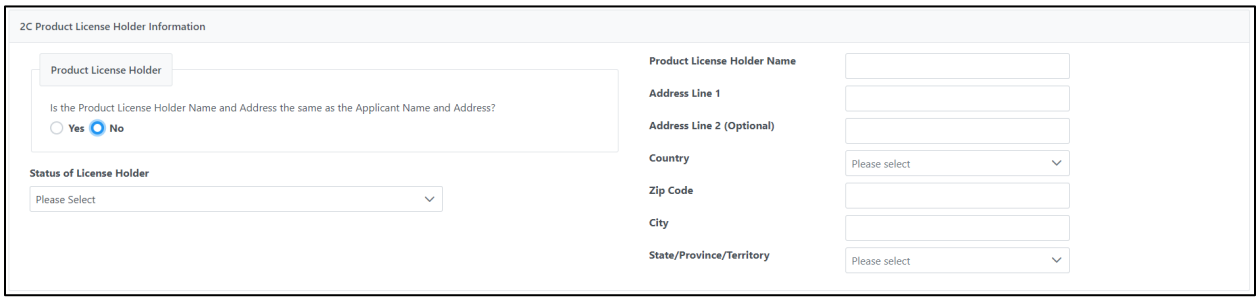
Note: Section 2C does not apply to an Unapproved Drug product type.

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

The following applies to all product types including AADA, ANDA, NDA, and BLA:

1. 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’s name and address information.
2. Additionally, you must select a “Status of License Holder” option from the dropdown list, as shown in Figure 38 (below).

Figure 38 - Product License Holder Name and Address



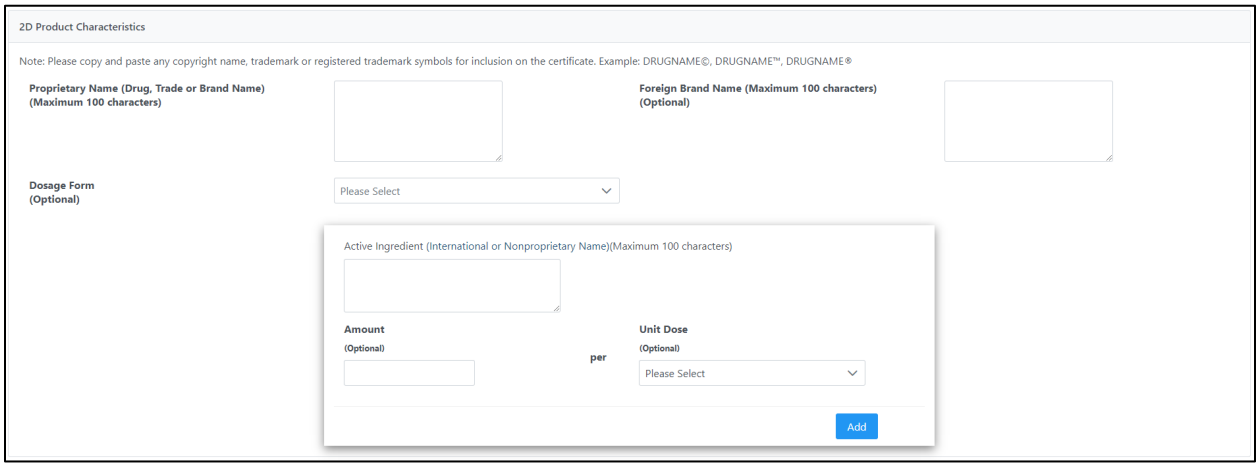
4.7 Section 2D – Product Characteristics

4.7.1 Approved Drug Product

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

1. Enter the following product characteristics information, as shown in Figure 39 (below):
    - Proprietary Name
    - Foreign Brand Name (Optional)
    - Dosage Form (Optional)
    - Active Ingredient
    - Amount (Optional)
    - Unit Dose (Optional)

Figure 39 – Approved Drug Product Characteristics

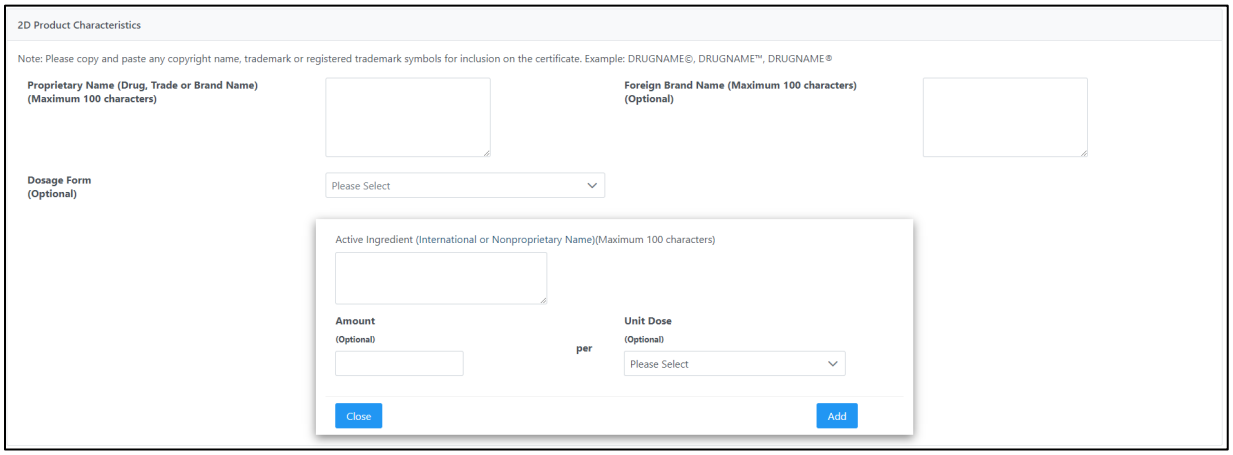


2. Click “Next” to navigate to Section 3A.

4.7.2 Over-the-Counter Drug (OTC)

1. Enter the following product characteristics information, as shown in Figure 40 (below):
    - Proprietary Name
    - Foreign Brand Name (Optional)
    - Dosage Form (Optional)
    - Active Ingredient
    - Amount (Optional)
    - Unit Dose (Optional)

Figure 40 – OTC Product Characteristics

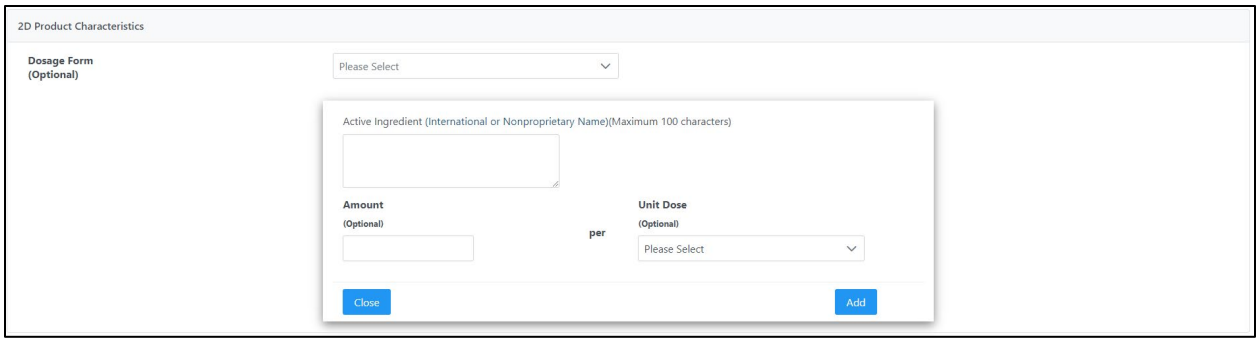


2. Click the “Next” button to navigate to Section 3A.

4.7.3 Active Pharmaceutical Ingredient (API)

1. Enter the following product characteristics information, as shown in Figure 41 (below):
    - Dosage Form (Optional)
    - Active Ingredient (International or Non-Proprietary Name)
    - Amount (Optional)
    - Unit Dose (Optional)

Figure 41 - Product Characteristics – API

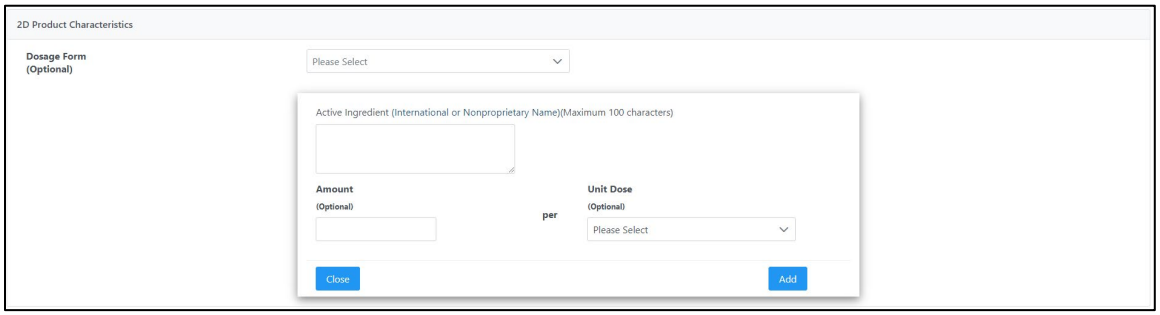


2. Click the “Next” button to navigate to Section 3B. Note: Section 3A does not apply to the API product type.

4.7.4 Unapproved Drug Product

1. Enter the following product characteristics information, as shown in Figure 42 (below):
    - Dosage Form (Optional)
    - Active Ingredient
    - Amount (Optional)
    - Unit Dose (Optional)

Figure 42 - Product Characteristics – Unapproved Drug



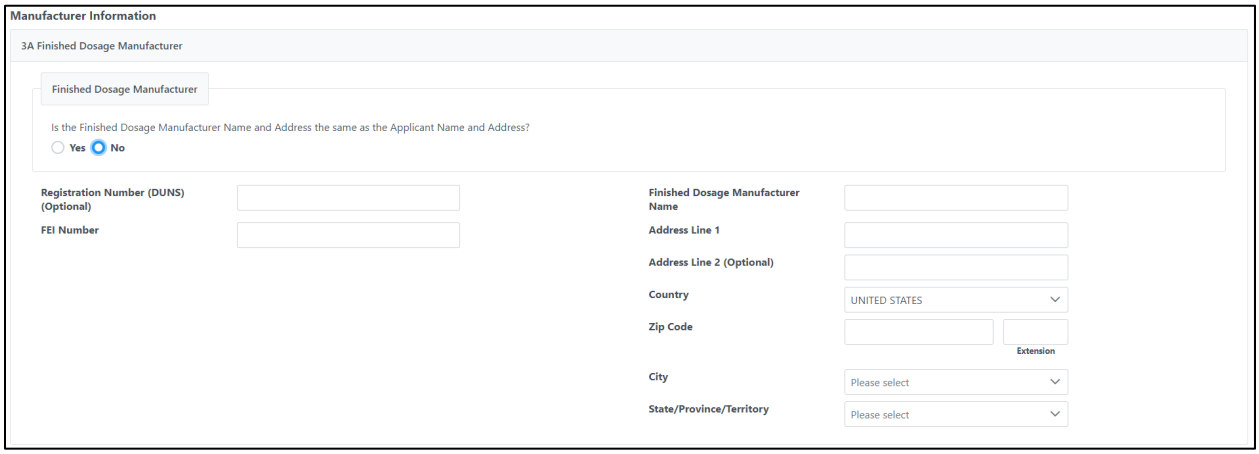
2. Click the “Next” button to navigate to Section 3A.

4.8 Section 3A – Finished Dosage Manufacturer

The Finished Dosage Manufacturer is applicable for all product types except API.

1. 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 43 (below).
2. If you select “Yes”, enter the following Finished Dosage Manufacturer information, as shown in Figure 43 and Figure 44 (below):
    - Registration Number (DUNS)
    - FEI Number
3. If you select “No”, enter the following Finished Dosage Manufacturer information:
    - Registration Number (DUNS)
    - FEI/CFN Number
    - Finished Dosage Manufacturer Name
    - Address Line 1
    - Country
    - Zip Code
    - City
    - State/Province

Figure 43 - Finished Dosage Manufacturer Contact Information

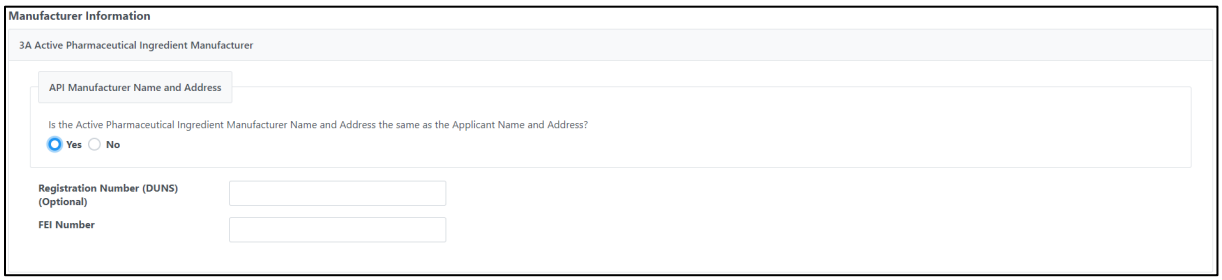


4.9 Section 3A – Active Pharmaceutical Ingredient Manufacturer

The Active Pharmaceutical Manufacturer is applicable only to the product type API.

1. Select “Yes” or “No” based on whether the API Manufacturer Name and Address is the same as the Applicant Name and Address
2. If “Yes” is selected, enter the following, as shown in Figure 44 (below):
    - Registration Number (DUNS)
    - FEI

Figure 44 - API Manufacturer same as Applicant



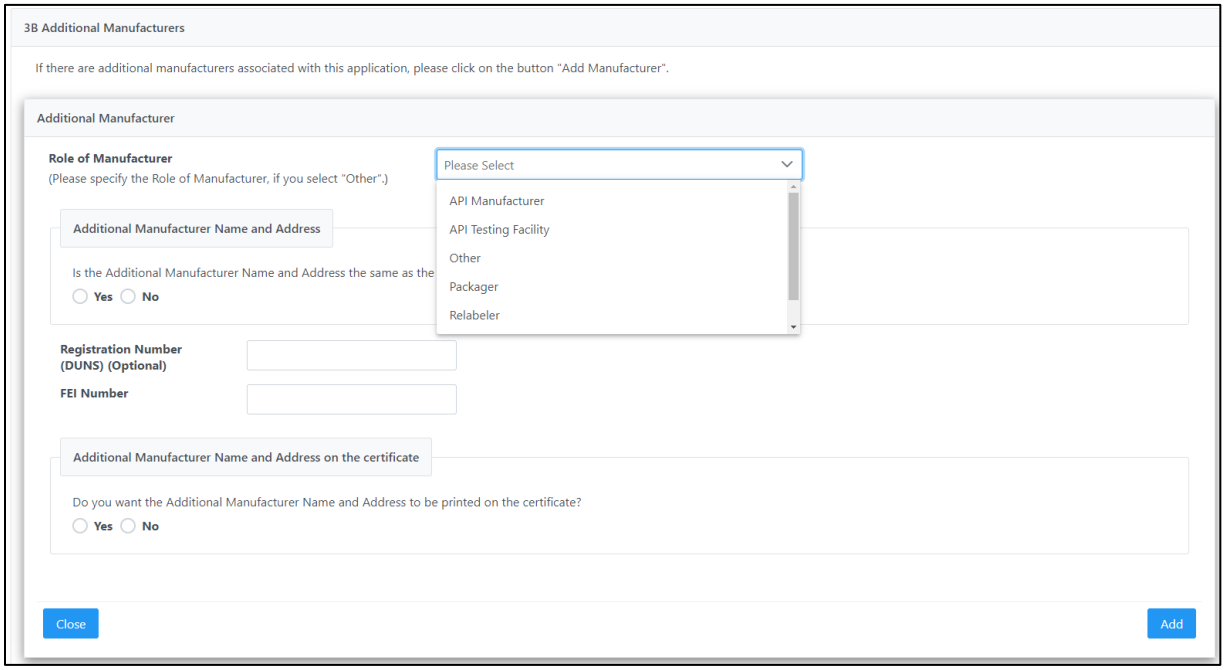
3. If “No” is selected, enter the following:
    - Registration Number (DUNS)
    - FEI Number
    - API Manufacturer Name
    - Address Line 1
    - Country
    - Zip Code

- City
- State/Province/Territory

4.10 Section 3B – Additional Manufacturers

1. 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). Select the “Role of Manufacturer”. Note: The API Manufacturer option will not be available for API product type.

Figure 45 – Add Additional Manufacturers

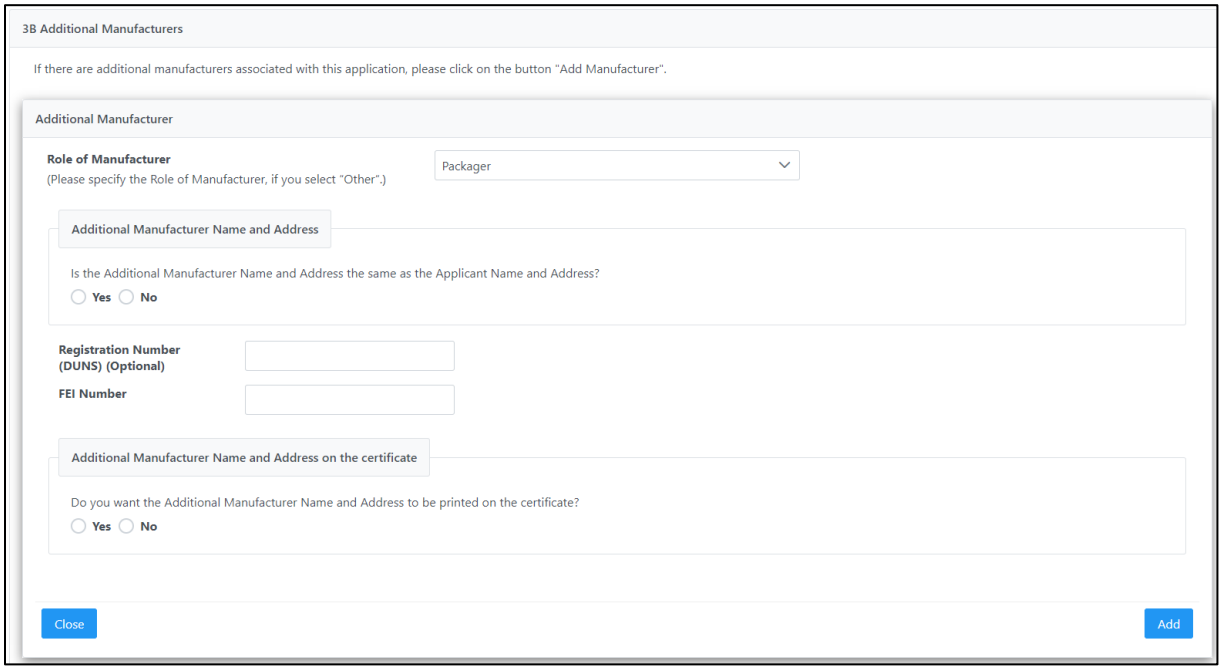


2. Select “Yes” or “No” based on whether the Additional Manufacturer’s Name and Address is the same as the Applicant Name and Address, as shown in Figure 46 (below).
3. If you select “Yes”, enter the following Manufacturer information:
    - Registration Number (DUNS)
    - FEI Number
4. If you select “No”, enter the following Finished Dosage Manufacturer information:
    - Registration Number (DUNS)
    - FEI
    - Manufacturer Name
    - Address Line 1
    - Country

- Zip Code
- City
- State/Province

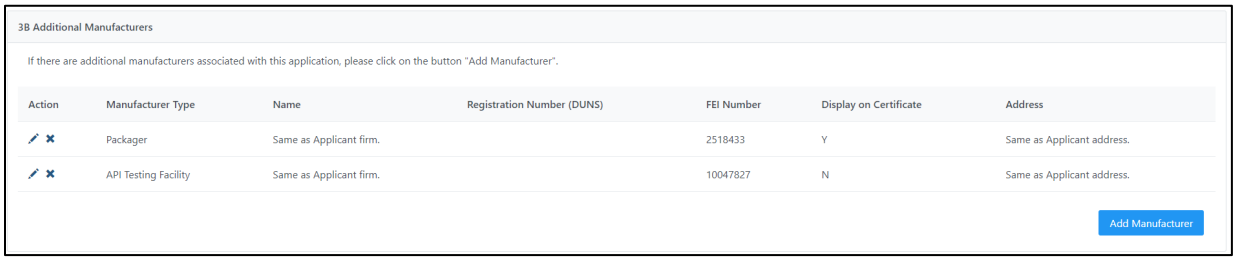
5. Select “Yes” or “No” to indicate if you want the additional manufacturer’s name and address to be printed on the certificate.

Figure 46 – Additional Manufacture Information and Certificate Display



6. Click “Add”. The manufacturer is added.
7. Click “Add Manufacturer” to add additional manufacturers. The additional manufacturers are displayed, as shown in Figure 47 (below).
8. Once all additional manufacturers are added, click “Next”.

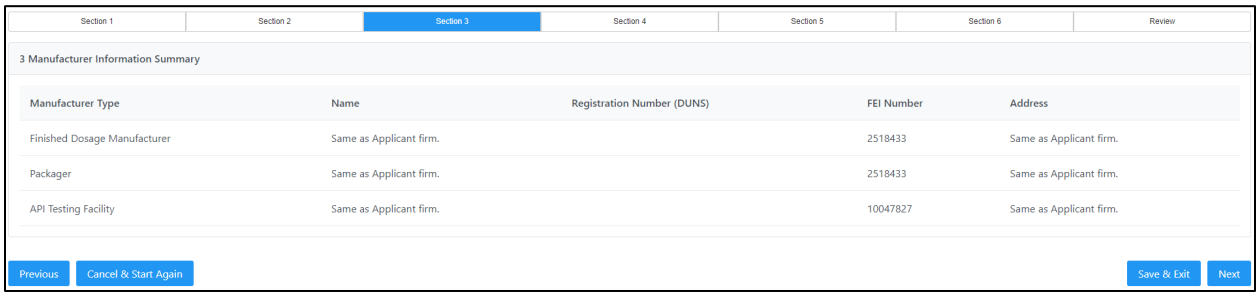
Figure 47 – 3B Additional Manufacturers



4.11 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, as shown in Figure 48 (below). Please review each manufacturer entered.

Figure 48 - Summary Page – Manufacturers



1. If modifications/updates are needed, click the “Previous” button to return to Section 3B.
2. In Section 3B, click the Edit (“paper and pencil”) icon next to the facility you wish to modify/update, as shown in Figure 47 (above).
3. Click “Next”.

4.12 Section 4A – Importing Country List

Name of Country or Countries:

Select one or more countries to indicate the product destination, as shown in Figure 49 (below). If more than one additional manufacturer is added, select one or more countries for each manufacturer, as shown in Figure 50 (below).

Note: Another method for selecting countries (other than scrolling through the list) is to select a country from the country list and 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 on your keyboard and select multiple countries.

Figure 49 - List of Countries

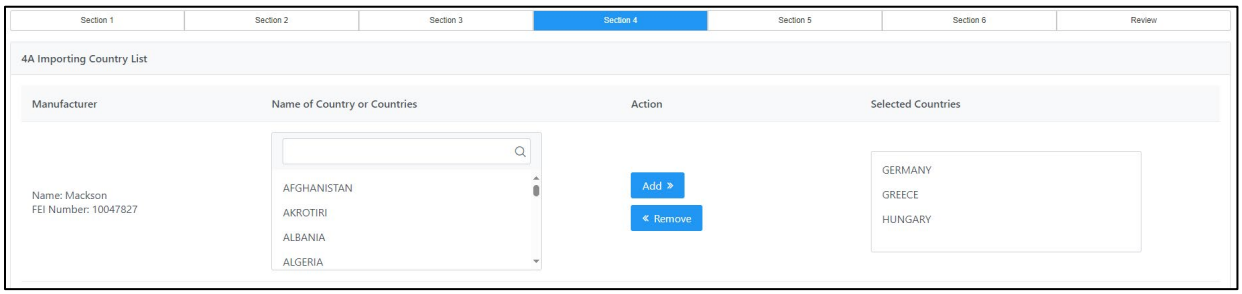
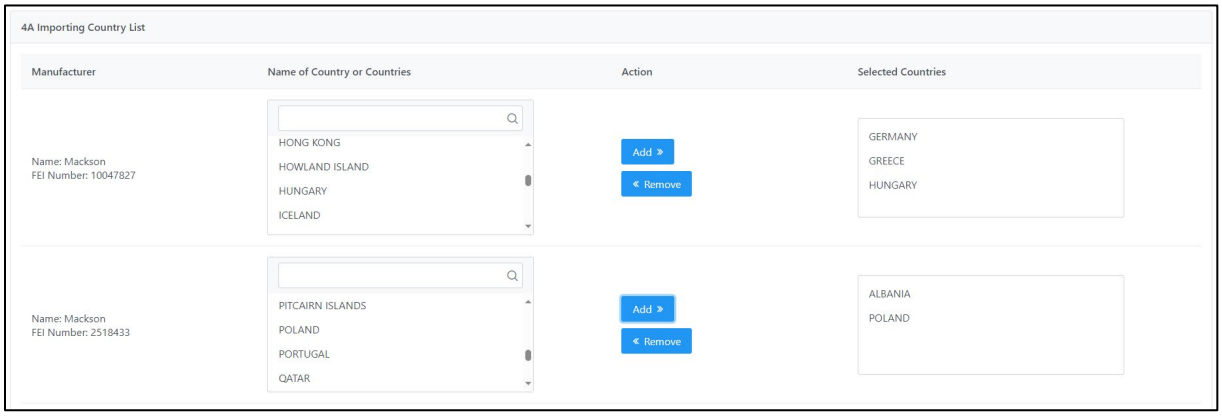


Figure 50 - List of Countries if Multiple Additional Manufacturers



4.13 Section 4B – Number of Certificates

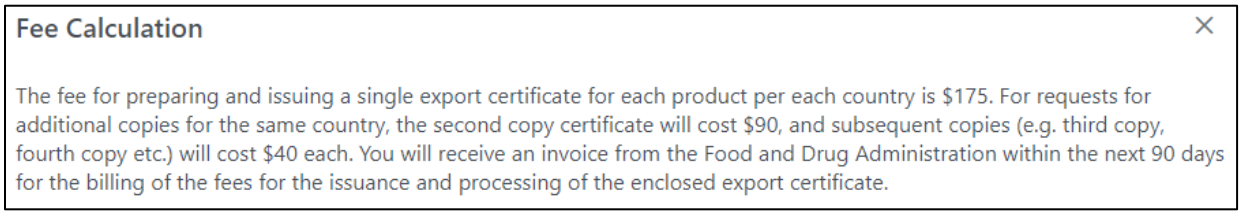
The system will display the selected country or countries (from Section 4A). You will be able to request additional certificate copies by country, as shown in Figure 51 (below).

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



4.14 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

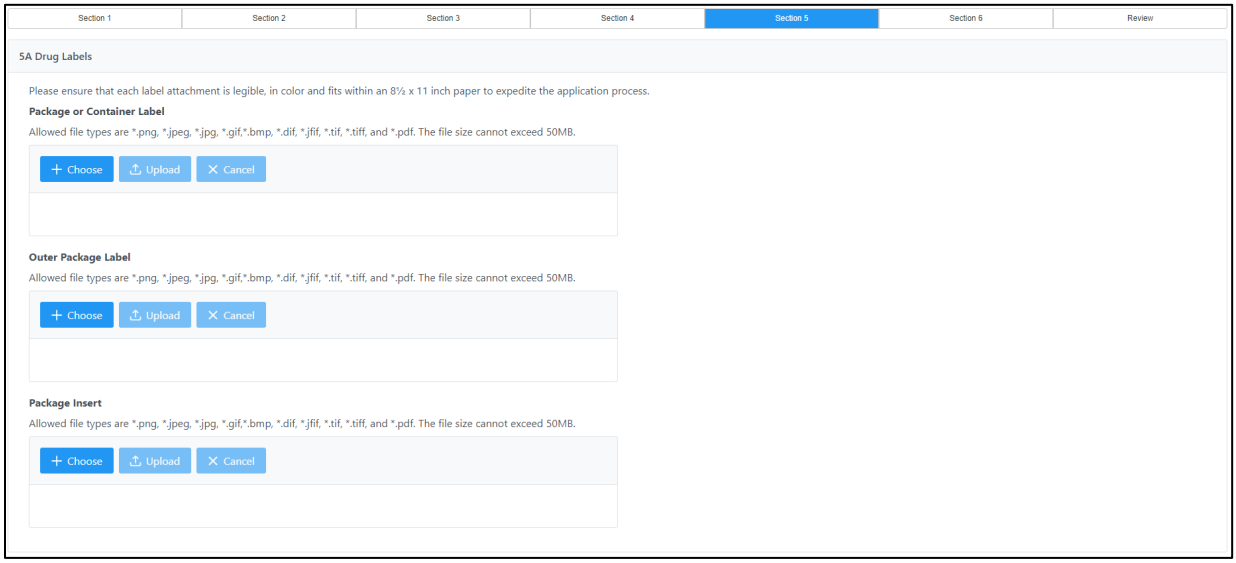
- Package or Container Label

For an Unapproved Drug

- Outer Package Label
- Formulation page

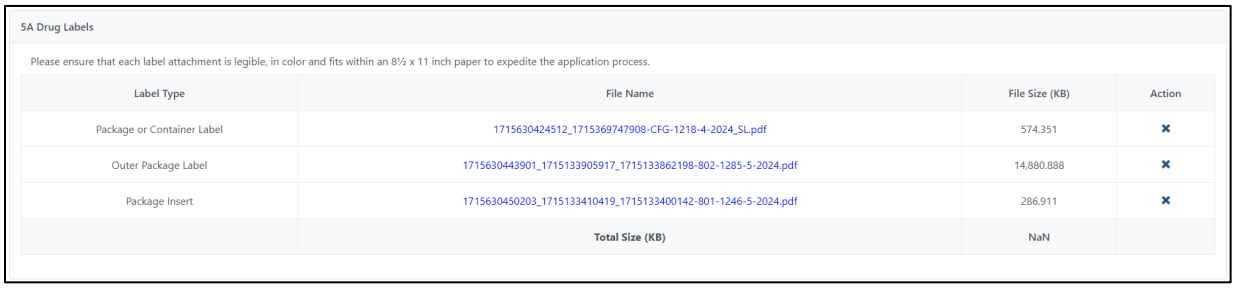
Note: Users can include formulation information in the “Supplemental Doc” section of the application for “Approved”, “OTC”, and “APIs”. Figure 53 (below) displays the labels required for an Approved Drug Type.

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 may click on the hyperlink to view the label. You can also 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.

4.15 Section 5B – Supplemental Documents

In this section, you have the option to attach additional supporting documents for your application. To add additional documents:

1. Select the “Yes” radio button, as shown in Figure 55 (below). Otherwise, click “No” and proceed to Section 5D.

Figure 55 - Add Supplemental Documents Prompt

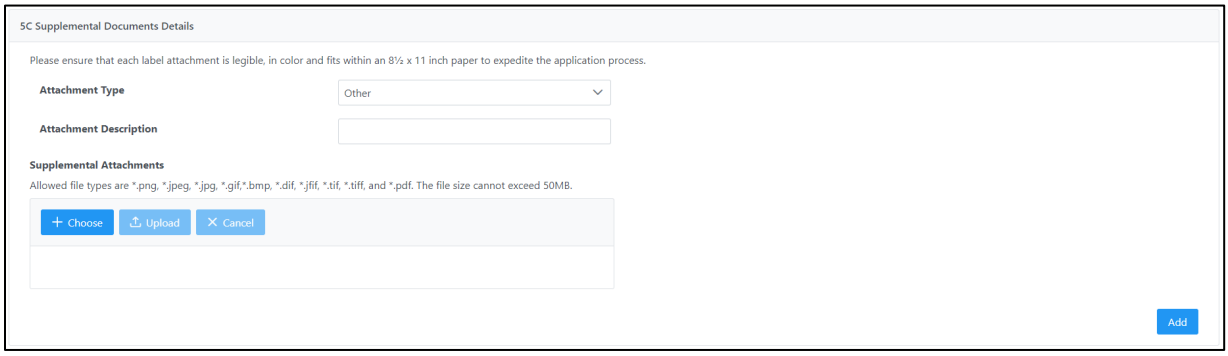
2. If you select “Yes”, Section 5C Supplemental Documents Details is displayed. Continue to Section 5C.

4.16 Section 5C –Supplemental Documents Details

To add a supplemental document:

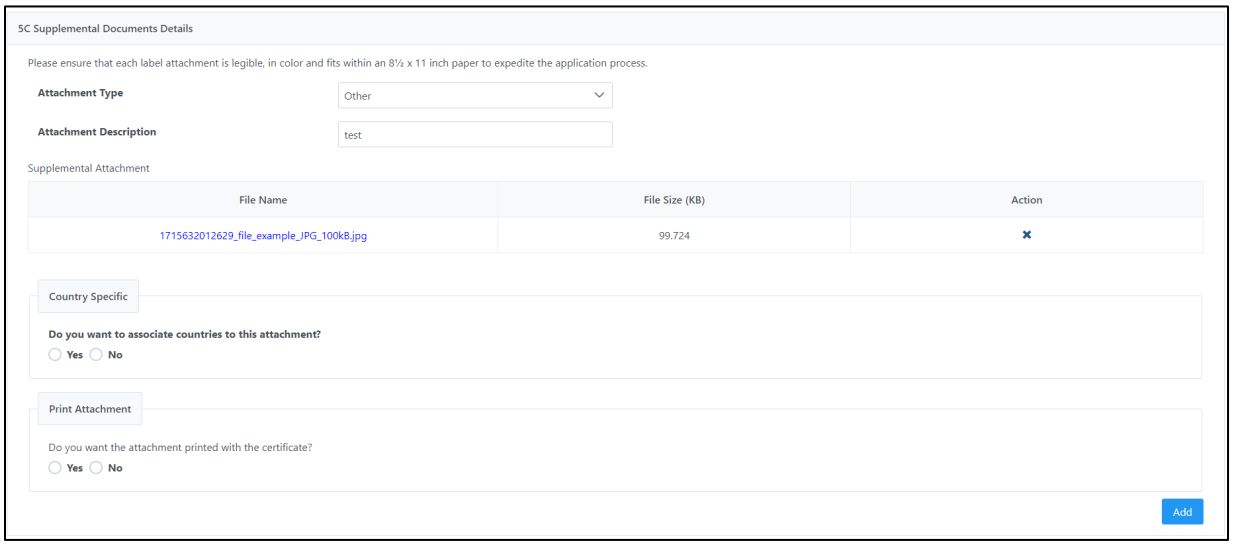
1. Select an option from the “Attachment Type” dropdown list.
2. If you select “Other”, you must provide a description of the attachment in the freeform text field, as shown in Figure 56 (below).

Figure 56 - Attachment Type and Attachment Description



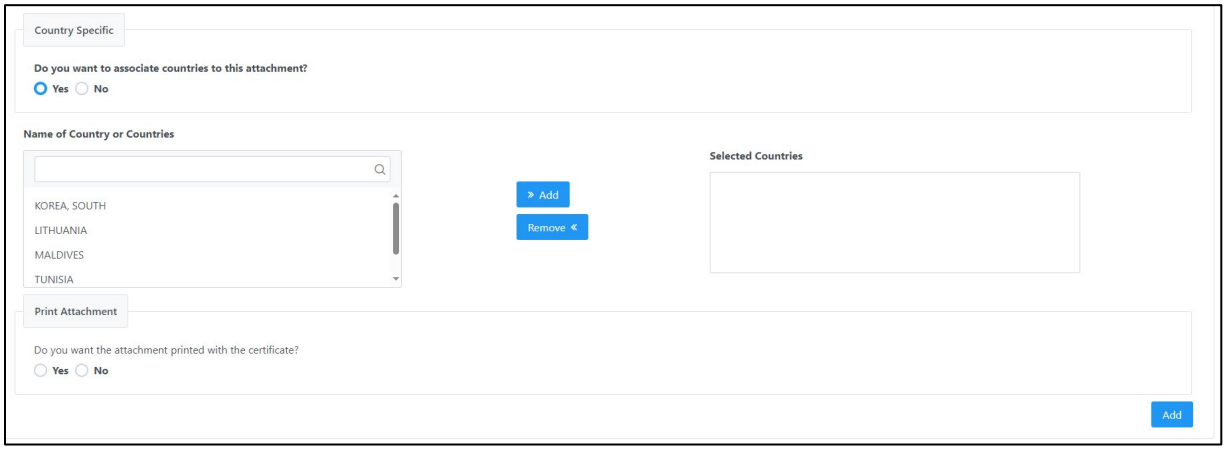
3. Click the “Choose” button, select a file, and click the “Upload” button. The system will display attachments as hyperlinks. You may click on the hyperlink(s) to view the document(s). You can remove any attachment or add documents, as shown in Figure 57 (below).

Figure 57 – Attachment Type and Associate Document with Country and Print on Certificate Prompt



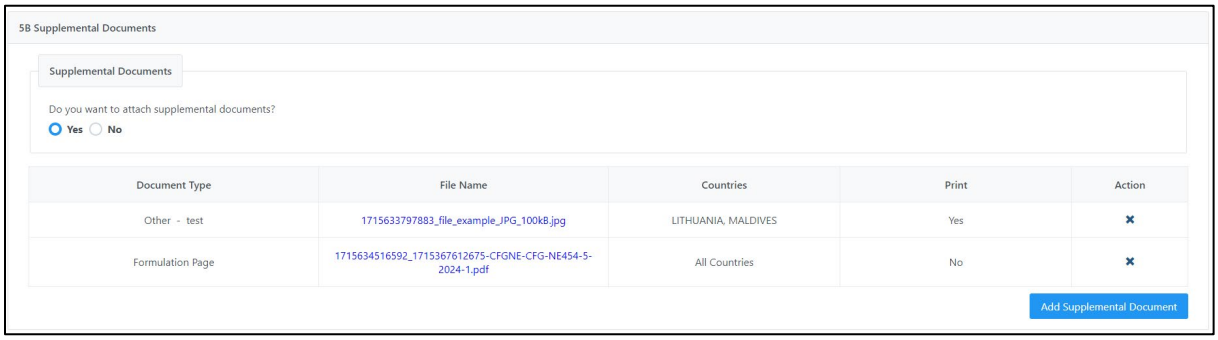
4. Select a response to the Country Specific question “Do you want to associate countries to this attachment?” using the radio buttons. If the response is “Yes”, the system will display all the countries selected in Section 4A. Please select one or more countries to associate to the Supplemental Attachment, as shown in Figure 58 (below).

Figure 58 – Associate Countries to Supplemental Attachment



5. Select a response to the Print Attachment question.
6. Click the “Add” button. The system will display attachments as hyperlinks, as shown in Figure 59 (below). You may click on the hyperlink(s) to view the document(s). You can remove any attachments.

Figure 59 – Display Added Supplemental Documents



7. To add additional supplemental documents, click the “Add Supplemental Document” button and Section 5C is displayed. Repeat the steps above.

4.17 Section 5D – Remarks

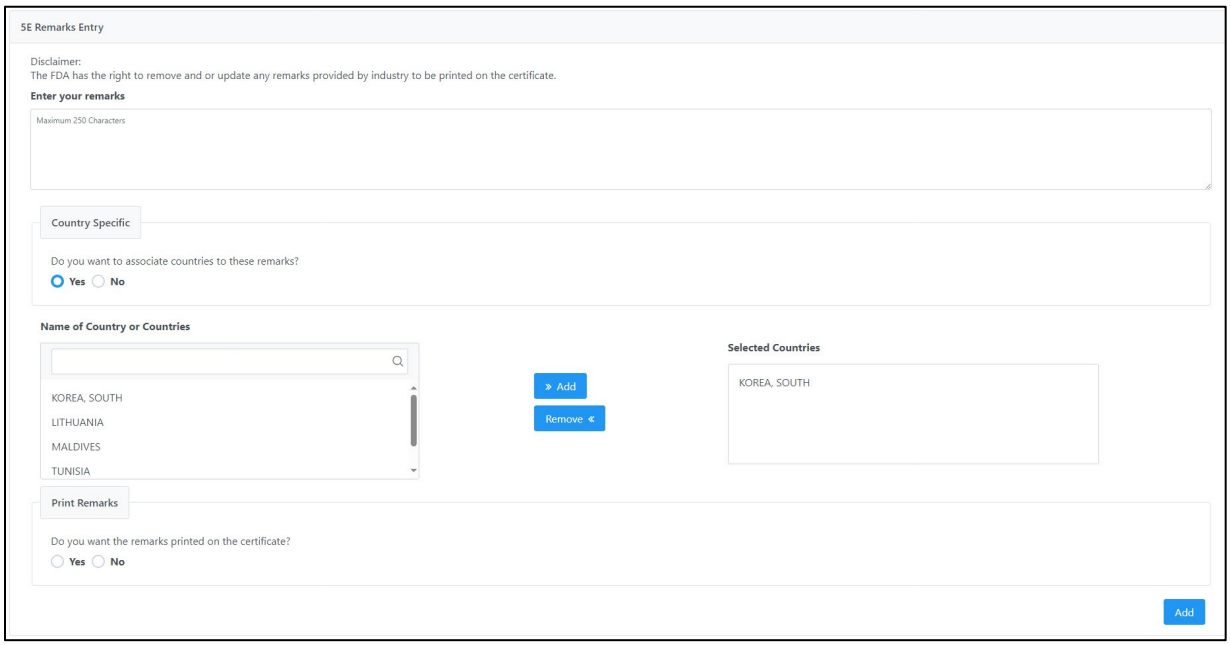
In this section, you have the option to add remarks, as shown in Figure 60 (below). To add a remark, click the “Yes” radio button. Section 5R Remarks Entry is displayed, Otherwise, click “No” and click the “Next” button to proceed to the next section.

Figure 60 - Add a Remark Prompt

4.18 Section 5E – Remarks Entry

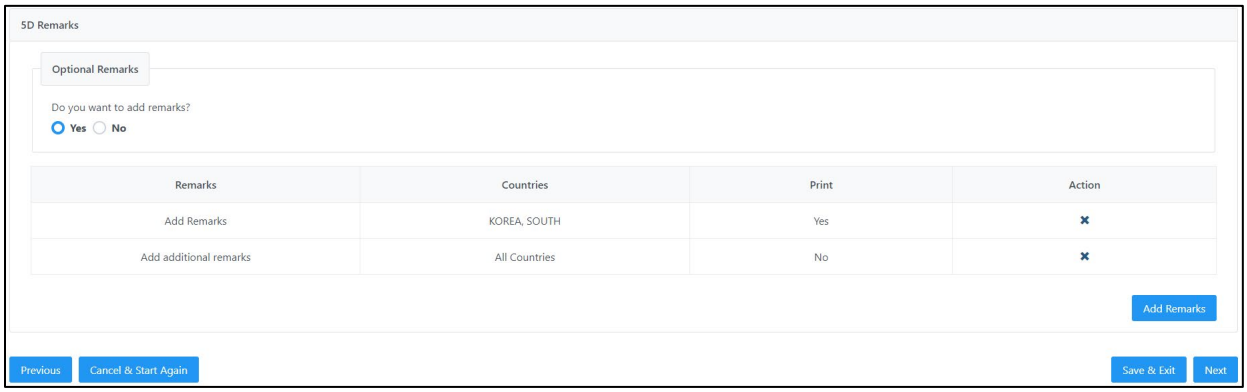
1. If you select “Yes”, please enter your remark in the freeform text field.
2. Select a response to Country Specific question using the radio buttons. If you select “Yes” to associate one or more countries to this remark, the system will display all the countries selected in Section 4A. Please select one or more countries, as shown in Figure 61 (below).
3. If you select “Yes” to print the remark on the certificate, the system will print this remark in the “Remarks” section of the certificate.

Figure 61 - Remarks Entry



4. Click the “Add” 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 62 (below).

Figure 62 - Summary of Remarks



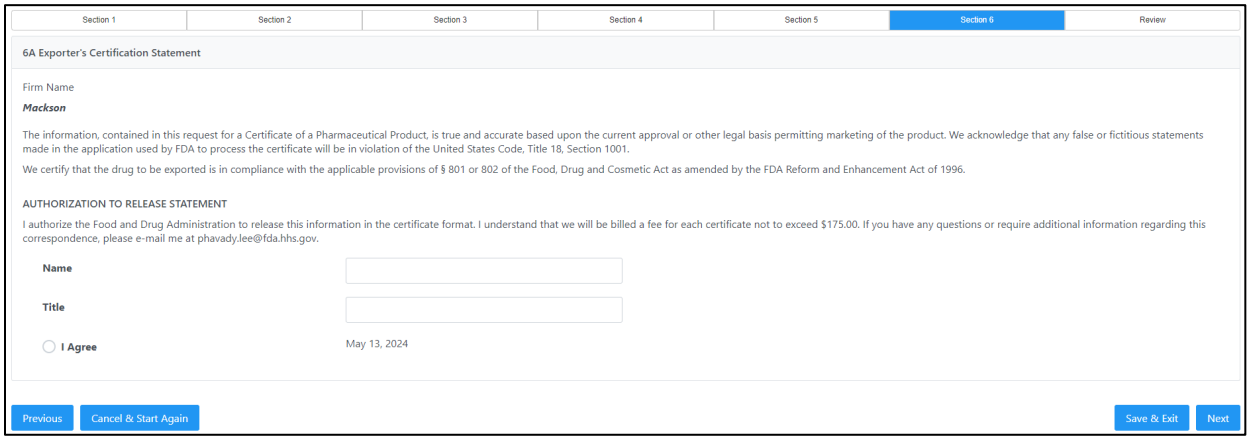
5. To add additional remarks, click the “Add Remarks” button and Section 5E is displayed. Repeat above steps.
6. Click the “Next” button.

4.19 Section 6A – Exporter's Certification Statement (ECS)

The Exporter's Certification Statement (ECS) acknowledges that you, the responsible official or designee, certify the facilities and the products 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.

1. You must click on the "I Agree" button located at the bottom of this section and enter your full name and title. Note: You will not be able to continue with the application until these fields have been completed, as shown in Figure 63 (below).

Figure 63 - Exporter's Certification Statement



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

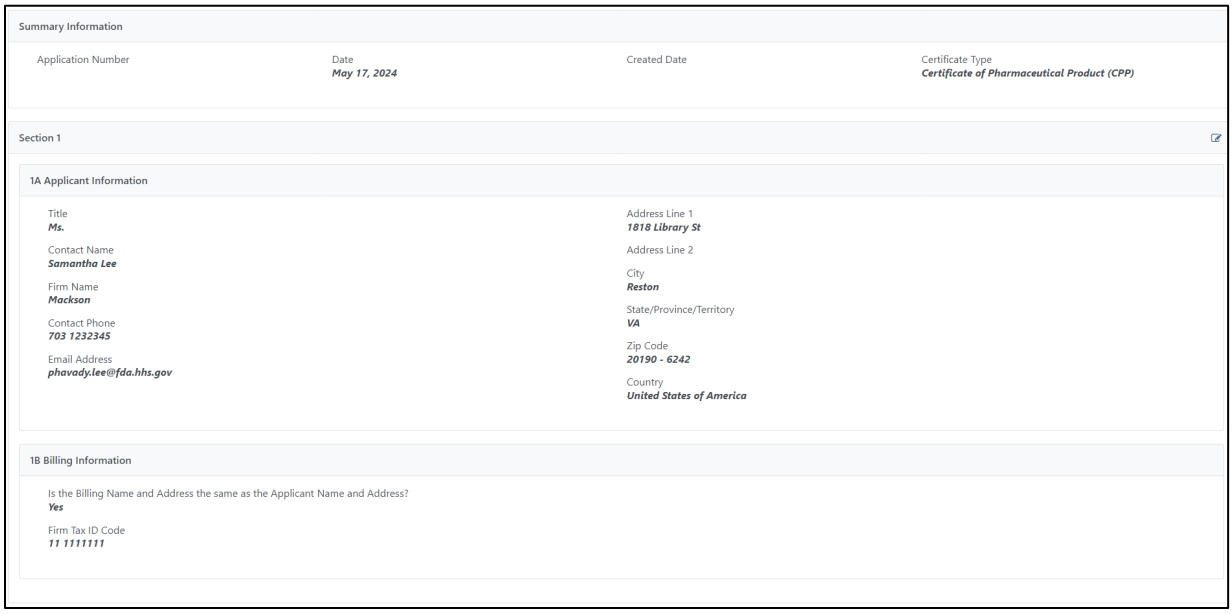
4.20 Final Review Page

The system will display the entire application (broken out by section), as shown in Figure 64 - Figure 69 (below). You may choose to modify a section by selecting the Edit ("paper and pencil") icon next to the step(s) to be updated.

Note: Section 2 displays different information based on the Product Type. Figure 65 (below) uses API as the example.

The system will display the data entry screen corresponding to your chosen section. You may make changes, as needed.

Figure 64 - Final Review Page Section 1



Summary Information

Application Number

Date
May 17, 2024

Created Date

Certificate Type
Certificate of Pharmaceutical Product (CPP)

Section 1

1A Applicant Information

Title
Ms.

Contact Name
Samantha Lee

Firm Name
Mackson

Contact Phone
703 1232345

Email Address
phavady.lee@fda.hhs.gov

Address Line 1
1818 Library St

Address Line 2

City
Reston

State/Province/Territory
VA

Zip Code
20190 - 6242

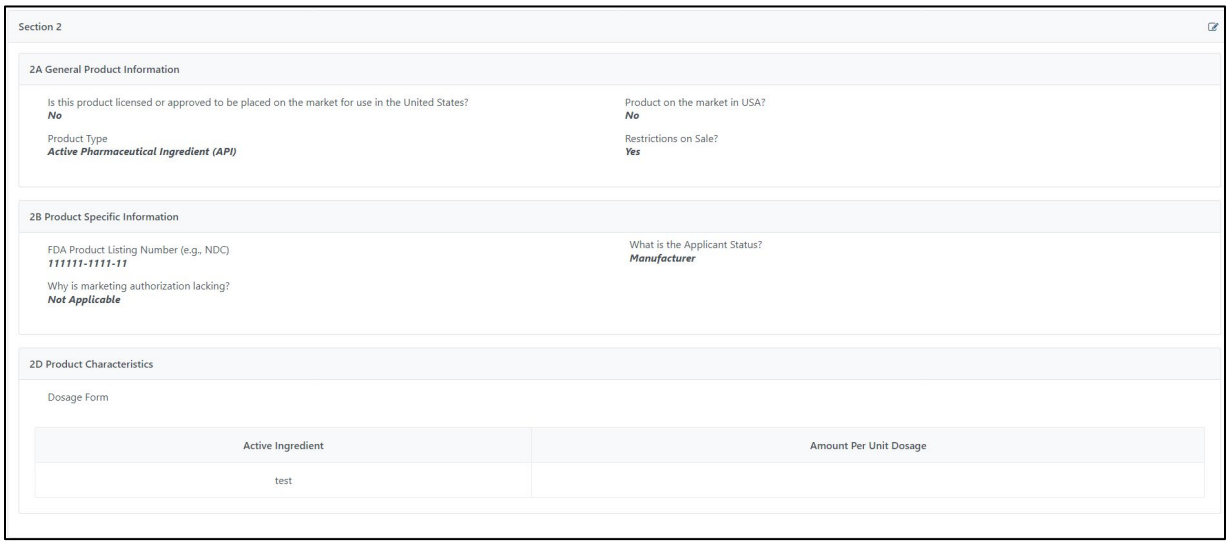
Country
United States of America

1B Billing Information

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

Firm Tax ID Code
11 1111111

Figure 65 - Final Review Page Section 2 - API



Section 2

2A General Product Information

Is this product licensed or approved to be placed on the market for use in the United States?
No

Product Type
Active Pharmaceutical Ingredient (API)

Product on the market in USA?
No

Restrictions on Sale?
Yes

2B Product Specific Information

FDA Product Listing Number (e.g., NDC)
11111-1111-11

Why is marketing authorization lacking?
Not Applicable

What is the Applicant Status?
Manufacturer

2D Product Characteristics

Dosage Form

Active Ingredient	Amount Per Unit Dosage
test	

Figure 66 - Final Review Page Section 3

Figure 67 - Final Review Page Section 4

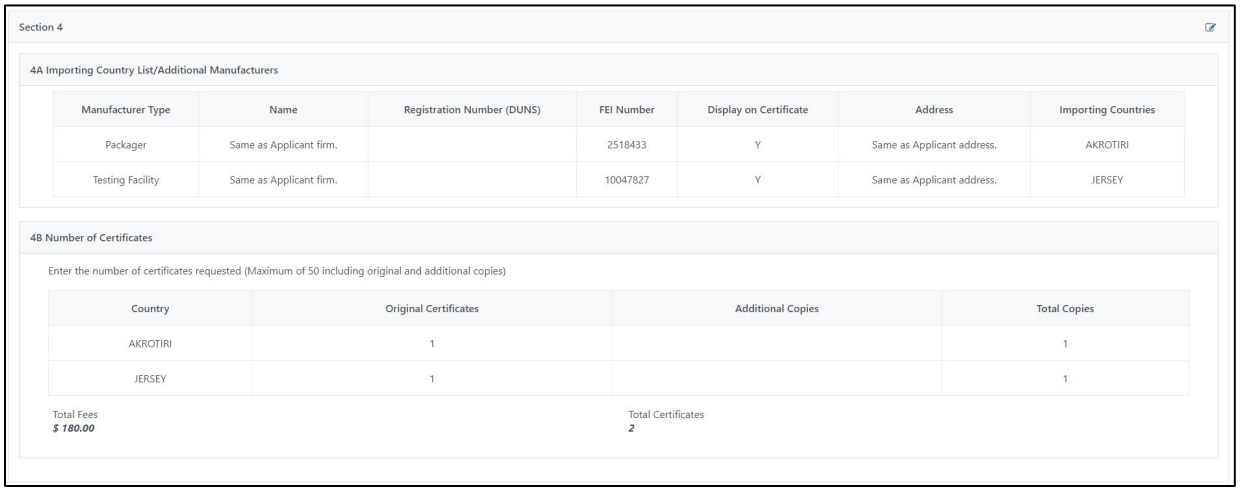


Figure 68 - Final Review Page Section 5

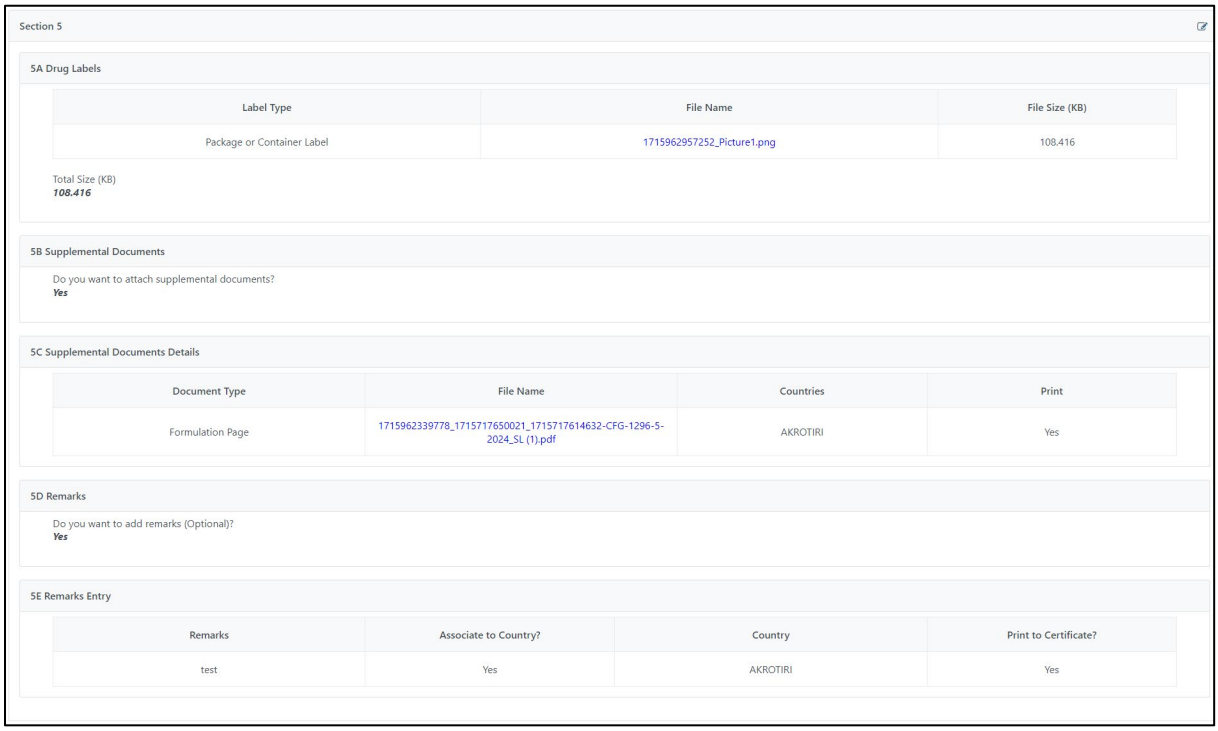
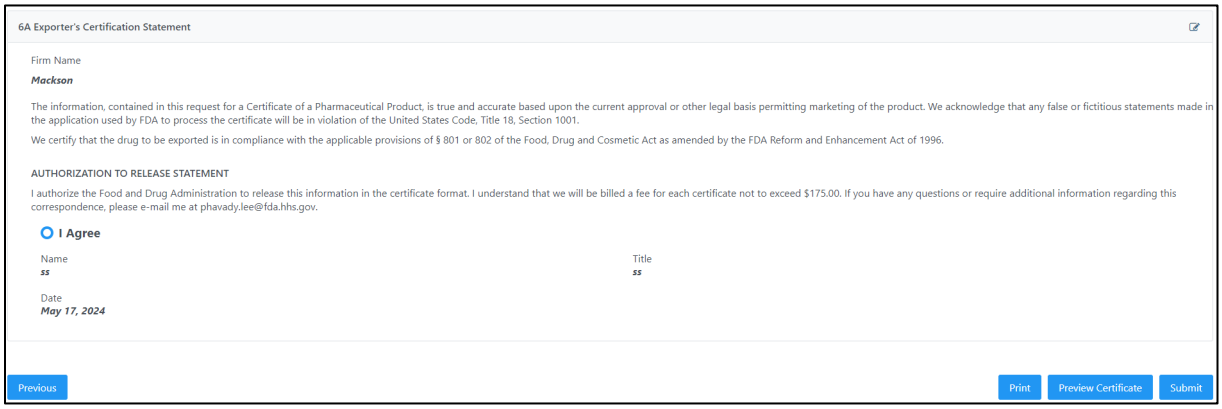


Figure 69 - Final Review Page Section 6

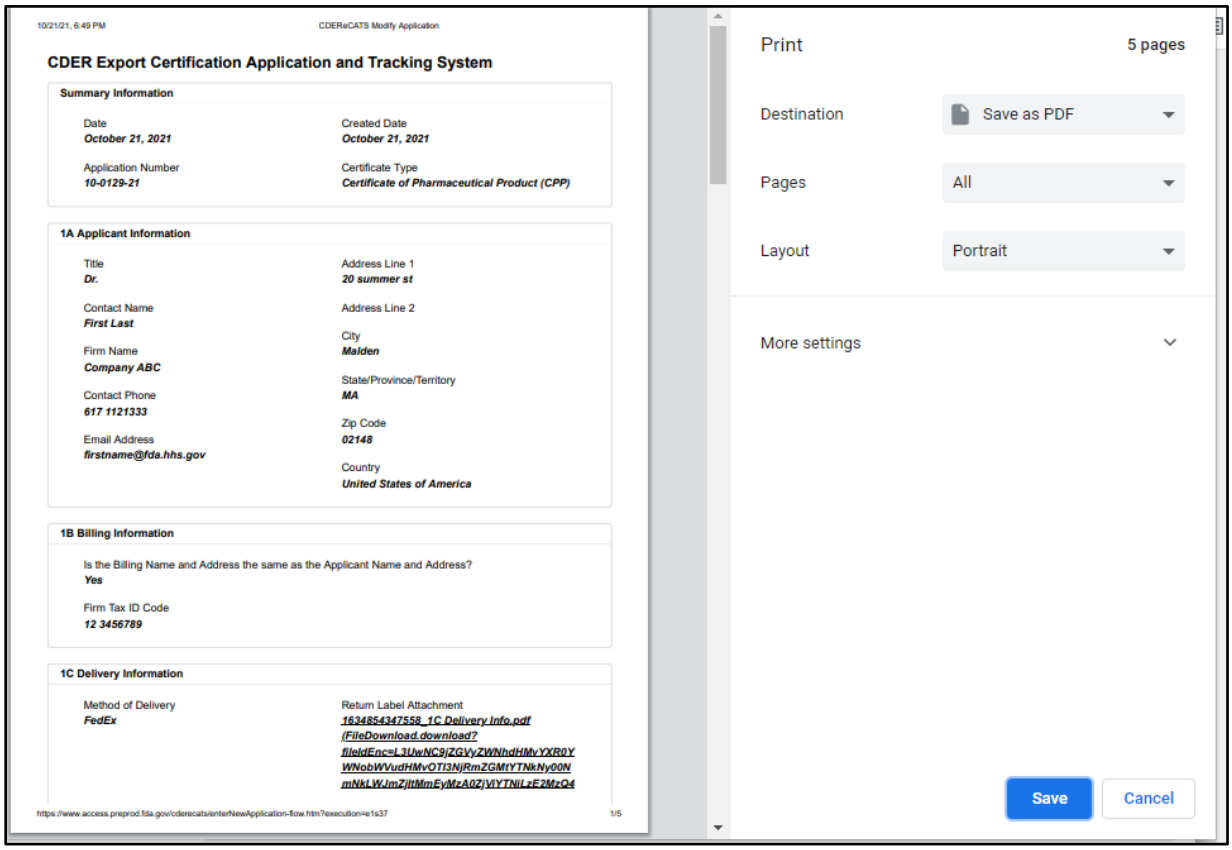


4.21 Print the Application

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 70 (below).

Figure 70 - Print Application



4.22 Preview Certificate

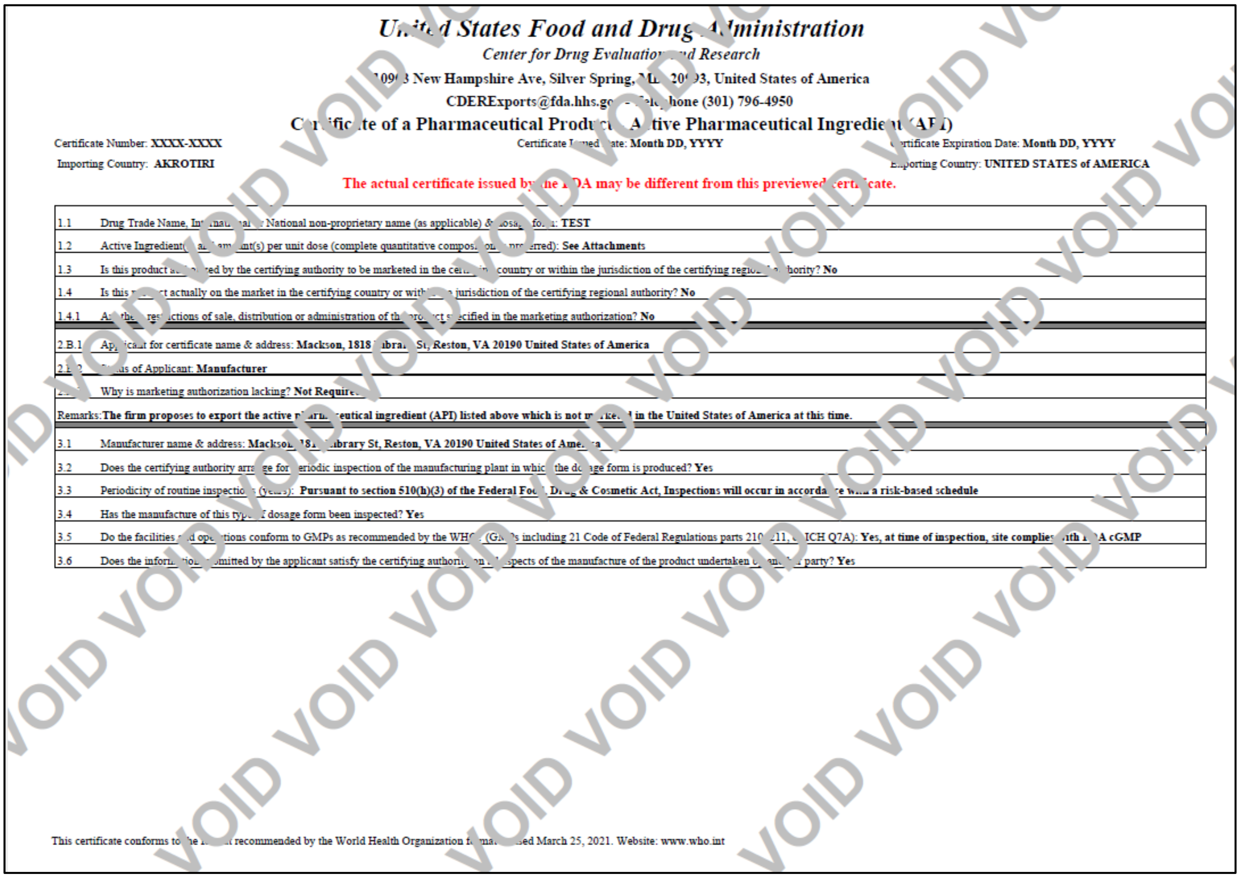
You may choose to preview the certificate prior to submission.

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 71 (below).

Figure 71 - Preview Certificate



United States Food and Drug [illegible]ministration

Center for Drug Evaluatio[illegible] Research

[illegible] New Hampshire Ave, Silver Spring, [illegible], United States of America

CDERExports@fda.hhs.go[illegible] - [illegible]hone (301) 796-4950

C[illegible]fic[illegible]te of a Pharmaceutical Produ[illegible] A[illegible]tive Pharmaceutical Ingredie[illegible] (A[illegible])

Certificate Number: **XXXX-XXXX** — Certificate I[illegible]ate: **Month DD, YYYY** — [illegible]rtificate Expiration Date: **Month DD, YYYY**

Importing Country: **AKROTIRI** — [illegible]porting Country: **UNITED STATES of AMERICA**

The actual certificate issued by [illegible] [illegible]DA may be different from this previewed [illegible]cate.

1.1	Drug Trade Name, In[illegible] National non-proprietary name (as applicable) & [illegible] fo[illegible]: **TEST**
1.2	Active Ingredient[illegible] a[illegible] am[illegible]unt(s) per unit dose (complete quantitative compos[illegible]ferred): **See Attachments**
1.3	Is this product a[illegible]ed by the certifying authority to be marketed in the ce[illegible] country or within the jurisdiction of the certifying regio[illegible]hority? **No**
1.4	Is this [illegible]t actually on the market in the certifying country or with[illegible] jurisdiction of the certifying regional authority? **No**
1.4.1	A[illegible] the[illegible] res[illegible]ictions of sale, distribution or administration of th[illegible] pro[illegible]ct s[illegible]ecified in the marketing authorization? **No**
2.B.1	Ap[illegible]icant for certificate name & address: **Mackson, 1818 [illegible]brar[illegible] St, Reston, VA 20190 United States of America**
2.[illegible]	[illegible]us of Applicant: **Manufacturer**
[illegible]	Why is marketing authorization lacking? **Not Require[illegible]**
Remarks:	**The firm proposes to export the active p[illegible]ceutical ingredient (API) listed above which is not m[illegible] in the United States of America at this time.**
3.1	Manufacturer name & address: **Macks[illegible] 18[illegible] [illegible]brary St, Reston, VA 20190 United States of Ame[illegible]a**
3.2	Does the certifying authority arra[illegible]ge for [illegible]eriodic inspection of the manufacturing plant in whic[illegible] the do[illegible]age form is produced? **Yes**
3.3	Periodicity of routine inspectio[illegible] (ye[illegible]): **Pursuant to section 510(h)(3) of the Federal Foo[illegible], Dr[illegible] & Cosmetic Act, Inspections will occur in accorda[illegible]e w[illegible] a risk-based schedule**
3.4	Has the manufacture of this typ[illegible] dosage form been inspected? **Yes**
3.5	Do the facilities [illegible]d ope[illegible]tions conform to GMPs as recommended by the WH[illegible] (G[illegible]s including 21 Code of Federal Regulations parts 210[illegible]211, [illegible] ICH Q7A): **Yes, at time of inspection, site complies [illegible]th [illegible]A cGMP**
3.6	Does the infor[illegible]mitted by the applicant satisfy the certifying authori[illegible] on [illegible]spects of the manufacture of the product undertaken [illegible] party? **Yes**

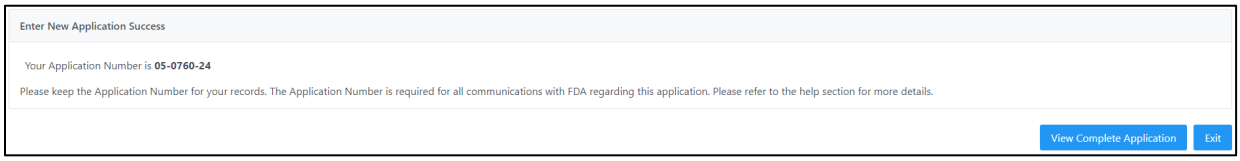
This certificate conforms to [illegible] recommended by the World Health Organization f[illegible]sed March 25, 2021. Website: www.who.int

4.23 Submitting the Application

When your application is ready for submission, click the "Submit" button – also located at the bottom of the Final Review page. The system will display a message noting your application was submitted, as shown in Figure 72 (below). The system will then provide you with an application number. Select the "Exit" button to return to the Home dashboard.

Note: 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 72 - Submission Page



5 Electronic Certificates Issued for Approved Applications

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 into FDA Industry System's CDER Export Certification Application and Tracking System (CDER eCATS). Select the Print icon from the CDER eCATS Home 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 CDER Exports Compliance Program at CDERExports@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

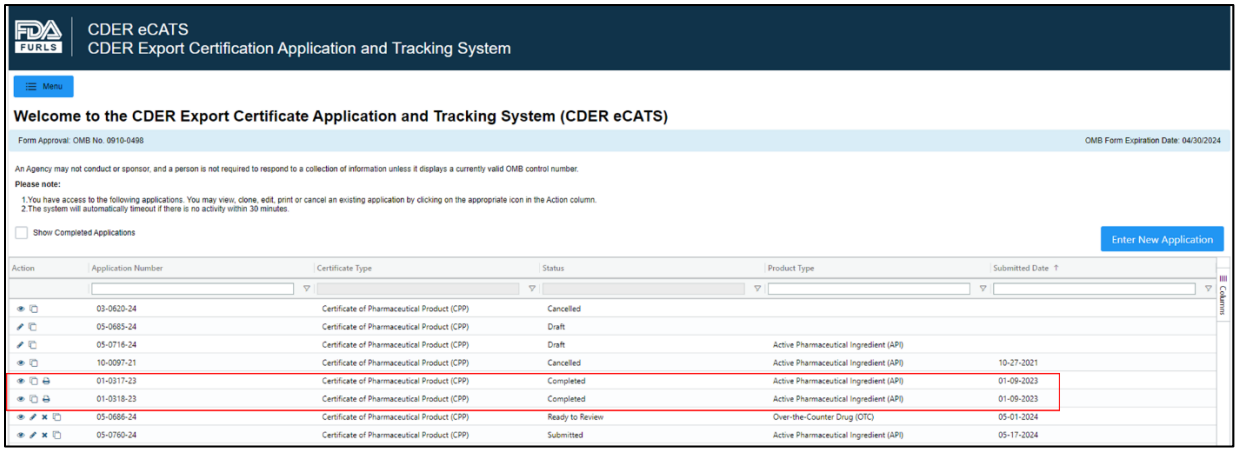
Center for Drug Evaluation and Research

U.S. Food and Drug Administration

5.2 View and Print Electronic Certificate

View your approved application and print the electronic certificate from the Home dashboard. The Print (“printer”) icon is displayed for all approved applications. The application status is “Completed”, as shown in Figure 73 (below).

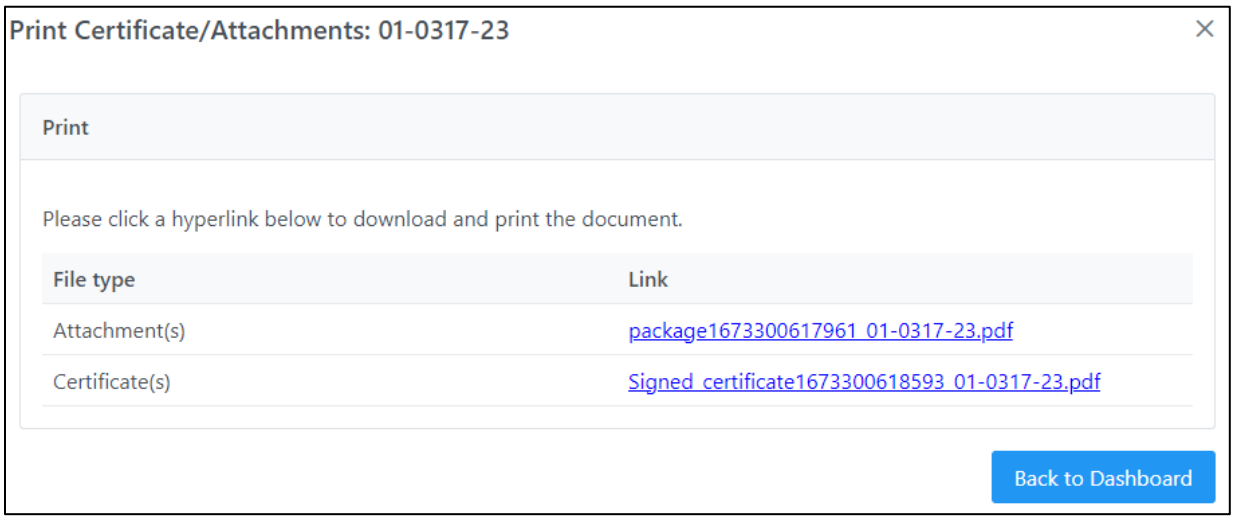
Figure 73 - Home Dashboard – Print Icon for Approved Applications



View and Print Electronic Certificate:

1. Click on the “Print” icon in the “Action” column.
2. The “Print Certificate/Attachments” window, as shown in Figure 74 (below), is displayed with hyperlinks for the attachment(s) and the generated certificate PDF(s).

Figure 74 – Select Attachment(s) or Certificate(s) to Print



3. The attachment PDF includes all the selected label and supplemental attachments to be displayed with the certificate.
4. The electronic certificate(s) include(s) a unique ribbon/seal color based on the product type:
    - **Approved Drug Products or Approved Drug Products with a Foreign Manufacturer** – Red Ribbon (see Figure 75 and Figure 76 below)
    - **Unapproved Drug Products** – Blue Ribbon (see Figure 77 below)
    - **API** – Orange Ribbon (see Figure 78 below)
    - **OTC Drug** – Purple Ribbon (see Figure 79 below)

    Note: Also included in the footer is a QR Code that can be used to authenticate the certificate.
5. Select the hyperlink to download the PDF to print. Use your browser's print settings to print the certificate(s). Figure 75 - Figure 79 illustrate examples of the electronic certificates issued.
6. Click the "Return to Dashboard" button to close the window and return to the Home dashboard.

Figure 75 - 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

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

Certificate of a Pharmaceutical Product - Approved Drug Product

Certificate Number: **ADZ2-ZVGA** Certificate Issued Date: **May 01, 2024** Certificate Expiration Date: **May 01, 2026**

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

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **TEST A**
1.2	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **test b**
1.3	Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? **Yes**
1.4	Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? **Yes**
1.4.1	Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? **No**
2.A.1	Number of marketing authorization & date of issuance: **074926 04/01/2024**
2.A.2	Marketing authorization holder (name and address): **Nights Watch, 1 The Wall, Frederick, MD 21703 United States of America**
2.A.3	Status of marketing authorization holder: **Manufacturer**
2.A.4	Is a summary basis for approval appended? **No**
2.A.5	Is the attached product information, complete and consistent with the marketing authorization? **Yes**
2.A.6	Applicant name & address for certificate (if different than the marketing authorization holder): **N/A**
2.A.7	Center weblinks to marketing authorization: Orangebook for approved drug products and Purplebook for CDER-regulated Biologics License Applications
Remarks:	
3.1	Manufacturer name & address: **Nights Watch, 1 The Wall, Frederick, MD 21703 United States of America**
3.2	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**
3.3	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**
3.4	Has the manufacture of this type of dosage form been inspected? **Yes**
3.5	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**
3.6	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**

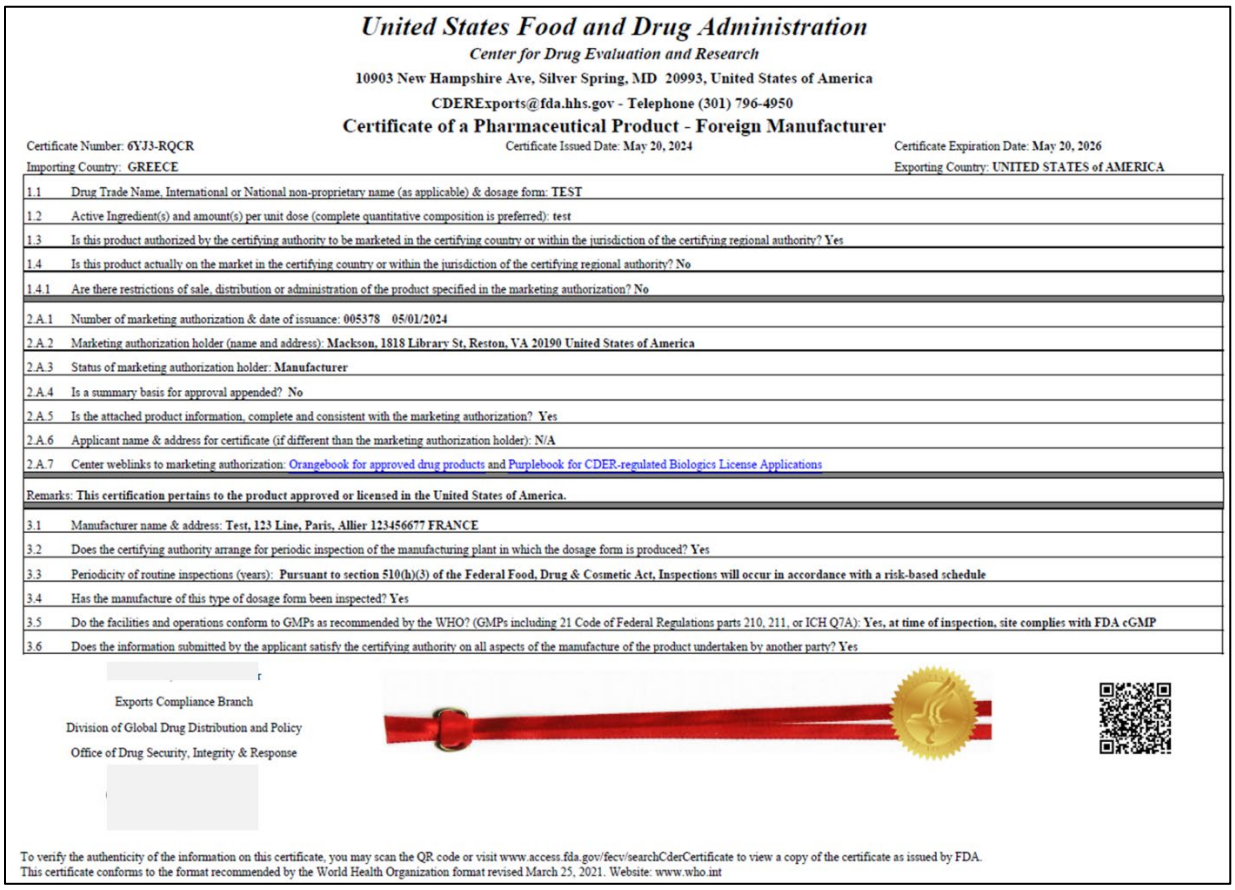
Exports Compliance Branch

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.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 March 25, 2021. Website: www.who.int

Figure 76 - Electronic Certificate – Approved Drug Product with Foreign Manufacturer



United States Food and Drug Administration

Center for Drug Evaluation and Research

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

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

Certificate of a Pharmaceutical Product - Foreign Manufacturer

Certificate Number: 6YJ3-RQCR | Certificate Issued Date: May 20, 2024 | Certificate Expiration Date: May 20, 2026

Importing Country: GREECE | Exporting Country: UNITED STATES of AMERICA

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: TEST
1.2	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): test
1.3	Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? Yes
1.4	Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? No
1.4.1	Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? No
2.A.1	Number of marketing authorization & date of issuance: 005378 05/01/2024
2.A.2	Marketing authorization holder (name and address): Mackson, 1818 Library St, Reston, VA 20190 United States of America
2.A.3	Status of marketing authorization holder: Manufacturer
2.A.4	Is a summary basis for approval appended? No
2.A.5	Is the attached product information, complete and consistent with the marketing authorization? Yes
2.A.6	Applicant name & address for certificate (if different than the marketing authorization holder): N/A
2.A.7	Center weblinks to marketing authorization: Orangebook for approved drug products and Purplebook for CDER-regulated Biologics License Applications
Remarks:	This certification pertains to the product approved or licensed in the United States of America.
3.1	Manufacturer name & address: Test, 123 Line, Paris, Allier 123456677 FRANCE
3.2	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes
3.3	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
3.4	Has the manufacture of this type of dosage form been inspected? Yes
3.5	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
3.6	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

[redacted]

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[redacted]

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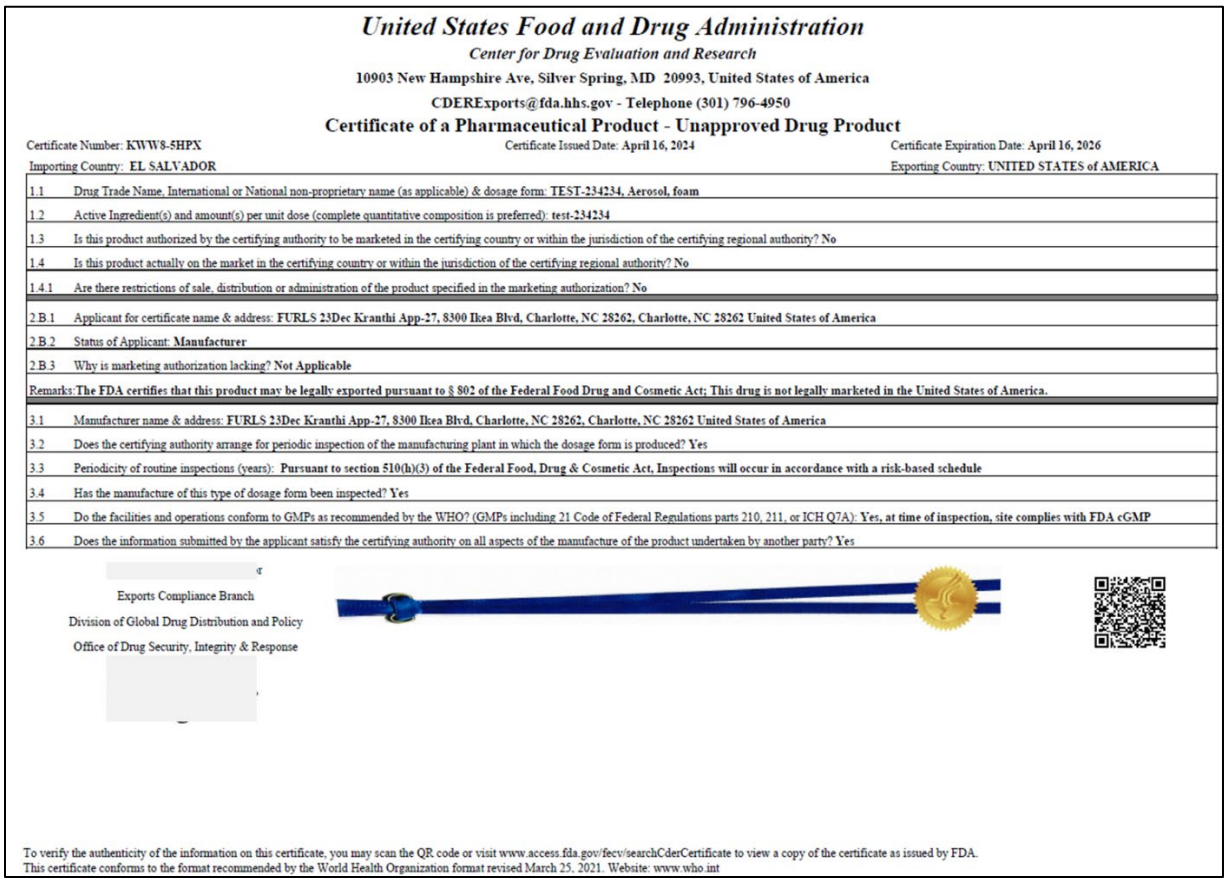
This certificate conforms to the format recommended by the World Health Organization format revised March 25, 2021. Website: www.who.int

Figure 77 - 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

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

Certificate of a Pharmaceutical Product - Unapproved Drug Product

Certificate Number: KWW8-5HPX | Certificate Issued Date: April 16, 2024 | Certificate Expiration Date: April 16, 2026

Importing Country: EL SALVADOR | Exporting Country: UNITED STATES of AMERICA

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: TEST-234234, Aerosol, foam
1.2	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): test-234234
1.3	Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? No
1.4	Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? No
1.4.1	Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? No
2.B.1	Applicant for certificate name & address: FURLS 23Dec Kranthi App-27, 8300 Ikea Blvd, Charlotte, NC 28262, Charlotte, NC 28262 United States of America
2.B.2	Status of Applicant: Manufacturer
2.B.3	Why is marketing authorization lacking? Not Applicable
Remarks:	The FDA certifies that this product may be legally exported pursuant to § 802 of the Federal Food Drug and Cosmetic Act; This drug is not legally marketed in the United States of America.
3.1	Manufacturer name & address: FURLS 23Dec Kranthi App-27, 8300 Ikea Blvd, Charlotte, NC 28262, Charlotte, NC 28262 United States of America
3.2	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes
3.3	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
3.4	Has the manufacture of this type of dosage form been inspected? Yes
3.5	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
3.6	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

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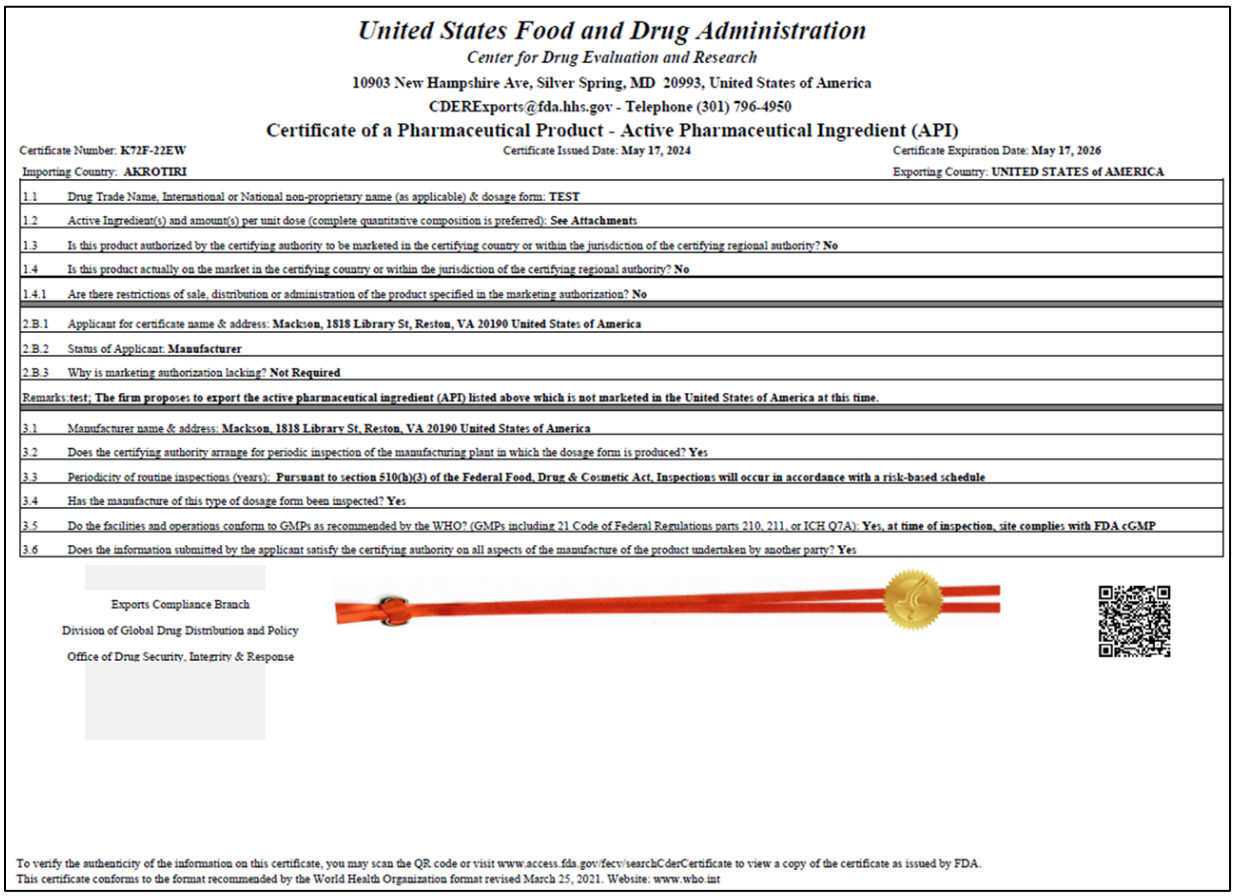
Office of Drug Security, Integrity & Response

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.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 March 25, 2021. Website: www.who.int

Figure 78 - Electronic Certificate – Active Pharmaceutical Ingredient (API)



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

Certificate of a Pharmaceutical Product - Active Pharmaceutical Ingredient (API)

Certificate Number: **K72F-22EW** Certificate Issued Date: **May 17, 2024** Certificate Expiration Date: **May 17, 2026**

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

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **TEST**
1.2	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **See Attachments**
1.3	Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? **No**
1.4	Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? **No**
1.4.1	Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? **No**
2.B.1	Applicant for certificate name & address: **Mackson, 1818 Library St, Reston, VA 20190 United States of America**
2.B.2	Status of Applicant: **Manufacturer**
2.B.3	Why is marketing authorization lacking? **Not Required**
Remarks:	test; **The firm proposes to export the active pharmaceutical ingredient (API) listed above which is not marketed in the United States of America at this time.**
3.1	Manufacturer name & address: **Mackson, 1818 Library St, Reston, VA 20190 United States of America**
3.2	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**
3.3	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**
3.4	Has the manufacture of this type of dosage form been inspected? **Yes**
3.5	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**
3.6	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**

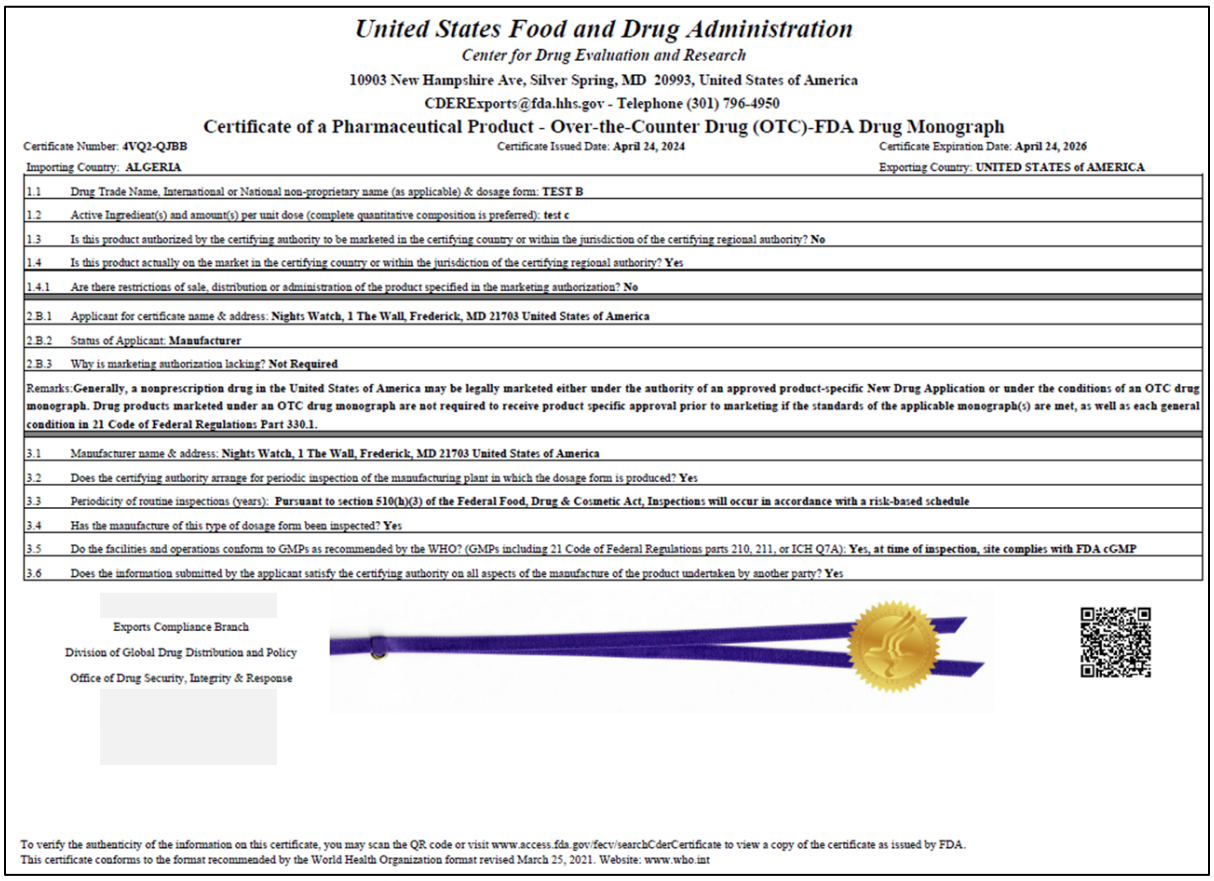
Exports Compliance Branch

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.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 March 25, 2021. Website: www.who.int

Figure 79 - Electronic Certificate – OTC



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

Certificate of a Pharmaceutical Product - Over-the-Counter Drug (OTC)-FDA Drug Monograph

Certificate Number: **4VQ2-QJBB** Certificate Issued Date: **April 24, 2024** Certificate Expiration Date: **April 24, 2026**

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

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **TEST B**
1.2	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **test c**
1.3	Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? **No**
1.4	Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? **Yes**
1.4.1	Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? **No**
2.B.1	Applicant for certificate name & address: **Nights Watch, 1 The Wall, Frederick, MD 21703 United States of America**
2.B.2	Status of Applicant: **Manufacturer**
2.B.3	Why is marketing authorization lacking? **Not Required**
Remarks:	**Generally, a nonprescription drug in the United States of America may be legally marketed either under the authority of an approved product-specific New Drug Application or under the conditions of an OTC drug monograph. Drug products marketed under an OTC drug monograph are not required to receive product specific approval prior to marketing if the standards of the applicable monograph(s) are met, as well as each general condition in 21 Code of Federal Regulations Part 330.1.**
3.1	Manufacturer name & address: **Nights Watch, 1 The Wall, Frederick, MD 21703 United States of America**
3.2	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**
3.3	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**
3.4	Has the manufacture of this type of dosage form been inspected? **Yes**
3.5	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**
3.6	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**

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Office of Drug Security, Integrity & Response

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This certificate conforms to the format recommended by the World Health Organization format revised March 25, 2021. Website: www.who.int

5.3 Additional Certificate Pages

If additional manufacturers are selected to display on the certificate, or large remarks are added, a second certificate page is generated. The second certificate page displays the following header information:

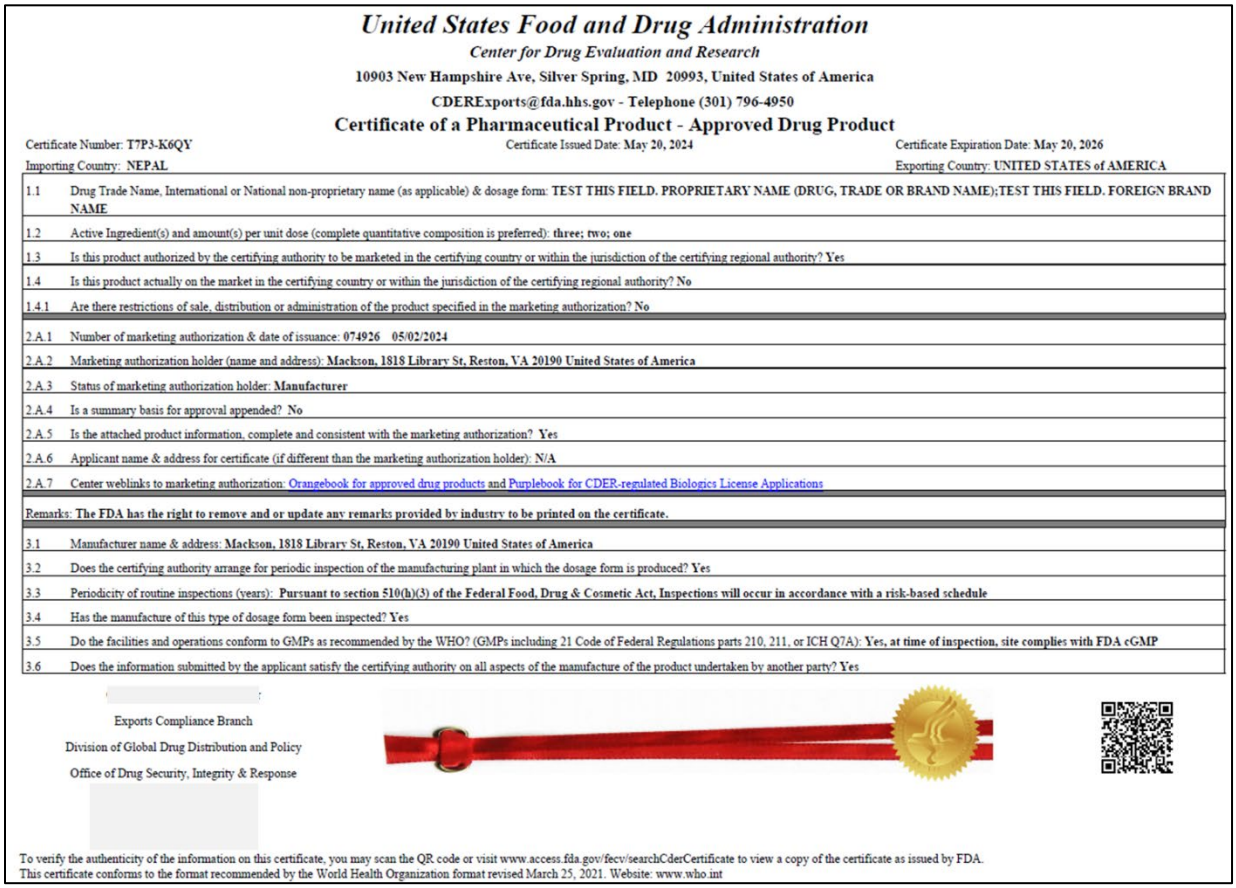
- Certificate Number
- Certificate Issued Date
- Certificate Expiration Date
- Importing Country
- Exporting Country
- Product Name

Additional Manufacturers

If any additional manufacturers are added to the application, and selected to display on the certificate, the first manufacturer information is displayed in Line 3.1; see Figure 80 (below).

Any additional manufacturers' information is displayed on a second page; see Figure 81 (below).

Figure 80 - Electronic Certificate – Manufacturer Information



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

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

Certificate of a Pharmaceutical Product - Approved Drug Product

Certificate Number: T7P3-K6QY | Certificate Issued Date: May 20, 2024 | Certificate Expiration Date: May 20, 2026

Importing Country: NEPAL | Exporting Country: UNITED STATES of AMERICA

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: TEST THIS FIELD. PROPRIETARY NAME (DRUG, TRADE OR BRAND NAME);TEST THIS FIELD. FOREIGN BRAND NAME
1.2	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): three; two; one
1.3	Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? Yes
1.4	Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? No
1.4.1	Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? No
2.A.1	Number of marketing authorization & date of issuance: 074926 05/02/2024
2.A.2	Marketing authorization holder (name and address): Mackson, 1818 Library St, Reston, VA 20190 United States of America
2.A.3	Status of marketing authorization holder: Manufacturer
2.A.4	Is a summary basis for approval appended? No
2.A.5	Is the attached product information, complete and consistent with the marketing authorization? Yes
2.A.6	Applicant name & address for certificate (if different than the marketing authorization holder): N/A
2.A.7	Center weblinks to marketing authorization: Orangebook for approved drug products and Purplebook for CDER-regulated Biologics License Applications
Remarks:	The FDA has the right to remove and or update any remarks provided by industry to be printed on the certificate.
3.1	Manufacturer name & address: Mackson, 1818 Library St, Reston, VA 20190 United States of America
3.2	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes
3.3	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
3.4	Has the manufacture of this type of dosage form been inspected? Yes
3.5	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
3.6	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

Exports 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.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 March 25, 2021. Website: www.who.int

Figure 81 - Electronic Certificate – Additional Manufacturer Information

FOR A CDER - REGULATED HUMAN DRUG

Certificate Number: T7P3-K6QY | Certificate Issued Date: May 20, 2024 | Certificate Expiration Date: May 20, 2026

Importing Country: NEPAL | Exporting Country: UNITED STATES of AMERICA

Product Name: TEST THIS FIELD. PROPRIETARY NAME (DRUG, TRADE OR BRAND NAME);TEST THIS FIELD. FOREIGN BRAND NAME

ADDITIONAL MANUFACTURER INFORMATION

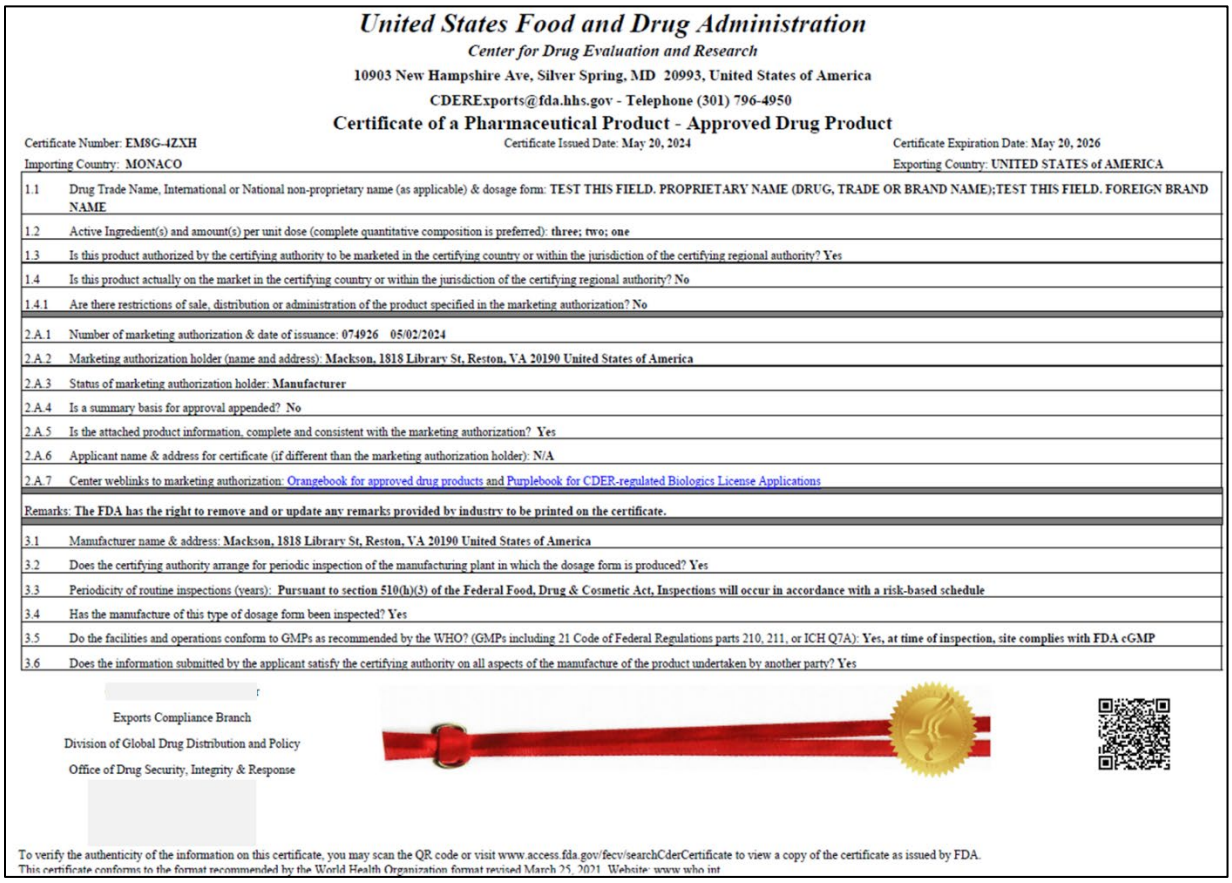
This attachment is to attest that the establishments listed below may manufacture, prepare, market, and legally export the products associated with the human drug identified in the CPP number listed above as of the date of this certificate issuance date. The facilities listed below are subject to the jurisdiction of FDA and are subject to periodic inspections. The last inspection at each facility showed substantial compliance with Current Good Manufacturing Practice (CGMP) regulations as required by the Federal Food, Drug, and Cosmetic Act. The list of facilities may not include all sites that may manufacture, prepare, market, and legally export the product identified above, but are sites that the applicant of this request included on this certificate request to review by CDER. Any facility associated with the manufacture, preparation, or marketing of the drug that is the subject of the associated CPP that did not achieve substantial compliance with CGMPs is not listed on this declaration.

Name of Manufacturing Site	Address	Activity
Add Man1	Man1 Line1, Herndon, VA 20190	Packager
Add Man2	Man2 Line2, Herndon, VA 20170	Relabeler

Large Remarks

For applications with large Remarks selected to display on the certificate, the Remarks will display as truncated text in the Remarks row on the certificate, as shown in Figure 82 (below). The complete Remarks will be displayed on the second page, as shown in Figure 83 (below).

Figure 82 - Electronic Certificate – Long Remarks Truncated



United States Food and Drug Administration

Center for Drug Evaluation and Research

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

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

Certificate of a Pharmaceutical Product - Approved Drug Product

Certificate Number: EM8G-4ZXH | Certificate Issued Date: May 20, 2024 | Certificate Expiration Date: May 20, 2026

Importing Country: MONACO | Exporting Country: UNITED STATES of AMERICA

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: TEST THIS FIELD. PROPRIETARY NAME (DRUG, TRADE OR BRAND NAME);TEST THIS FIELD. FOREIGN BRAND NAME
1.2	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): three; two; one
1.3	Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? Yes
1.4	Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? No
1.4.1	Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? No
2.A.1	Number of marketing authorization & date of issuance: 074926 05/02/2024
2.A.2	Marketing authorization holder (name and address): Mackson, 1818 Library St, Reston, VA 20190 United States of America
2.A.3	Status of marketing authorization holder: Manufacturer
2.A.4	Is a summary basis for approval appended? No
2.A.5	Is the attached product information, complete and consistent with the marketing authorization? Yes
2.A.6	Applicant name & address for certificate (if different than the marketing authorization holder): N/A
2.A.7	Center weblinks to marketing authorization: Orangebook for approved drug products and Purplebook for CDER-regulated Biologics License Applications
Remarks:	The FDA has the right to remove and or update any remarks provided by industry to be printed on the certificate.
3.1	Manufacturer name & address: Mackson, 1818 Library St, Reston, VA 20190 United States of America
3.2	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes
3.3	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
3.4	Has the manufacture of this type of dosage form been inspected? Yes
3.5	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
3.6	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

Exports Compliance Branch

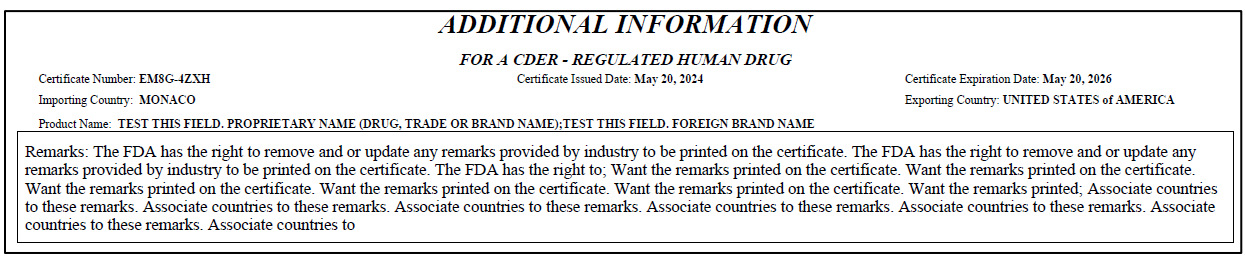
Division of Global Drug Distribution and Policy

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.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 March 25, 2021. Website: www.who.int

Figure 83 - Electronic Certificate – Additional Information (Remarks)



ADDITIONAL INFORMATION

FOR A CDER - REGULATED HUMAN DRUG

Certificate Number: EM8G-4ZXH | Certificate Issued Date: May 20, 2024 | Certificate Expiration Date: May 20, 2026

Importing Country: MONACO | Exporting Country: UNITED STATES of AMERICA

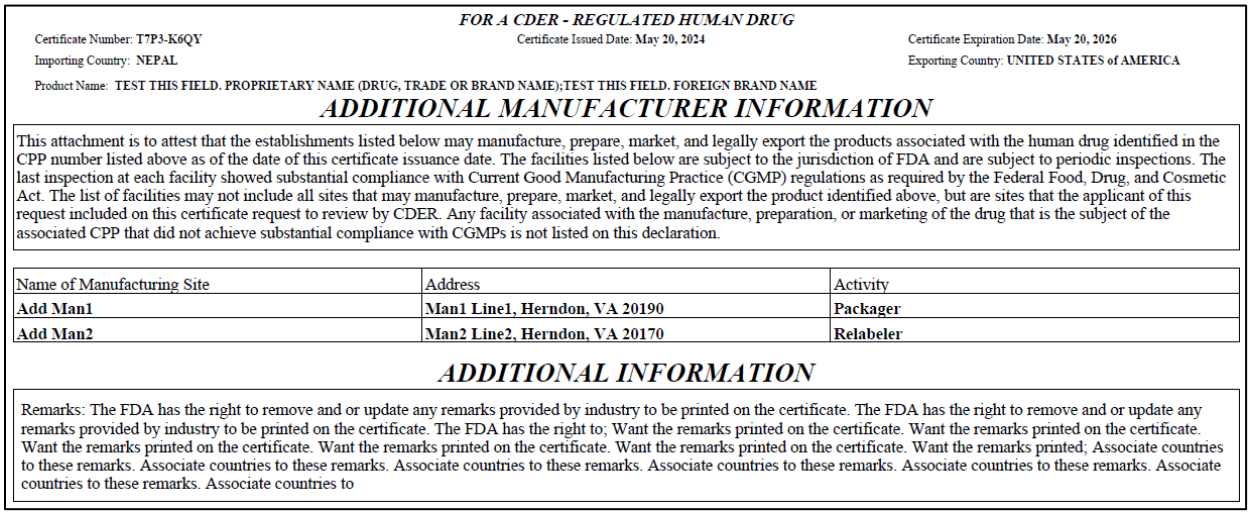
Product Name: TEST THIS FIELD. PROPRIETARY NAME (DRUG, TRADE OR BRAND NAME);TEST THIS FIELD. FOREIGN BRAND NAME

Remarks: The FDA has the right to remove and or update any remarks provided by industry to be printed on the certificate. The FDA has the right to remove and or update any remarks provided by industry to be printed on the certificate. The FDA has the right to; Want the remarks printed on the certificate. Want the remarks printed on the certificate. Want the remarks printed on the certificate. Want the remarks printed on the certificate. Want the remarks printed on the certificate. Want the remarks printed; Associate countries to these remarks. Associate countries to these remarks. Associate countries to these remarks. Associate countries to these remarks. Associate countries to these remarks. Associate countries to these remarks. Associate countries to

Additional Manufacturers and Larger Remarks

For applications with more than two manufacturers and larger Remarks – both of which are selected to display on the certificate – the manufacturer list and full Remarks will display on the second page, as shown in Figure 84 (below).

Figure 84 - Electronic Certificate – Additional Manufacturers and Long Remarks



FOR A CDER - REGULATED HUMAN DRUG

Certificate Number: T7P3-K6QY | Certificate Issued Date: May 20, 2024 | Certificate Expiration Date: May 20, 2026

Importing Country: NEPAL | Exporting Country: UNITED STATES of AMERICA

Product Name: TEST THIS FIELD. PROPRIETARY NAME (DRUG, TRADE OR BRAND NAME);TEST THIS FIELD. FOREIGN BRAND NAME

ADDITIONAL MANUFACTURER INFORMATION

This attachment is to attest that the establishments listed below may manufacture, prepare, market, and legally export the products associated with the human drug identified in the CPP number listed above as of the date of this certificate issuance date. The facilities listed below are subject to the jurisdiction of FDA and are subject to periodic inspections. The last inspection at each facility showed substantial compliance with Current Good Manufacturing Practice (CGMP) regulations as required by the Federal Food, Drug, and Cosmetic Act. The list of facilities may not include all sites that may manufacture, prepare, market, and legally export the product identified above, but are sites that the applicant of this request included on this certificate request to review by CDER. Any facility associated with the manufacture, preparation, or marketing of the drug that is the subject of the associated CPP that did not achieve substantial compliance with CGMPs is not listed on this declaration.

Name of Manufacturing Site	Address	Activity
Add Man1	**Man1 Line1, Herndon, VA 20190**	**Packager**
Add Man2	**Man2 Line2, Herndon, VA 20170**	**Relabeler**

ADDITIONAL INFORMATION

Remarks: The FDA has the right to remove and or update any remarks provided by industry to be printed on the certificate. The FDA has the right to remove and or update any remarks provided by industry to be printed on the certificate. The FDA has the right to; Want the remarks printed on the certificate. Want the remarks printed on the certificate. Want the remarks printed on the certificate. Want the remarks printed on the certificate. Want the remarks printed on the certificate. Want the remarks printed; Associate countries to these remarks. Associate countries to these remarks. Associate countries to these remarks. Associate countries to these remarks. Associate countries to these remarks. Associate countries to these remarks. Associate countries to

6 Responding to Return for Action

FDA Reviewers may return the application back to applicants to make modifications, as needed.

Review the Email Notification:

If your application is incomplete, the system will send you an email notification informing you the 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(s) and submit:

1. Locate the application which has the status of “Returned for Action”. See Section 7: Modify Application for detailed steps on modifying the application.
2. Make the required change(s) described in the email notification. Next, resubmit the application after filling out the “Attestation” section.

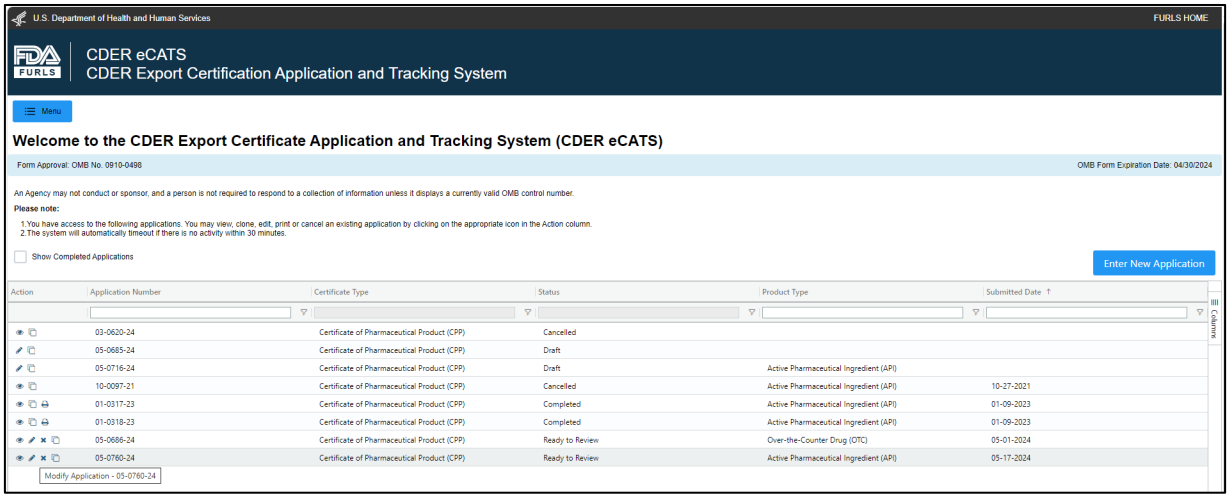
   Note: *You must complete and submit your return-for-action application within three business days of receipt*. A Return for Action (RFA) application is automatically canceled if it is not corrected and resubmitted within three business

days from the time it is returned for action by the FDA reviewer to the applicant.

7 Modify Application

The ability to modify an application is based on the application status. Applications that can be modified have the Modify (“pencil”) icon displayed, as shown in Figure 85 (below).

Figure 85 – Modify Application from the Home Dashboard



7.1 Modify Application

1. To modify an application, select the Modify (“pencil”) icon from the Home dashboard.
2. For applications in “Draft” status, the system will display Section 1 to continue completing the application.
3. For applications in any status except “Draft” or “Completed”, the system will display the Modify Application Type page, as shown in Figure 86 (below).

Figure 86 - Modify Application Type

4. Select the option “Modify an application based on a notification received” and click “Next” button. If the application is not in “Return for Action” status, an error message is displayed, as shown in Figure 87 (below).

Figure 87 – Modify Application Error Message

5. For applications in “Return for Action” status, the system will navigate you to the Final Review page. The system will display the application with an Edit (“paper and pencil”) icon next to each section, as shown in Figure 88 - Figure 93 (below).

Figure 88 - Final Review Page Section 1

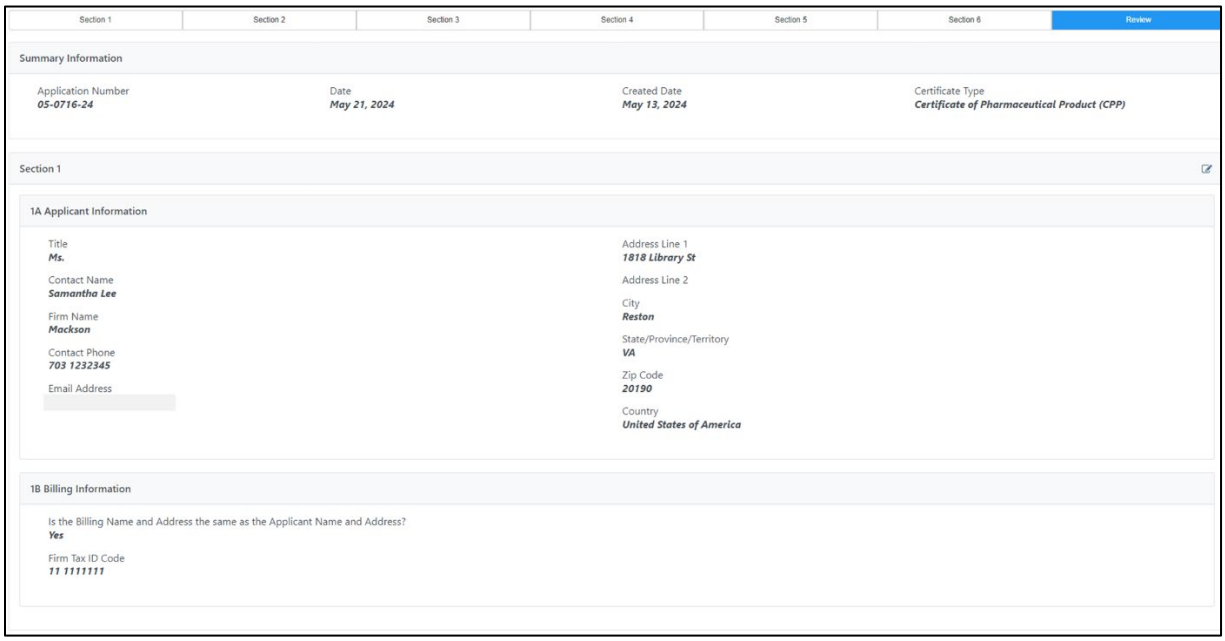


Figure 89 - Final Review Page Section 2

Note: Section 2 fields displayed are based on the Product Type.

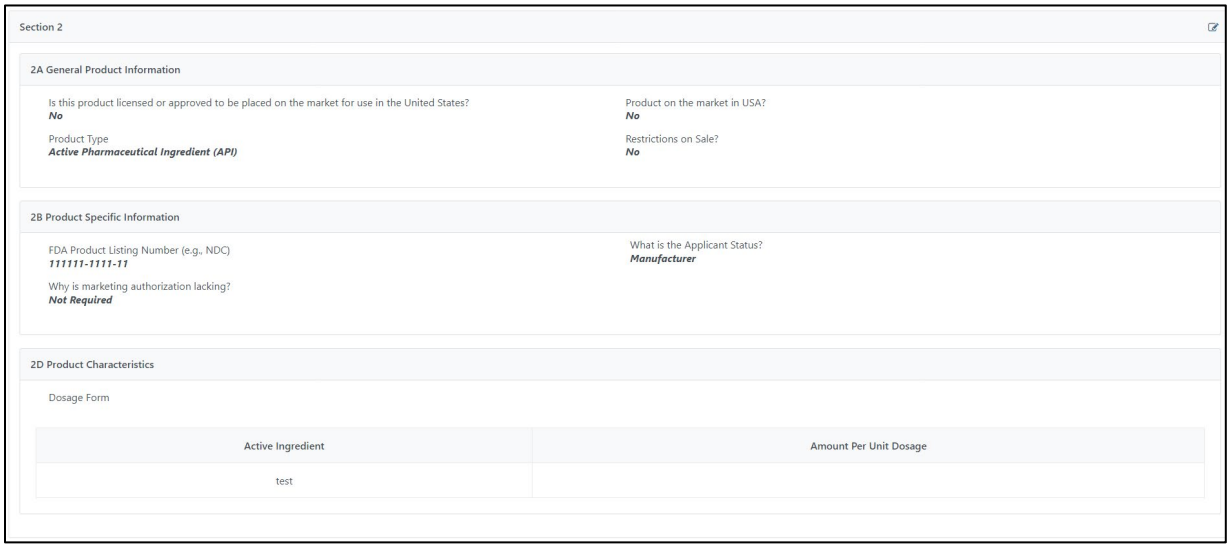


Figure 90 - Final Review Page Section 3

Figure 91 - Final Review Page Section 4

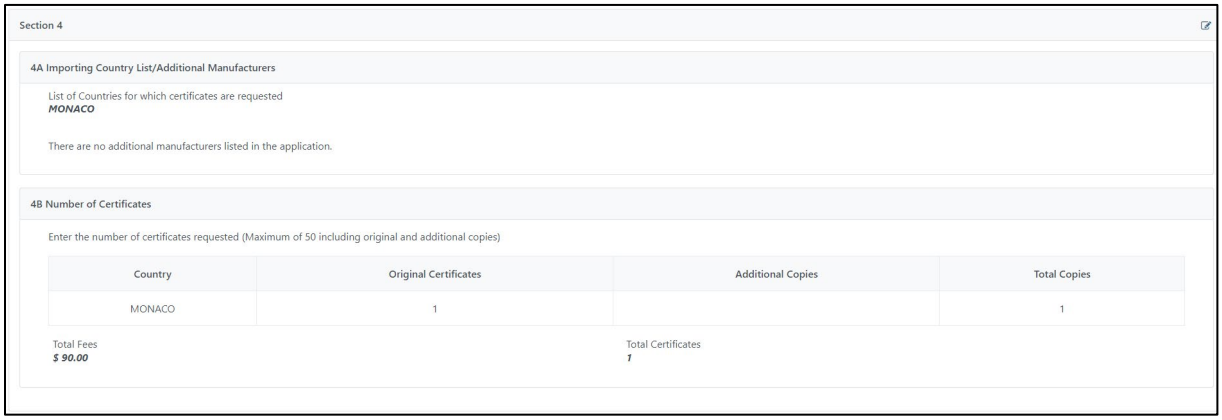


Figure 92 - Final Review Page Section 5

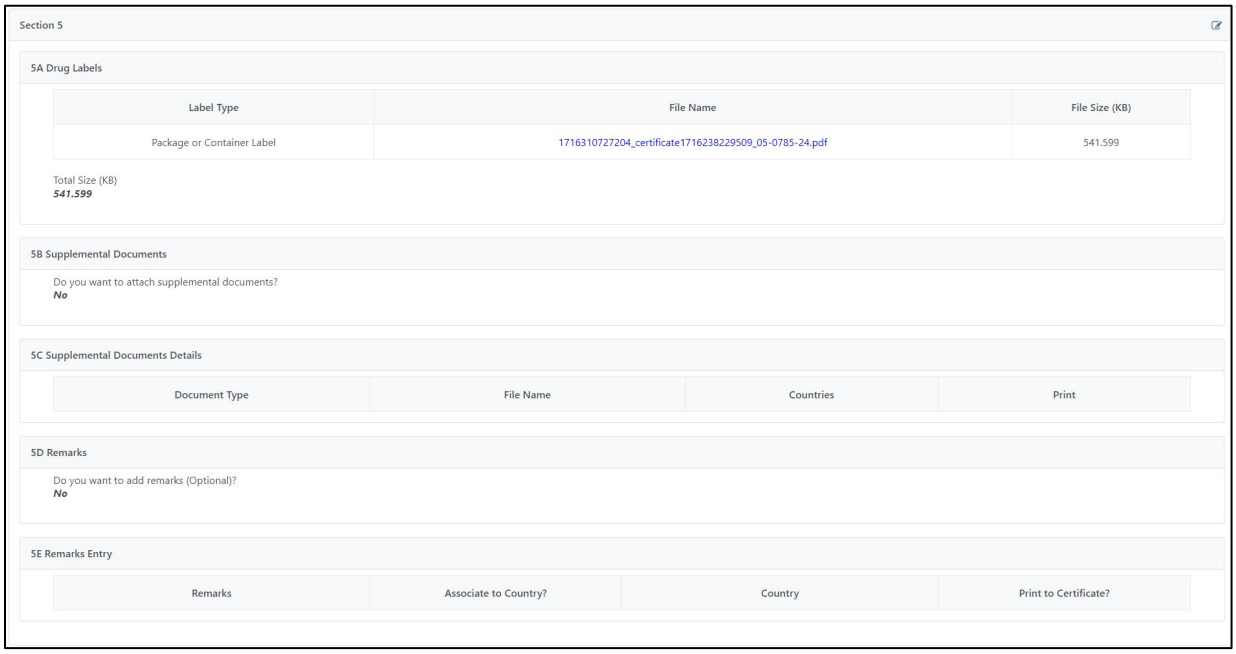
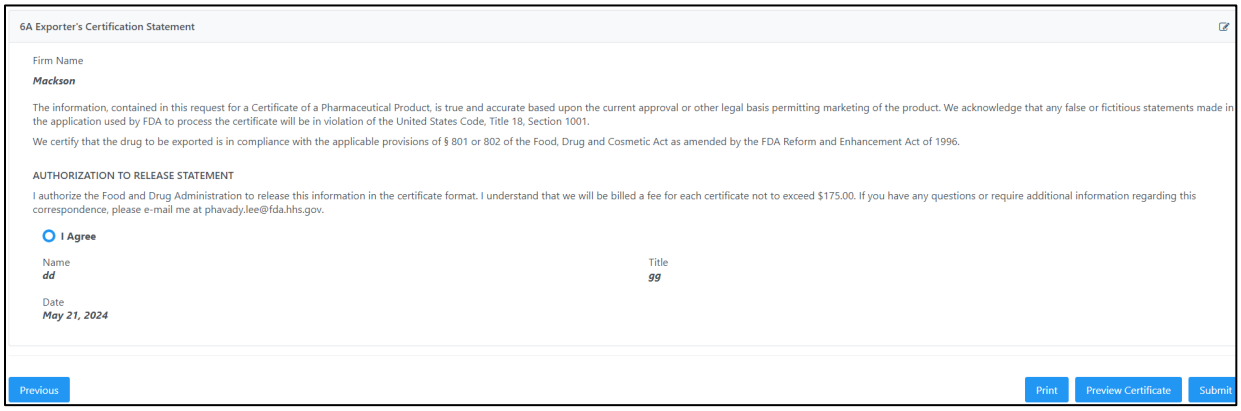


Figure 93 - Final Review Page Section 6



6. Click on the Edit ("paper and pencil") icon next to the section you would like to modify.
7. 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.
8. Click "Submit". The system will:
    - Displays the application number and a message stating the application has been successfully updated
    - Send a confirmation email

7.2 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 to update the number of certificates requested:

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

Note: Once the application is in a "Completed" status, you will not be able to update the number of certificates requested. You will need to submit a new application.

1. Select the Modify ("pencil") icon from the Home dashboard.
2. The system will display the Modify Application Type page, as shown in Figure 86 (above).
3. Select the "Update number of certificates requested" option and click "Next", as shown in Figure 94 (below).

Figure 94 - Update Number of Certificates Requested

1. The system will display the Final Review page. The Edit ("paper and pencil") icon will not be displayed for each section.
2. In Section 4B - Number of Certificates, the column "Additional Copies requested" is editable, as shown in Figure 95 (below).

Figure 95 - Final Review Page with Edit Option Only for Section 4B Number of Certificates

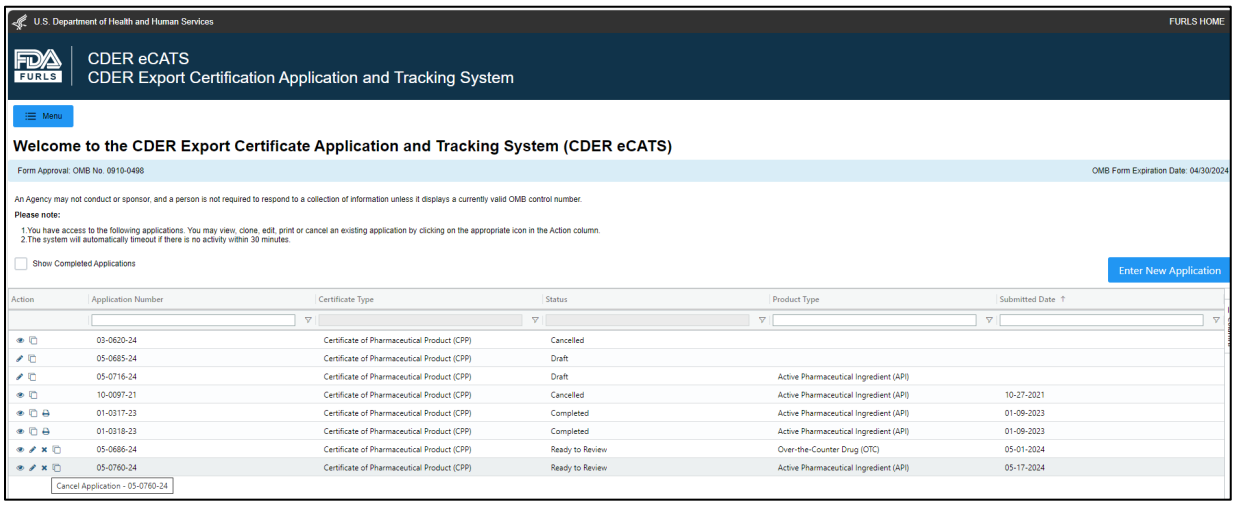
3. Enter the additional copies in the “Additional Copies Requested” field(s). This is available for each of countries you entered in the application.
4. Once you have entered the number click “Submit”. The system will perform the following:
    - Display the application number and a message confirming the application has been successfully updated
    - Send a confirmation email

8 Cancel an Application

The ability to cancel an application is based on the Application Status. Applications that can be modified has the Delete (“x”) icon displayed in the Home dashboard, as shown in Figure 96 (below). Only applications in one of the following statuses can be cancelled:

- Received
- Ready to Review
- Return for Action

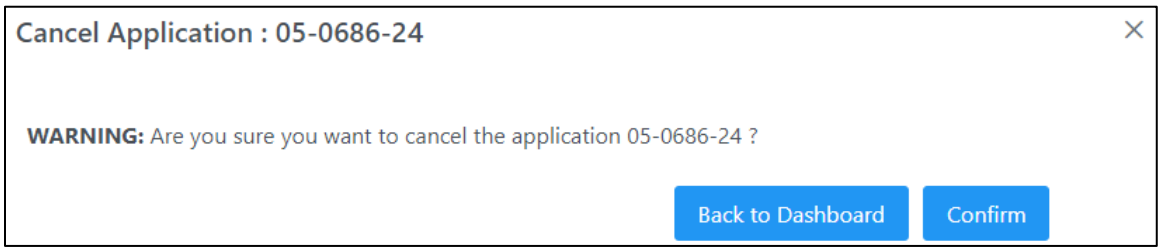
Figure 96 - Cancel Application from the Home Dashboard



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 cderexports@fda.hhs.gov if you have any questions.

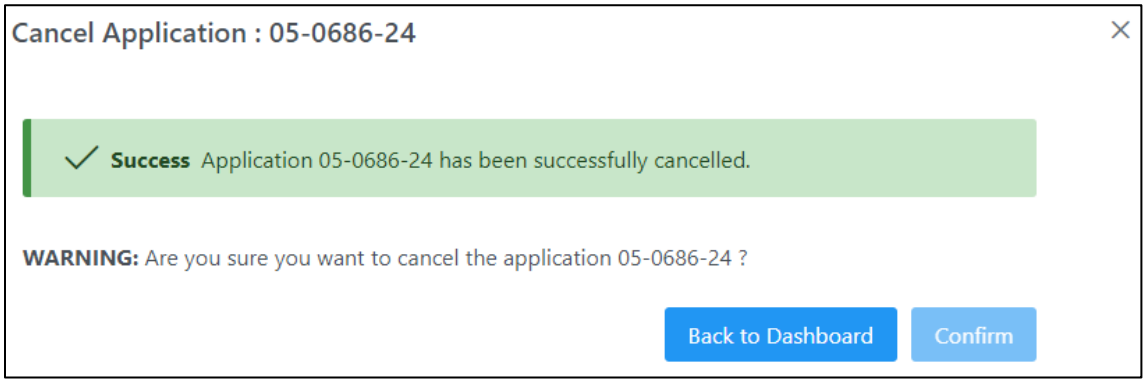
1. Click on the Delete (“x”) icon for the application to be cancelled.
   The system will display a warning message prior to cancelling an application, as shown in Figure 97 (below).

Figure 97 - Cancel the Application Warning



2. Select the “Confirm” button. Once confirmed, the system will cancel the application and display a success message, as shown in Figure 99 (below).
3. Select the “Return to Dashboard” button to close the window and return to the Home dashboard. The application remains in your list of applications with the status of “Cancelled”. You will receive an email notification confirming the cancelled application.

Figure 98 - Application Successfully Cancelled Message Displayed



9 Submitting an Export Notification Letter

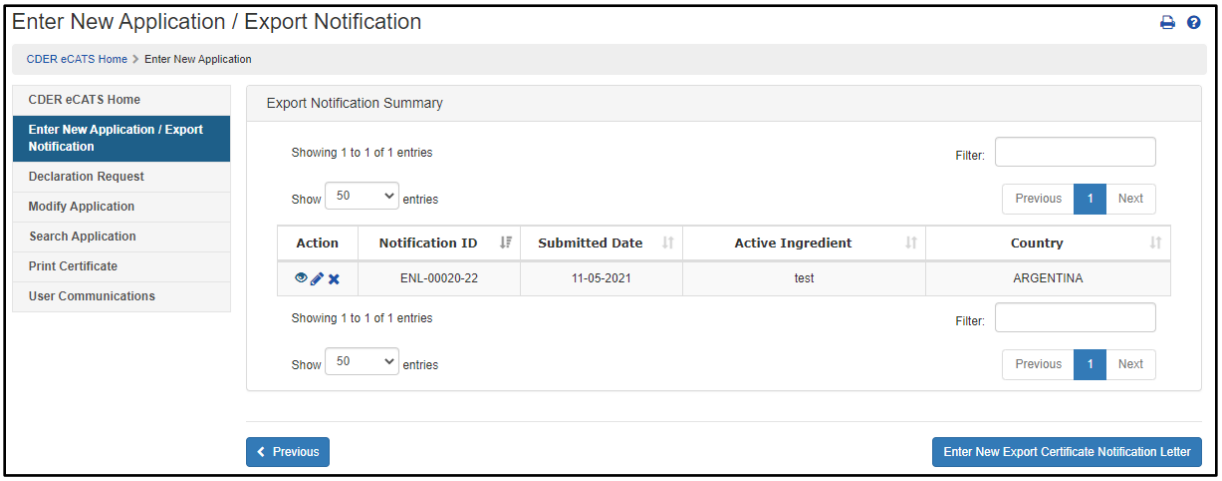
Once you have selected “CDER Export Certification Application & Tracking System”, the system will navigate you to the CDER eCATS Main Menu page.

1. 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 99 (below).

Figure 99 - Export Notification Letter

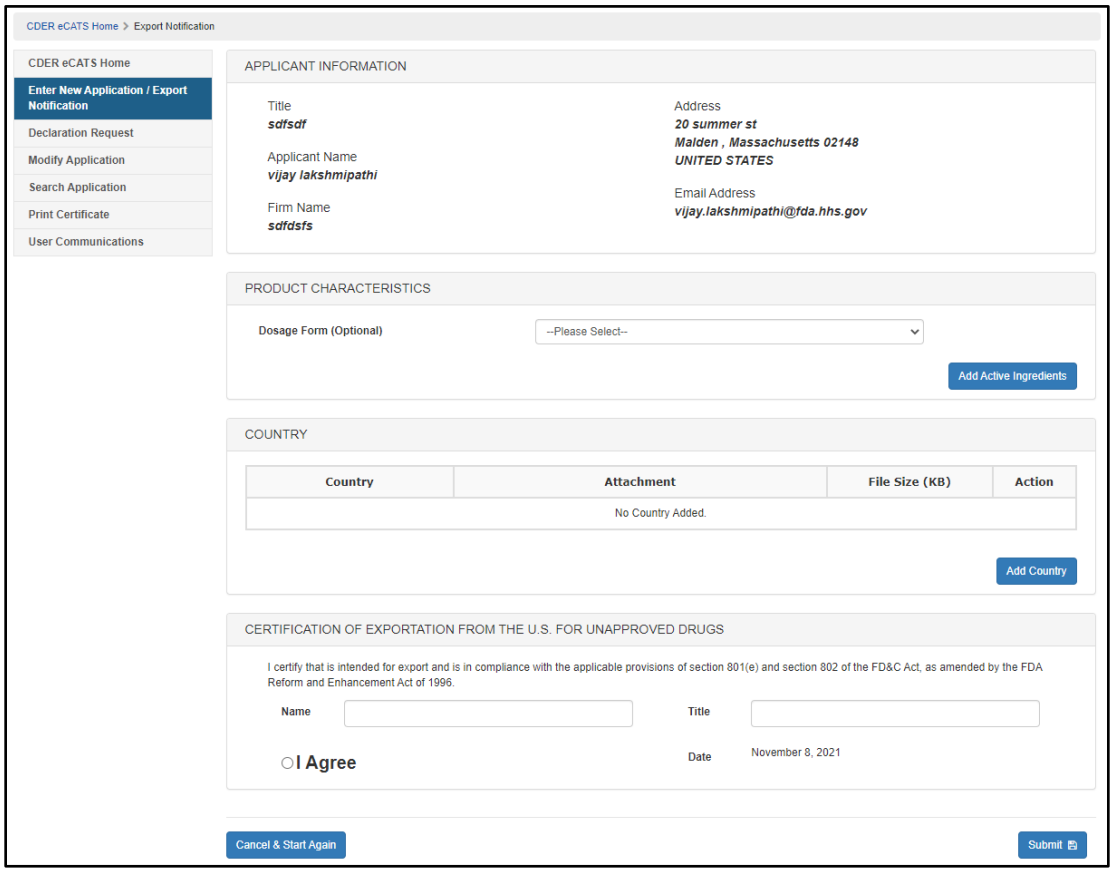
2. Select “Export Notification Letter”. All the export notification letters you have submitted will be displayed, as shown in Figure 100 (below).

Figure 100 - Account Export Notification Letters



3. 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 101 (below).

Figure 101 - Create New Export Notification Letter



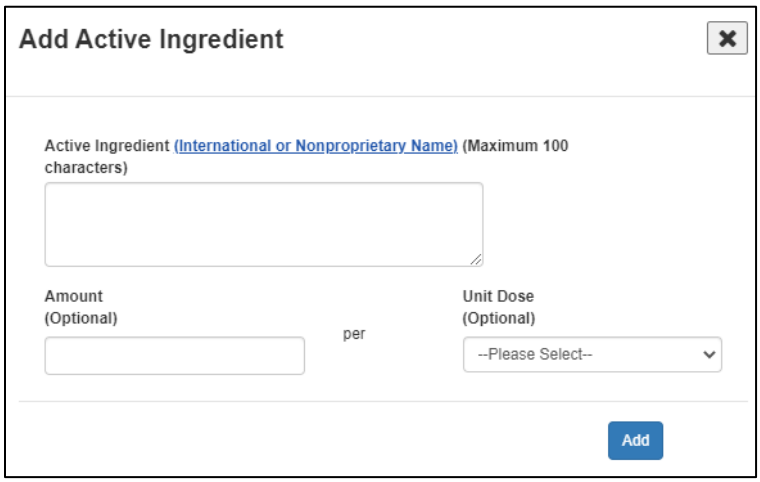
Applicant Information:

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 OAA and cannot be edited in CDER eCATS. If the information is incorrect, you can click on the “OAA Account” hyperlink and log into your account.

Product Characteristics:

1. Select the “Dosage Form”, if applicable.
2. Select the “Add Active Ingredient” button to add an active ingredient; at least one must be added.
3. Enter the “Active Ingredient” and click the “Add” button, as shown in Figure 102 (below).

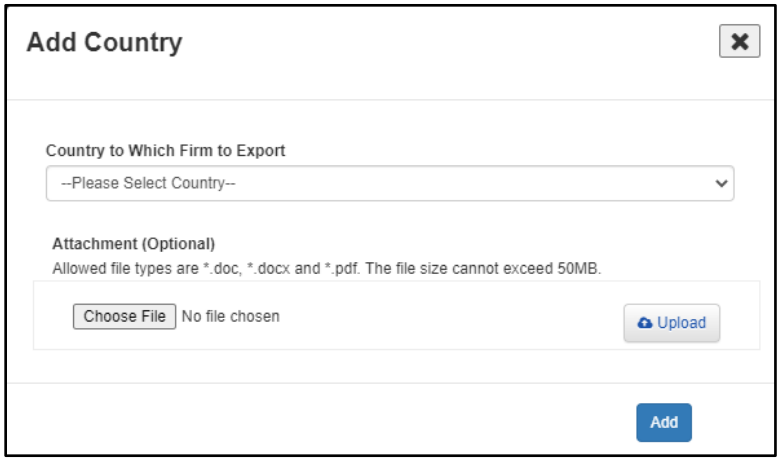
Figure 102 - Add Active Ingredient



Country:

1. Select the “Add Country” button to add country information, as shown in Figure 103 (below).
2. Select a country, add attachment(s) (if applicable), and click the “Add” button.

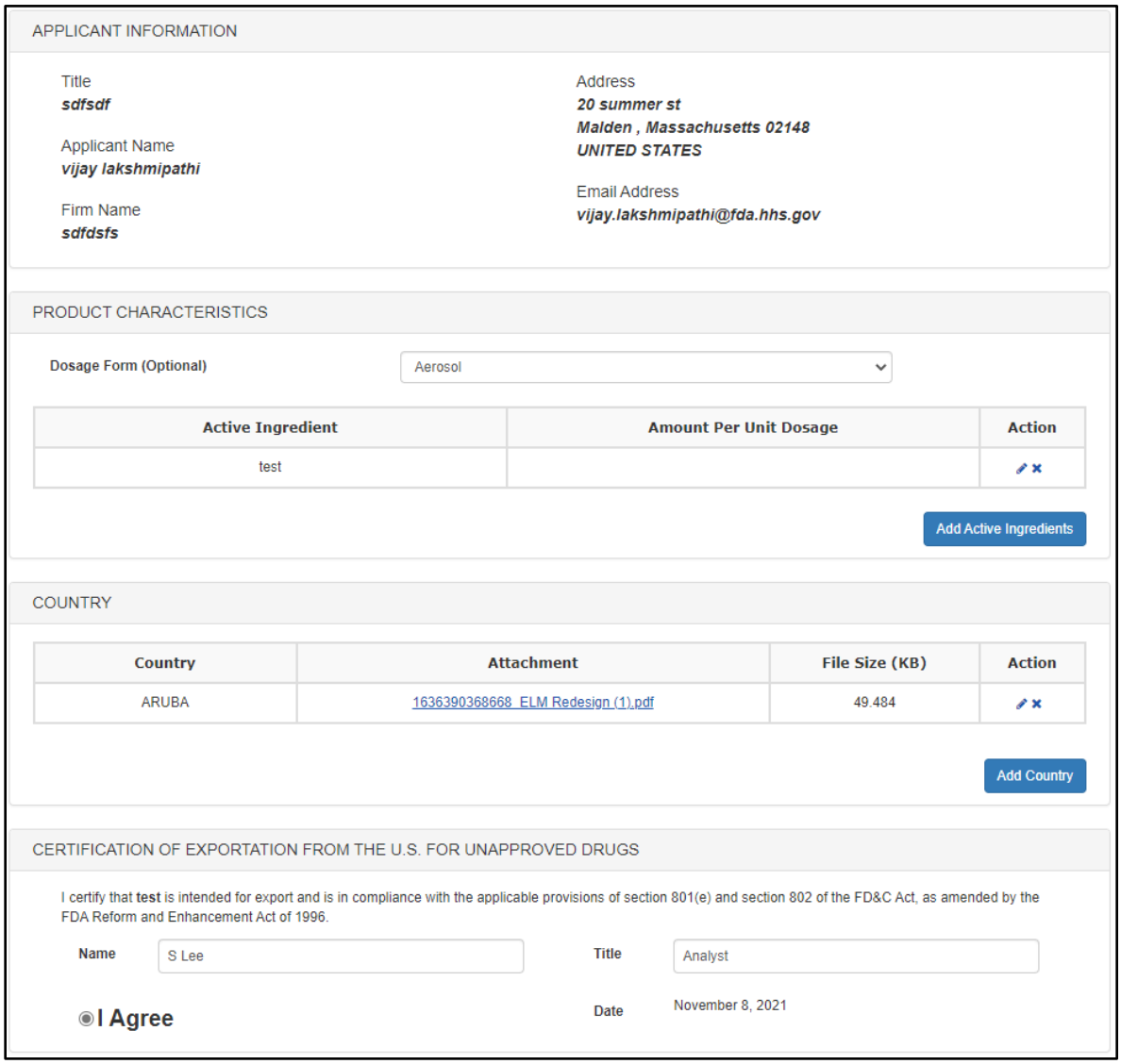
Figure 103 - Add Country



Submitting the Export Notification Letter:

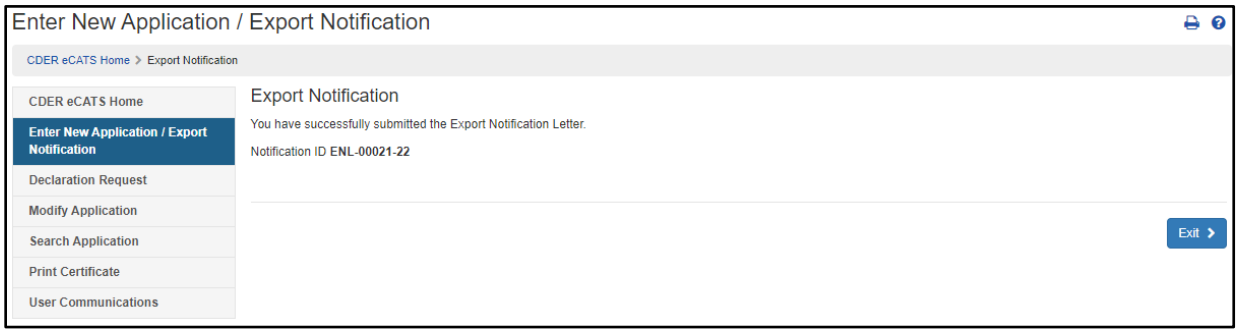
1. When your application is ready for submission, click on the “Submit” button located at the bottom of the page, as shown in Figure 104 (below).

Figure 104 - Review Export Notification Letter



2. The system will display a message stating your export notification letter was submitted, as shown in Figure 105 (below). The system will provide you with a "Notification ID" number. **Please save this number for future reference**.

Figure 105 - Submission Page

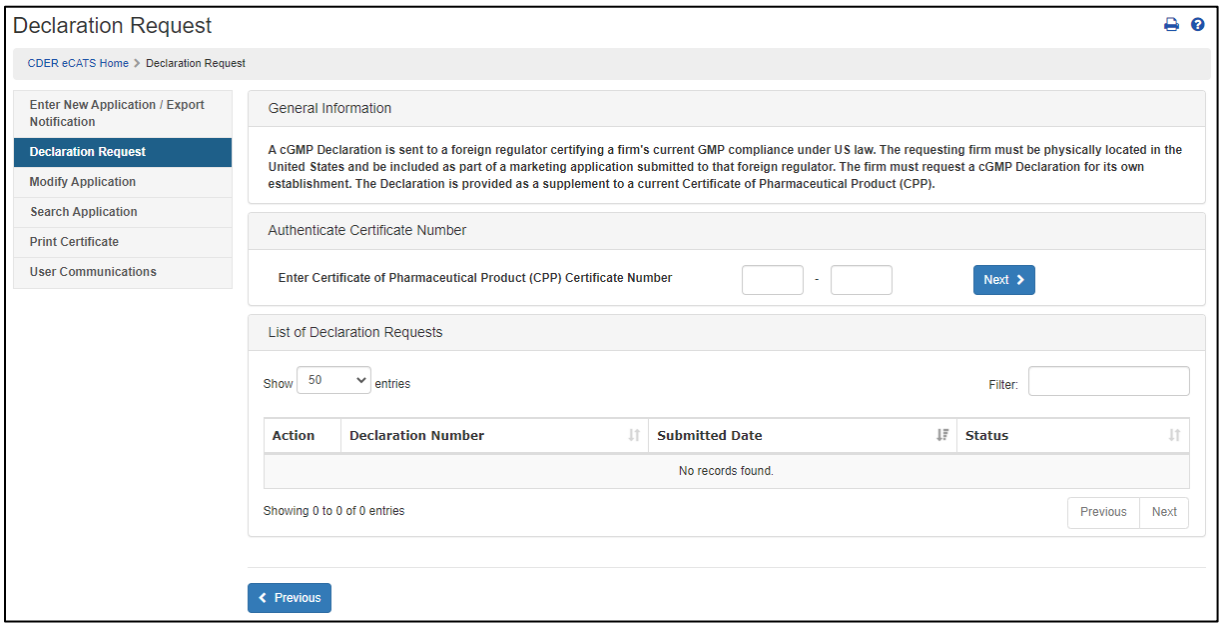


10 Declaration Request

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

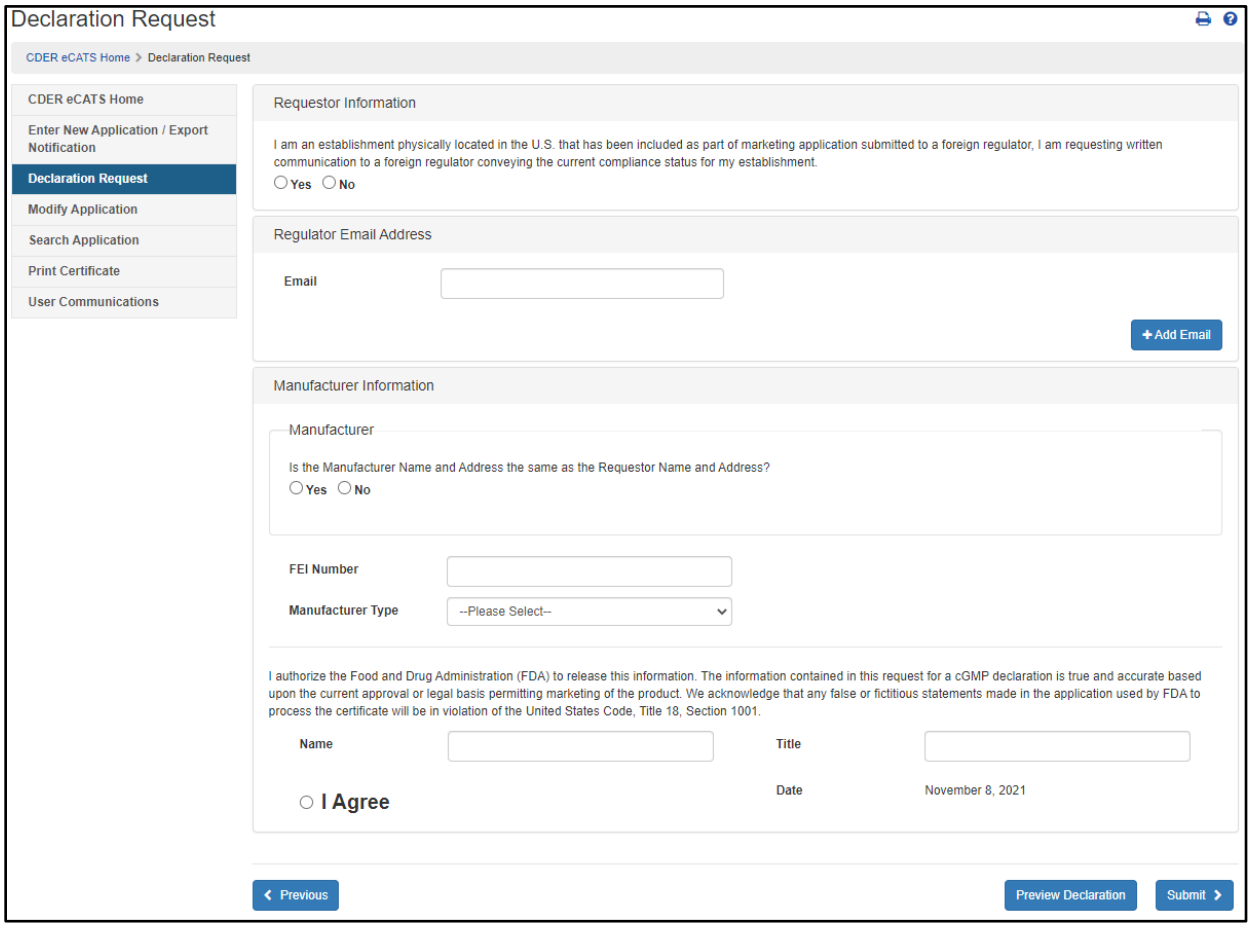
1. Select the “Declaration Request” option and all Declaration Requests you have submitted will be displayed, as shown in Figure 106 (below).

Figure 106 - Account Declaration Requests



2. Enter a CPP Certification Number and click “Next”. The Declaration Request will be displayed, as shown in Figure 107 (below).

Figure 107 - Create New Declaration Request



Requestor Information:

Select “Yes” or “No”.

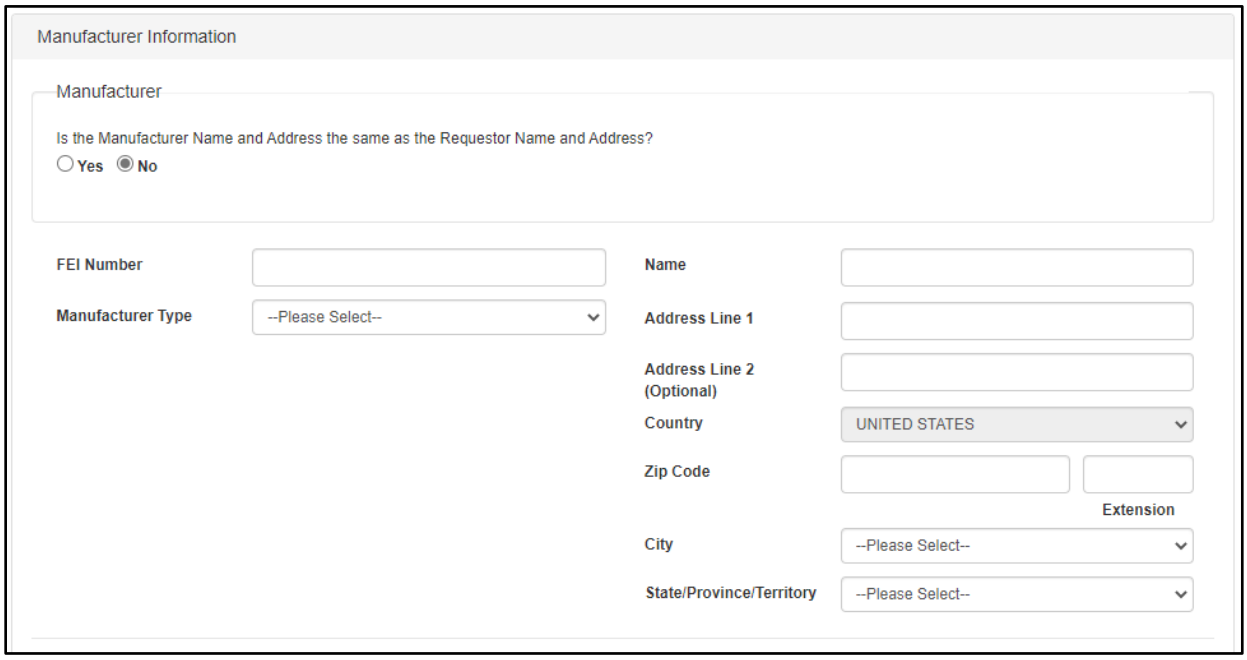
Regulator Email Address:

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” in response to the abovementioned prompt, the system displays the following to be filled out, as shown in Figure 108 (below).

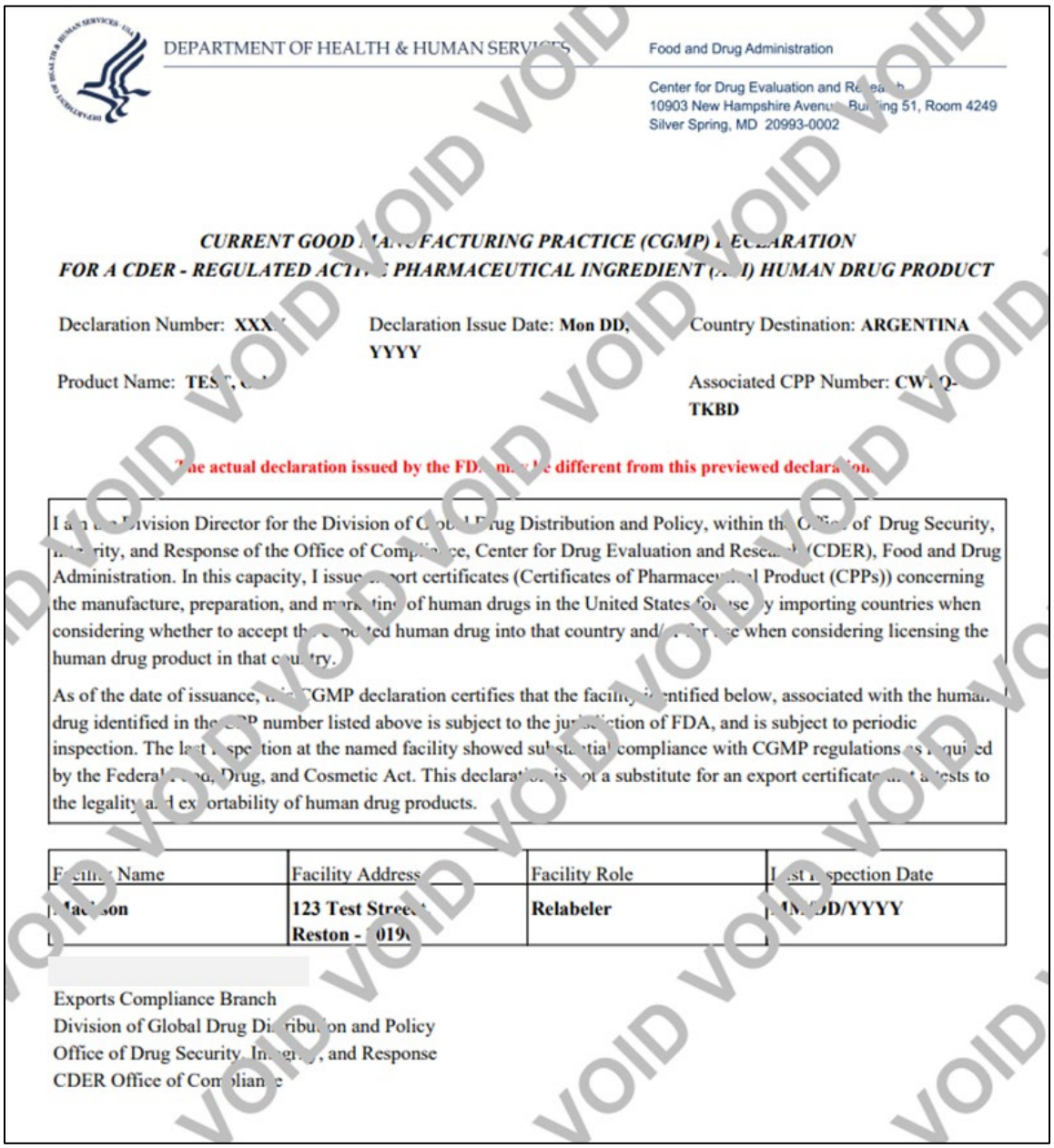
Figure 108 - Add Manufacturer Information



Previewing the Declaration Request:

To review the Declaration Request prior to submission, click the “Preview Declaration” button. This will save the request as a PDF; use your browser settings to view the PDF, as shown in Figure 109 (below).

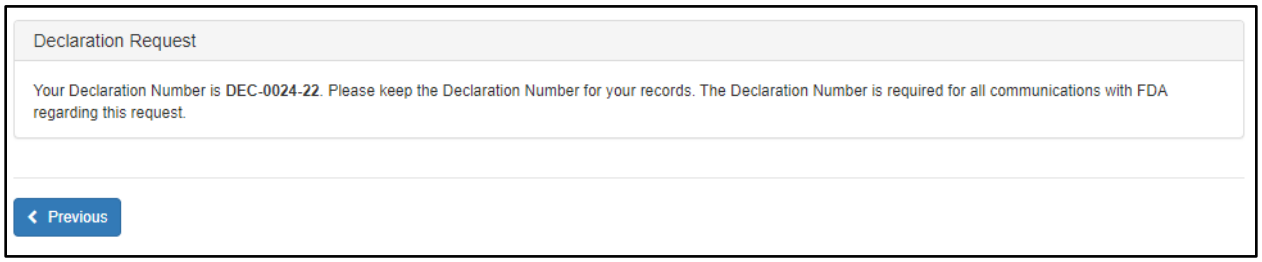
Figure 109 - Declaration Request Preview



Submitting the Declaration Request:

1. When your Declaration Request is ready for submission, click on the “Submit” button located at the bottom of the page.
2. The system will display a message confirming your declaration request was submitted, as shown in Figure 110 (below). The system will provide you with a Declaration Number. **Please save this number for future reference**.

Figure 110 - Declaration Request Submission



11 Search

11.1 Search Applications

1. To search for applications, select “Search Application” from the CDER eCATS Main Menu page.
2. Select the “Application” option, as shown in Figure 111 (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.

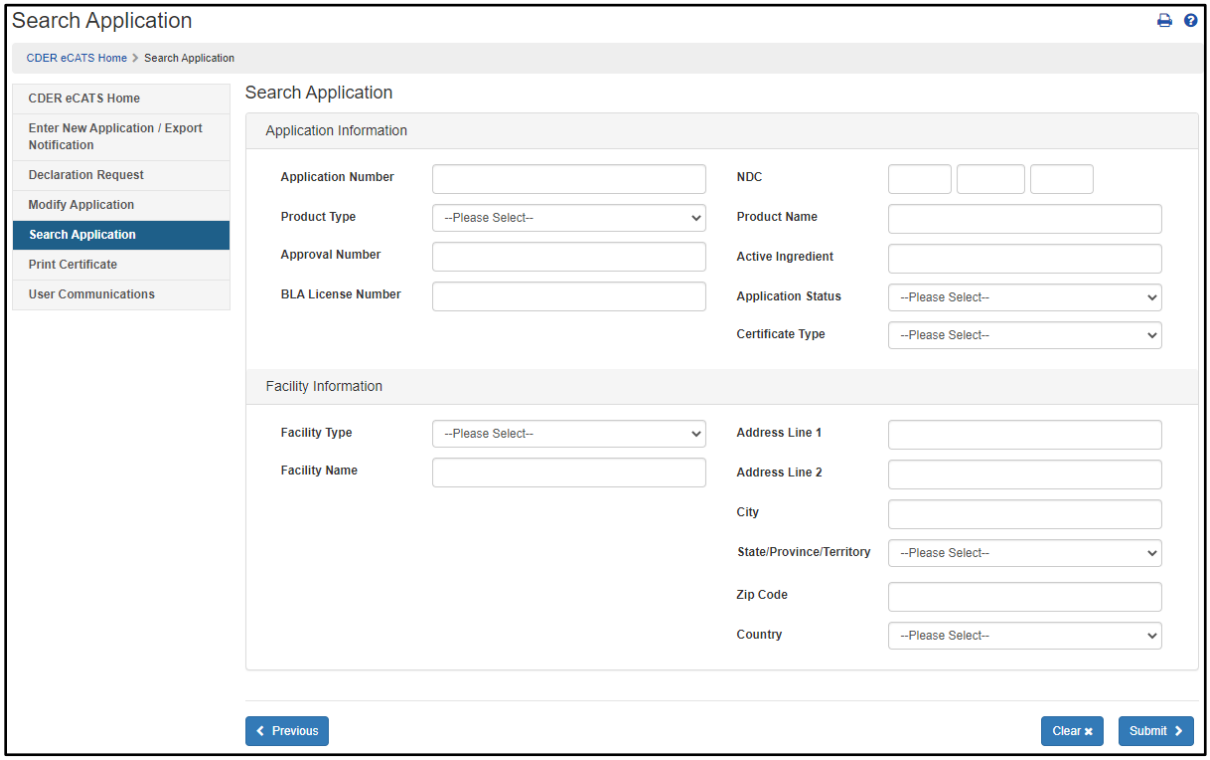
Figure 111 - Search Application

3. You can search using any or all of the following fields, as shown in Figure 112 (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 to perform a search using the “Facility Information” parameters.

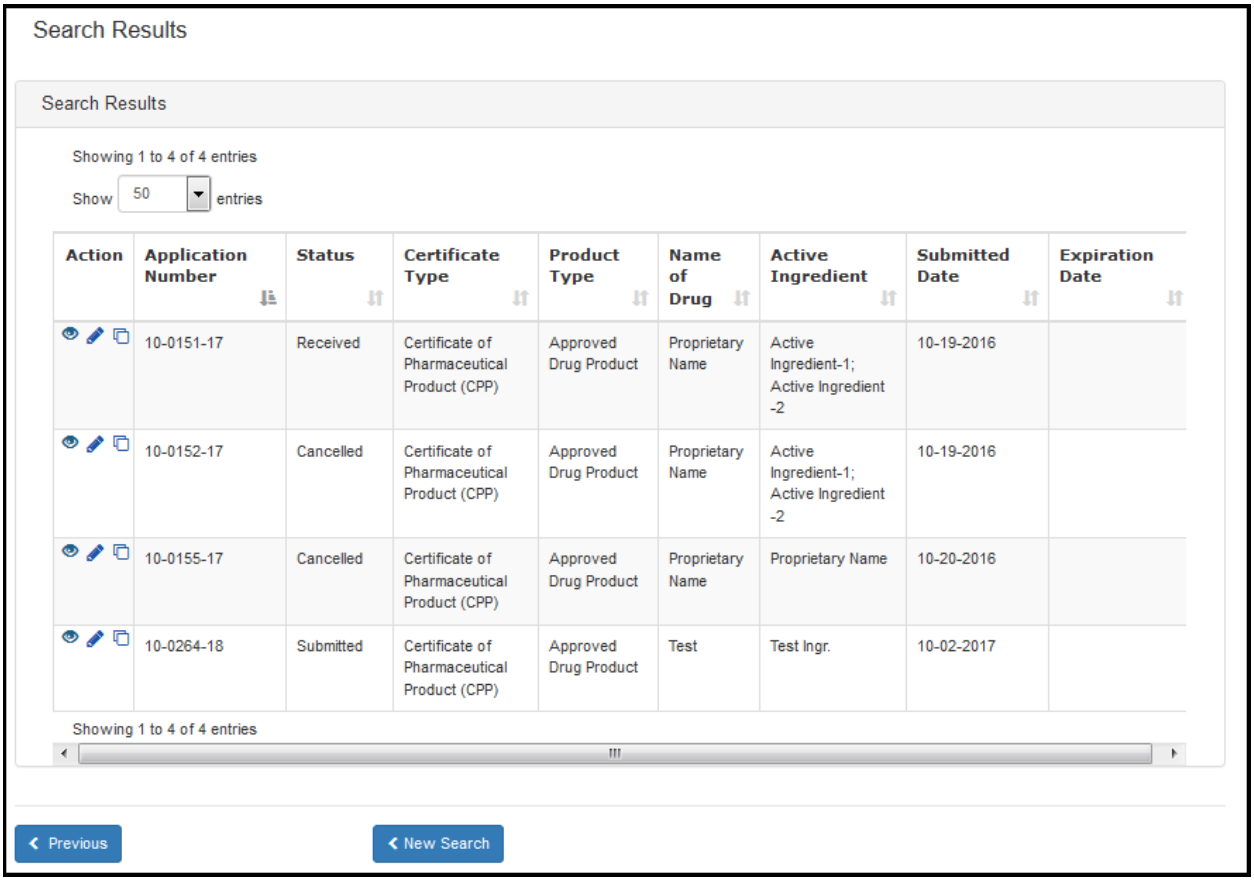
Figure 112 - Search Parameters



11.2 Search Results

The system will display the results which correspond to your search, as shown in Figure 113 (below).

Figure 113 - 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 View (“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 Modify (“pencil”) icon from the Action column.

Note: The application must be in a specific status in to see the Modify option. Refer to the Modify Application 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 Clone (“double book”) icon 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.

Note: The Clone icon is also available from the Home dashboard.

11.3 Search Export Notification Letters

1. To search for export notification letters, select “Search Application” from the CDER eCATS Main Menu page.
2. Select the “Export Notification Letter” option to search your letters by various criteria, as shown in Figure 114 (below). Once you have found the letter, you can view, modify, or delete it.

Figure 114 - Search Export Notification Letter

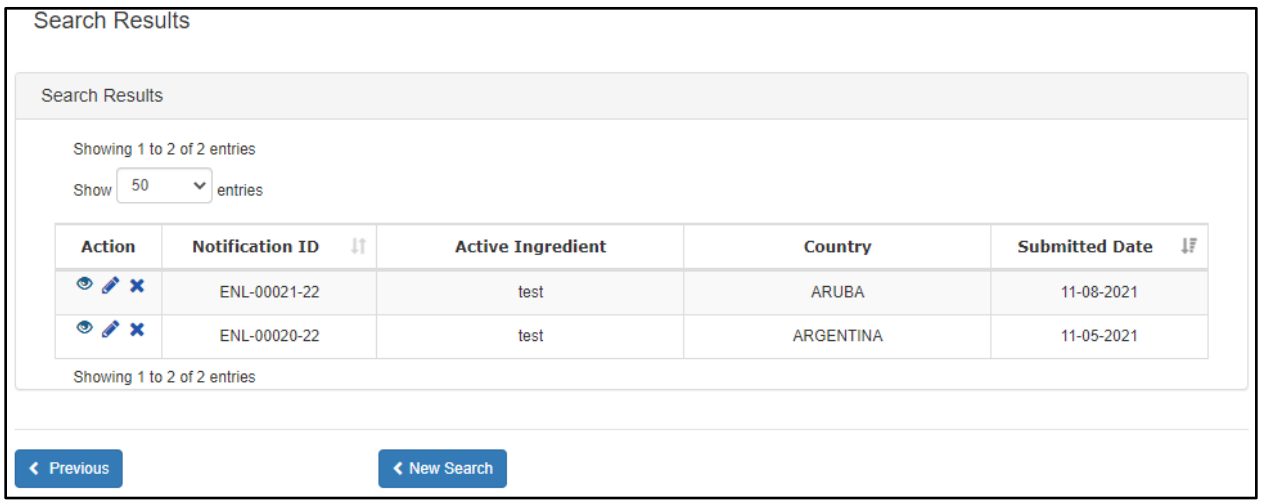
3. You can search using any or all the following fields, as shown in Figure 115 (below). You must enter at least one search criteria:
    - Submission Date Range – Start Date and End Date
    - Notification ID
    - Country

Figure 115 - Search Parameters

Search Results:

The system will display the results which correspond to your search, as shown in Figure 116 (below).

Figure 116 - 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 View (“eye”) icon from the Action column.

Modify an Export Notification Letter:

To modify an Export Notification Letter, select the Modify (“pencil”) icon from the Action column.

Delete Export Notification Letter:

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

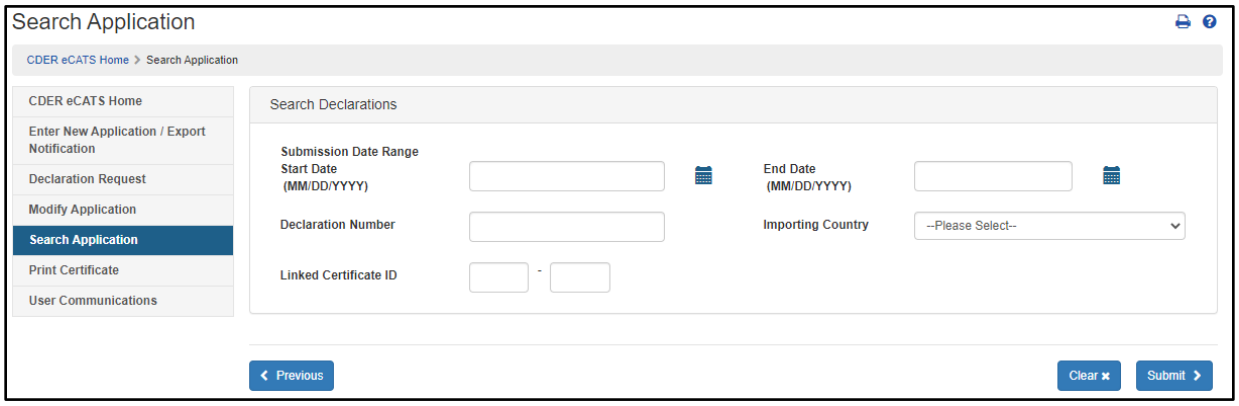
11.4 Search Declarations

1. To search for declarations, select “Search Application” from the CDER eCATS Main Menu page.
2. Select the “Declarations” option to search your declarations by various criteria, as shown below in Figure 117 (below). Once you have found the letter, you can view the declaration.

Figure 117 – Search Declarations

3. You can search using any or all of the following fields, as shown in Figure 118 (below). You must enter at least one search criteria:
    - Submission Date Range – Start Date and End Date
    - Declaration Number
    - Importing Country
    - Linked Certificate ID

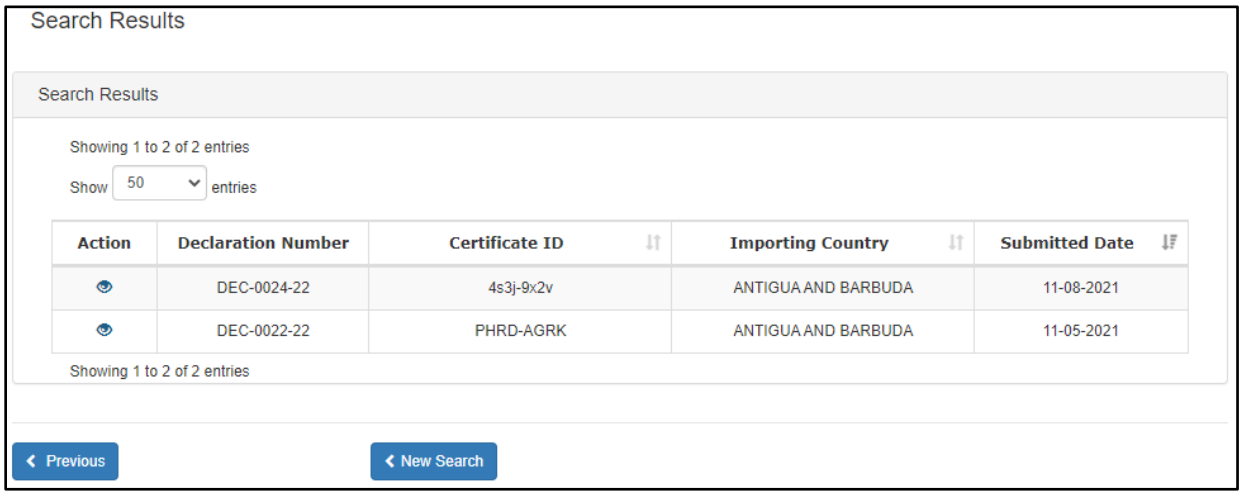
Figure 118 - Search Parameters



Search Results:

The system will display the results which correspond to your search, as shown in Figure 119 (below).

Figure 119 - 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:

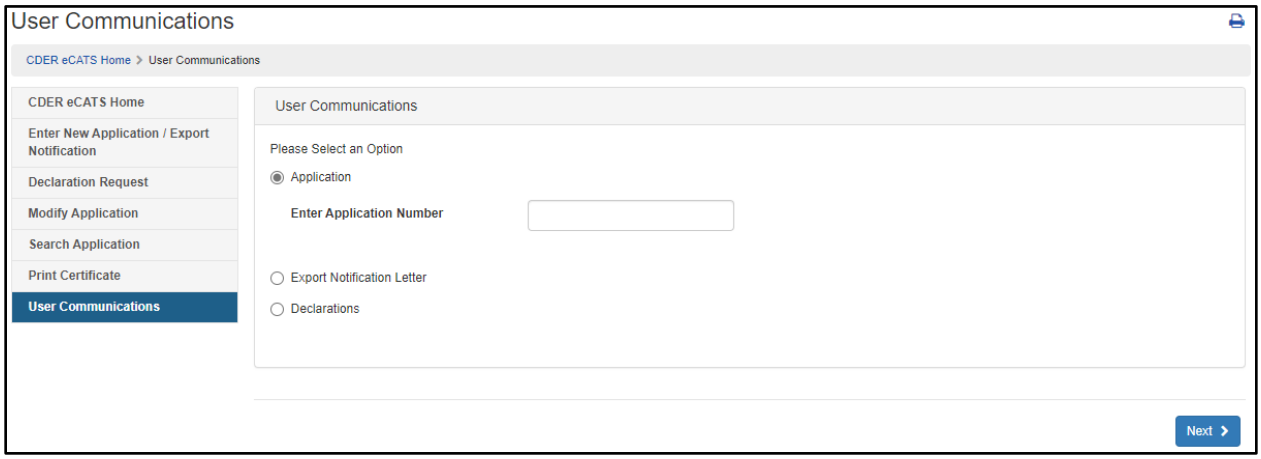
To view a Declaration Request, click on the View (“eye”) icon from the Action column.

12 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 Requestors and FDA reviewers in the CDER eCATS application.

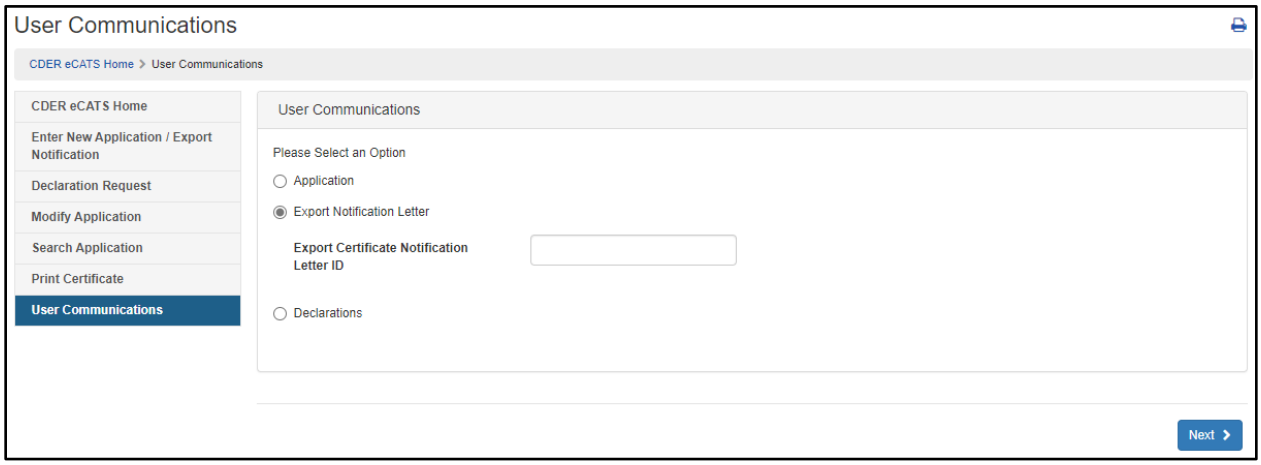
1. To send and respond to the communication related to your application, export notification letter or declaration request, click on the “User Communications” from the CDER eCATS Main Menu page.
2. For communications regarding your application, select the “Application” option and the system will provide an option to “Enter the Application Number”, as shown in Figure 120 (below). Click “Next”.

Figure 120 - Enter Application Number



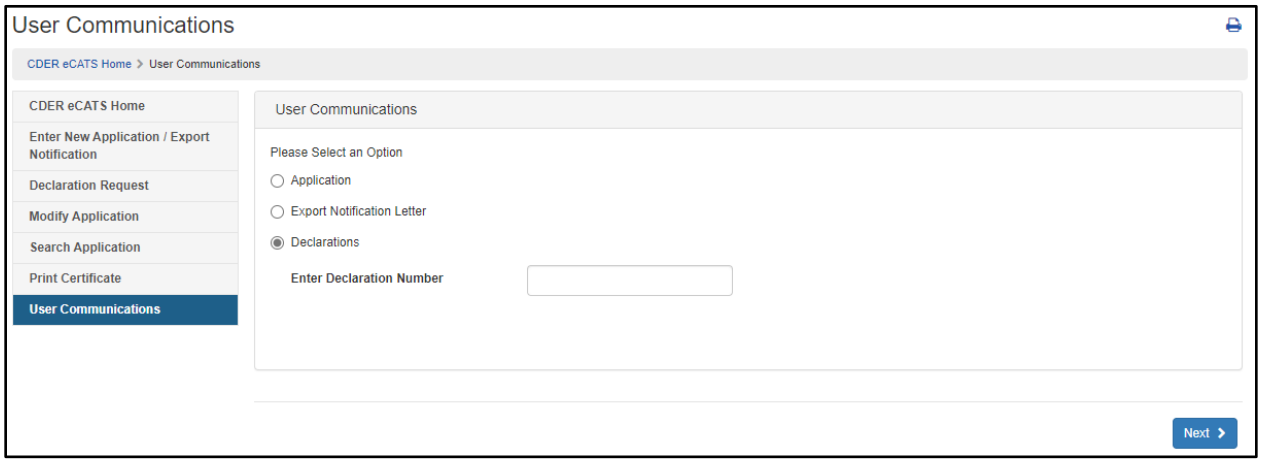
3. For communications regarding your export notification letter, select the “Export Notification Letter” option and the system will provide an option to enter the “Export Certificate Notification Letter ID”, as shown in Figure 121.
4. Click “Next”.

Figure 121 - Enter Notification ID



5. 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 122 (below).
6. Click “Next”.

Figure 122 - 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 123 (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.

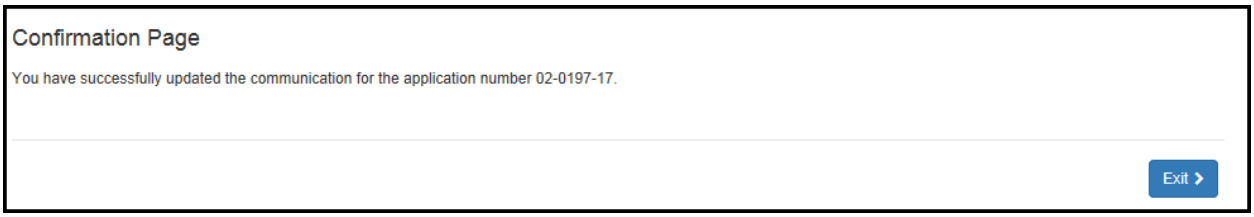
The data table will display the following fields:

- Comments
- Entered By
- Created Date

Figure 123 - Enter User Comments

Enter any user comments and click “Submit”. The system will display the confirmation message, as shown in Figure 124 (below)**.**

Figure 124 - 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.

13 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 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

14 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:

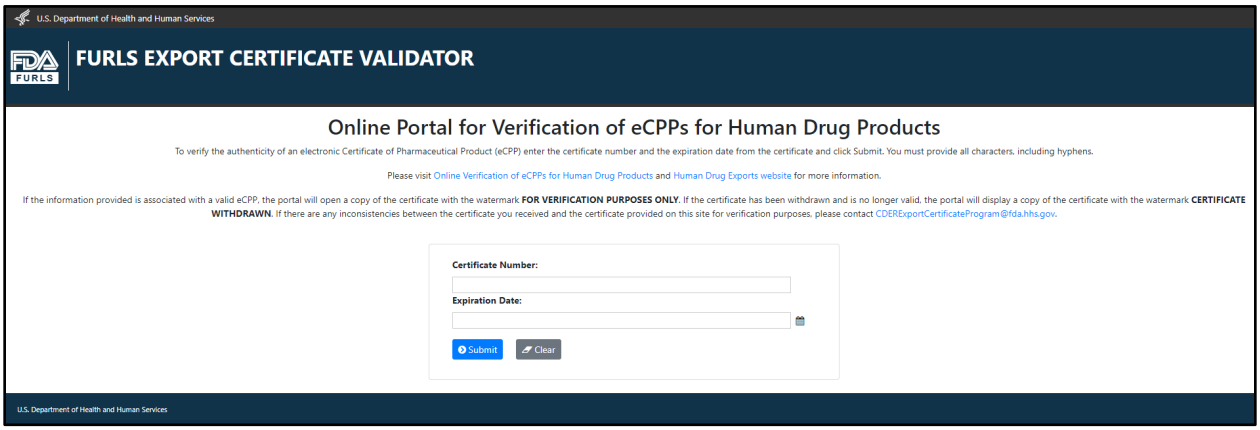
- Visit FDA’s Online Portal for Verification of Export Certificates for Drugs. This link is also included in the footer of each electronic certificate issued.

- 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 125 (below).

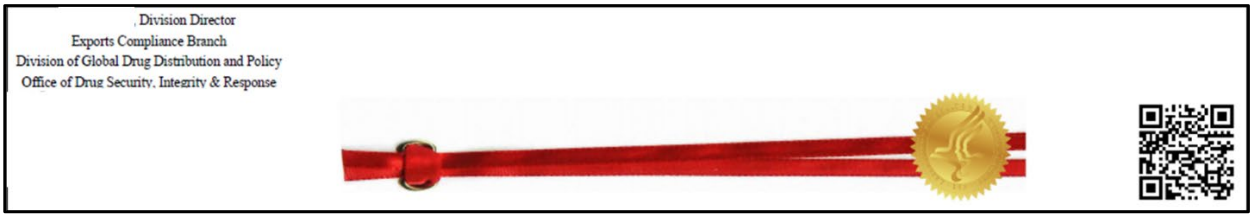
Figure 125 - FDA Online Portal for Verification of Export Certificates for Drugs



QR Code

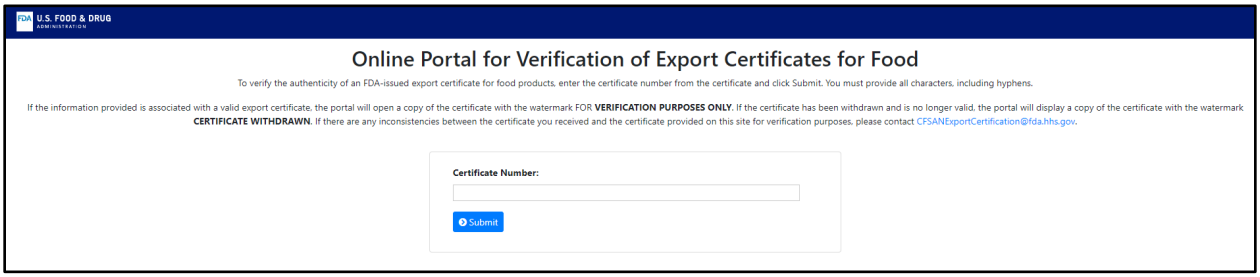
Use a QR Reader to scan the QR Code displayed on FDA's issued electronic certificates, as shown in Figure 126 (below).

Figure 126 – QR Code on eCPPs



1. The FGO will enter the Certificate Number and click the "Submit" button, as shown in Figure 127 (below).

Figure 127 – Certificate Verification using QR Code



2. If a certificate is not found, (i.e., the certificate expired or is no longer valid) an error message will be displayed.
3. 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.

4. Use your browser settings to view the PDF, as shown in Figure 128. Using the data displayed, you can verify the information based on the certificate the U.S. Exporter provided.

Figure 128 - Authenticated 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

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

Certificate of a Pharmaceutical Product - Approved Drug Product

Certificate Number: **EM8G-4ZXH** Certificate Issued Date: **May 20, 2024** Certificate Expiration Date: **May 20, 2026**

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

1.1	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **TEST THIS FIELD. PROPRIETARY NAME (DRUG, TRADE OR BRAND NAME);TEST THIS FIELD. FOREIGN BRAND NAME**
1.2	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **three; two; one**
1.3	Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? **Yes**
1.4	Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? **No**
1.4.1	Are there restrictions of sale, distribution or administration of the product specified in the marketing authorization? **No**
2.A.1	Number of marketing authorization & date of issuance: **074926 05/02/2024**
2.A.2	Marketing authorization holder (name and address): **Mackson, 1818 Library St, Reston, VA 20190 United States of America**
2.A.3	Status of marketing authorization holder: **Manufacturer**
2.A.4	Is a summary basis for approval appended? **No**
2.A.5	Is the attached product information, complete and consistent with the marketing authorization? **Yes**
2.A.6	Applicant name & address for certificate (if different than the marketing authorization holder): **N/A**
2.A.7	Center weblinks to marketing authorization: Orangebook for approved drug products and Purplebook for CDER-regulated Biologics License Applications
Remarks: **The FDA has the right to remove and or update any remarks provided by industry to be printed on the certificate.**	
3.1	Manufacturer name & address: **Mackson, 1818 Library St, Reston, VA 20190 United States of America**
3.2	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**
3.3	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**
3.4	Has the manufacture of this type of dosage form been inspected? **Yes**
3.5	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**
3.6	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**

Exports 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.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 March 25, 2021. Website: www.who.int